PRESBYTERIAN
Health Plan, Inc.

# Presbyterian Senior Care (HMO) / (HMO-POS)
# Presbyterian Dual Plus (HMO D-SNP)
# Criterios de autorización previa de la lista de medicamentos cubiertos
# Entra en vigor el 1º de febrero del 2026

Puede cambiar en cualquier momento la lista de medicamentos cubiertos [*formulary*]. Recibirá un aviso cuando sea necesario.

Para conseguir la lista de medicamentos más reciente, la información sobre cómo obtener una excepción o determinación de la cobertura u otras preguntas, favor de ponerse en contacto con el Centro de Servicio al Cliente de Presbyterian.

**Presbyterian Senior Care:**

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

**Del 1º de octubre al 31º de marzo:**
De las 8 a.m. a las 8 p.m., los siete días de la semana (salvo los días feriados)

**Del 1º de abril al 30 de septiembre:**
De las 8 a.m. a las 8 p.m., de lunes a viernes (salvo los días feriados)

**Presbyterian Dual Plus:**

(505) 923-7675
1-8855-465-7737
(TTY 711)

**www.phs.org/Medicare**

**Infórmese más a fondo acerca del aviso de no discriminación de Presbyterian y los servicios de intérpretes.**

Basado en la revisión del modelo de atención médica, el Comité Nacional de Control de Calidad [*National Committee for Quality Assurance, NCQA*] ha aprobado a Presbyterian Dual Plus (HMO D-SNP) para operar un plan de necesidades especiales [*Special Needs Plan, SNP*] hasta el 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 |

# 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 MG, 7.5 MG
- Torpenz

| 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 |

# 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 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 |

# 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 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 |

# Alecensa (alectinib)

**Products Affected**
- Alecensa

| 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 |

# Alunbrig (brigantinib)

**Products Affected**
- Alunbrig

| 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 |

# Amjevita (adalimumab-atto)

**Products Affected**

- Amjevita Subcutaneous Solution Auto-Injector
- Amjevita Subcutaneous Solution Prefilled Syringe 40 MG/0.4ML, 40 MG/0.8ML
- Amjevita-Ped 10kg to <15kg
- Amjevita-Ped 15kg to <30kg

| 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): Documented diagnosis of moderately to severely active CD as evidenced by colonoscopy, CT scan, MRI, or capsule endoscopy. 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): Documented diagnosis of moderately to severely active UC as evidenced by colonoscopy, CT scan, MRI, or capsule endoscopy. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a rheumatologist, dermatologist, gastroenterologist, or ophthalmologist. |
| **Coverage Duration** | One (1) year |
| **Other Criteria** | 8. Hidradenitis Suppurativa (HS): Documented diagnosis of Hurley Stage |

| PA Criteria | Criteria Details |
|---|---|
| | 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 |

# 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 |

# 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 Patient Titration Kit
- Austedo XR
- 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 stabilized or 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 |

# 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** | One (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 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 |

# Balversa (erdafitinib)

**Products Affected**
- Balversa

| 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 |

# 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 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 |

# Braftovi (encorafenib)

**Products Affected**
- Braftovi

| 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 |

# 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

| 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 |

# 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 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 |

# Calquence (acalabrutinib)

**Products Affected**
- Calquence

| 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 |

# 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 two 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 |

# Caprelsa (vandetanib)

**Products Affected**
- Caprelsa

| 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 |

# 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 (4 to 14 monthly migraine days with at least moderate disability (Migraine Disability Score - MIDAS- of at least 11 or HIT-6 - six-item Headache Impact Test - score greater than 50) or Chronic Migraines (15 or more monthly headache days). |
| **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** | a. Documentation of trial and failure of the following: i.Medium, high, or very high potency topical corticosteroid. ii. Topical calcineurin inhibitor. 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. |
| **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 |

# Colony Stimulating Factor

**Products Affected**

- Udenyca Subcutaneous Solution Prefilled Syringe
- Zarxio

| 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Therapy Required** | |

# Cometriq (cabozantinib)

**Products Affected**

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

# Copiktra (duvelisib)

**Products Affected**
- Copiktra

| 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 |

# 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 or intolerance to beta-blocker use. Documentation that the patient has tried/failed sacubitril/valsartan or has a contraindication or intolerance to sacubitril/valsartan use. 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 |

# 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 3% or more of their body surface area (BSA) affected by plaque psoriasis (or less than 3% if a crucial area of the body is affected. 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 two of the 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, or the patient has been treated with a targeted immunomodulator in past. Please provide date of therapy, duration of therapy, and drug name. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Rheumatologist or Dermatologist |
| **Coverage Duration** | Initial: 6 months Renewal: 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Non-radiographic axial spondyloarthritis: trial and failure of two non-steroidal anti-inflammatories for at least 4 weeks each at maximally tolerated doses, unless contraindicated or not tolerated. Hidradenitis suppurativa (HS): Documented diagnosis of Hurley Stage II or Stage III HS. Enthesitis-related arthritis: trial and failure of two non-steroidal anti-inflammatories for at least 4 weeks each at maximally tolerated doses, unless contraindicated or not tolerated.Continuation criteria: positive clinical response to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# Cotellic (cobimetinib)

**Products Affected**
- Cotellic

| 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 |

# 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 CMS-approved compendia, such as Micromedex and AHFS-Drug Information. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Three (3) months |
| **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 |

# 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 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 |

# 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 |
| **Prerequisite Therapy Required** | No |

# 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 |

# Drizalma (duloxetine)

**Products Affected**
- Drizalma Sprinkle

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Chart notes documenting a trial of, intolerance, or contraindication to duloxetine (Cymbalta) capsule or amitriptyline use in the last 180 days. |
| **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 |

# 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. Diagnosis of eosinophilic asthma. 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. 3. Bullous pemphigoid: Trial and failure of a high-potency topical steroid, oral steroid, or doxycycline. BP Disease Area Score of 24 or greater. Weekly average Peak Pruritus NRS score of 4 or greater. Will be used in combination with a tapered course of oral corticosteroids. Continuation: positive clinical response as evidenced by sustained remission and improvement in scores. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial: 6 months Continuation: 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **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: 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 nodular lesions. 6. COPD: FEV1/FVC ratio of less than 0.7 and post-bronchodilator FEV1 of 30%. 7. Chronic Spontaneous Urticaria: Trial and failure of two antihistamines at maximum tolerated doses for at least two weeks each, unless contraindicated or not tolerated. Member has not received prior anti-IgE therapy. Continuation: responded positively as evidenced by a decrease in itch severity, decrease in number of hives, or decrease in size of hives. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# 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** | Diagnosis of Episodic Migraines (4 to 14 monthly migraine days with at least moderate disability (Migraine Disability Score - MIDAS- of at least 11 or HIT-6 - six-item Headache Impact Test - score greater than 50), or documented diagnosis of episodic cluster headaches. |
| **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 |

# 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, 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. |
| **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. |

| PA Criteria | Criteria Details |
|---|---|
| | 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 |

# 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, hepatologist, or gastroenterologist. |
| **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 |

# Erivedge (vismodegib)

**Products Affected**
- Erivedge

| 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 |

# Erleada ( apalutamide)

**Products Affected**
- Erleada

| 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 |

# 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** | 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 |

# 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
- Fanapt Titration Pack A

| 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 two 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 |

# 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, 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. For Eosinophilic Granulomatosis with polyangiitis: within the past 2 years, the patient has experienced relapsing disease requiring dose or dose escalation of corticosteroids or immunosuppressant, or hospitalization -OR- with the prior 6 months following induction with standard therapy. Patient is currently on standard therapy (e.g., systemic corticosteroids) with or without immunosuppressive therapy (e.g., cyclophosphamide). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Allergist, Pulmonologist, Dermatologist, Rheumatologist, 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** | Yes |

| PA Criteria | Criteria Details |
|---|---|
| **Therapy Required** | |

# 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 tranfusional 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). 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 |

# 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: 6 months  Renewal: 1 year |
| **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 at least one other available osteoporosis therapy (oral bisphosphates, IV zolendronic acid). |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | Yes |
| **Prerequisite Therapy Required** | Yes |

# Fotivda (Tivozanib)

**Products Affected**
- Fotivda

| 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 |

# 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 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 |

# 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** | Documented diagnosis of short-bowel syndrome who require parenteral nutrition. |
| **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 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 |

# Gilotrif (afatinib)

**Products Affected**
- Gilotrif

| 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 |

# 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 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 |

# GLP-1 Agonists

**Products Affected**

- Mounjaro
- Trulicity

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis of Type 2 Diabetes Mellitus (T2DM). |
| **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 |

# 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): Documented diagnosis of moderately to severely active CD as evidenced by colonoscopy, CT scan, MRI, or capsule endoscopy. 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): Documented diagnosis of moderately to severely active ulcerative colitis. 8. Hidradenitis Suppurativa (HS): Documented diagnosis of Hurley Stage III HS or refractory Hurley Stage II hidradenitis suppurativa. |
| **Age Restrictions** | |
| **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. |

| PA Criteria | Criteria Details |
|---|---|
| **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 |

# 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 |

# 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** | 1 year |
| **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
- chlorproMAZINE HCl Oral Tablet
- Scopolamine

| 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** | |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# 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 at least two medications tried and failed for anxiety (e.g., buspirone, citalopram, fluoxetine, sertraline, duloxetine, venlafaxine). Pruritis: Chart notes documenting at least one medication used for itching (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 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 |

# 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 |

# Iclusig (ponatinib)

**Products Affected**
- Iclusig

| 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** | 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 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** | 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 |

# 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 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 |

# 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 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 |

# Inqovi (cedazuridine/decitabine)

**Products Affected**
- Inqovi

| 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 |

# Inrebic (fedratinib)

**Products Affected**
- Inrebic

| 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 |

# Iressa (gefitinib)

**Products Affected**
- Gefitinib

| 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 |

# 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 |

# 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 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 |

# Jakafi (ruxolitinib)

**Products Affected**
- Jakafi

| 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 |

# 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** | |
| **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 |

# 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. 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# Kalydeco (ivacaftor)

**Products Affected**

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

| 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 enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), unless otherwise contraindicated or not tolerated, Or, 5. Member has a documented diagnosis of heart failure with an ejection fraction of 40% or greater. |
| **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** | Yes |

# 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 |
| **Prerequisite Therapy Required** | No |

# 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 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 |

# Krazati (adagrasib)

**Products Affected**
- Krazati

| 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 |

# 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 |

# 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)

| 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 |

# 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 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 |

# Lorbrena (lorlatinib)

**Products Affected**
- Lorbrena

| 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 |

# 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 responsded 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 two 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 |
| **Prerequisite Therapy** | Yes |

| PA Criteria | Criteria Details |
|---|---|
| **Required** | |

# Lynparza (olaparib)

**Products Affected**
- Lynparza

| 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 |

# Lytgobi (futibatinib)

**Products Affected**

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

# Mavyret (glecaprevir/pibrentasvir)

**Products Affected**
- Mavyret

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Medical records documenting the diagnosis of acute or 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** | No |

# Mekinist (trametinib)

**Products Affected**
- Mekinist

| 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 |

# MEKTOVI (binimetinib)

**Products Affected**
- Mektovi

| 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 |

# 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 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** | 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 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 |

# Ninlaro (ixazomib)

**Products Affected**
- Ninlaro

| 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 |

# 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 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 |

# 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** | 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 |

# 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 |

# Odomzo (sonidegib)

**Products Affected**
- Odomzo

| 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 |

# 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 or rheumatologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Baseline Liver Function tests |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | No |

# 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 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 |

# 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 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 |

# 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 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 |

# 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** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# Onureg (Azacitidine)

**Products Affected**
- Onureg

| 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 |

# 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 |

# Orencia (abatacept SubQ)

**Products Affected**

- Orencia ClickJect Syringe
- Orencia Subcutaneous Solution Prefilled

| 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 (adult patients), 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 |

# 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 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** | 1 year |
| **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** | 1 year |
| **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
- Otezla XR

| 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 |

# Parathyroid Hormone Analogs

**Products Affected**

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

| 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) -OR- 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. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | Yes |
| **Prerequisite Therapy Required** | Yes |

# Pemazyre (pemigatinib)

**Products Affected**
- Pemazyre

| 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 |

# Piqray (alpelisib)

**Products Affected**

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

# Pomalyst (pomalidomide)

**Products Affected**
- Pomalyst

| 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 |

# 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 |

# 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** | 6 months |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# Pulmonary Arterial Hypertension - ERA

**Products Affected**

- Ambrisentan
- Bosentan

| 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 |

# 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 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 |

# Qinlock (ripretinib)

**Products Affected**
- Qinlock

| 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 |

# 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 |

# 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite** | Yes |

| PA Criteria | Criteria Details |
|---|---|
| **Therapy Required** | |

# Relistor (methylnaltrexone)

**Products Affected**
- Relistor

| 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** | |
| **Required Medical Information** | Treating provider attests to ONE of the following: a. Patient has been receiving at least 8 consecutive weeks. b. Patient is unable to tolerate* moderate- and high-intensity statins. ii. Patient has been receiving at least 8 consecutive weeks of low-intensity statin therapy and will continue to receive a low-intensity statin at maximally tolerated dose. d. Patient is unable to tolerate* low-, moderate-, and high-intensity statins, , or ii. Has a labeled contraindication to all statins or iii. Has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times the upper limit of normal (ULN). 2. LDL-C equal to or greater than 70mg/dl (or 55 mg/dl if using for the prevention of major adverse cardiac events or in those at high high risk for major adverse cardiac events), or less than 50% LDL-C reduction from baseline while on maximally tolerated lipid lowering regimen. 3. Medication is used as adjunct to a low-fat diet and exercise. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with one of the following: cardiologist, endocrinologist, or lipid specialist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Trial and failure of the preferred formulary drug (Repatha) is required before consideration of non-formulary drugs in this class. All drugs are subject to formulary quantity limits and approved dosages. *Statin Intolerance for the purpose of this criteria is defined as intolerable and persistent (i.e. more than 2 weeks) symptoms: 1) Myalgia (muscle symptoms without CK elevations), or 2) Myositis (muscle symptoms with CK elevations greater than 10 times upper limit of normal [ULN])Table 1.HIGH-INTENSITY statin atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg MODERATE-INTENSITY statin atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin greater than 20 mg, pravastatin more than 40 mg, lovastatin 40 mg, fluvastatin XL 80 mg, fluvastatin 40 mg |

| PA Criteria | Criteria Details |
|---|---|
| | twice daily, or pitavastatin greater than 2 mg LOW-INTENSITY statin simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, pitavastatin 1 mg Quantity limit: 120 mg every 2 weeks or 420 mg once monthly. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# Retevmo (selpercatinib)

**Products Affected**
- Retevmo

| 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 |

# 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 |

# Revlimid (lenalidomide)

**Products Affected**
- Lenalidomide

| 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 |

# 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 |

# 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 |
| **Prerequisite Therapy Required** | Yes |

# 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. c. Prescribed by or in consultation with a hepatologist or gastroenterologist. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Hepatologist or gastroenterologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Continuation criteria: positive clinical response to therapy as evidenced by improvement in liver fibrosis and no worsening of steatohepatitis. |
| **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 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 |

# 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 |

# Rozlytrek (entrectinib)

**Products Affected**
- Rozlytrek

| 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 |

# Rubraca (rucaparib)

**Products Affected**
- Rubraca

| 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 |

# Rydapt (midostaurin)

**Products Affected**
- Rydapt

| 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 |

# Scemblix

**Products Affected**
- Scemblix

| 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 |

# 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 |

# 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 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 |

# Sirturo (bedaquiline)

**Products Affected**

- Sirturo Oral Tablet 100 MG

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Documented diagnosis of multi-drug resistant tuberculosis (MDR-TB). |
| **Age Restrictions** | 2 years of age weighing at least 8 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: 6 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 |

# 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 at least 3% of their body surface area (BSA) affected by plaque psoriasis, or less than 3% if the condition affects a crucial area of the body. 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: Documented diagnosis of moderately to severely active CD as evidenced by colonoscopy, CT scan, MRI, or capsule endoscopy. Inadequate response to Amjevita or Hadlima. Ulcerative Colitis (UC): Documented diagnosis of moderately to severely active UC as evidenced by colonoscopy, CT scan, MRI, or capsule endoscopy. |
| **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. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite** | Yes |

| PA Criteria | Criteria Details |
|---|---|
| **Therapy Required** | |

# Stivarga (regorafenib)

**Products Affected**
- Stivarga

| 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 |

# 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** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | No |

# Sutent (sunitinib)

**Products Affected**
- SUNItinib Malate

| 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 |

# 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** | 1 year |
| **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** | 1 year |
| **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 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 |

# Tabrecta (capmatinib)

**Products Affected**
- Tabrecta

| 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 |

# 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** | All FDA-approved Indications. |
| **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 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 |

# Tagrisso (osimertinib)

**Products Affected**
- Tagrisso

| 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 |

# 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** | Initial: 6 months Renewal: 1 year |
| **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 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 |

# Tarceva (erlotinib)

**Products Affected**

- Erlotinib HCl

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | FFor 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 |

# Targretin (bexarotene)

**Products Affected**
- Bexarotene

| 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 |

# Tasigna (nilotinib)

**Products Affected**
- Nilotinib HCl

| 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 |

# 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. 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 |

# Tazverik (tazemetostat)

**Products Affected**
- Tazverik

| 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** | must be at least 16 years old |
| **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** | No |

# Tepmetko (tepotinib)

**Products Affected**
- Tepmetko

| 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 |

# Testosterone injection

**Products Affected**

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

| 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 |

# 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 |

# Tibsovo (ivosidenib)

**Products Affected**
- Tibsovo

| 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 |

# 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 |

# 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 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 |

# 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 |

# Tukysa (tucatinib)

**Products Affected**
- Tukysa

| 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 |

# 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 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 |

# 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): Documented diagnosis of JIA. 3. Adult patients with Giant Cell Arteritis (GCA): Documented diagnosis of GCA. 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** | 1. RA/JIA/GCA - prescribed by or in consultation with a rheumatologist. 2. SSc-ILD prescribed by or in consultation with a pulmonologist or a rheumatologist. |
| **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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy** | Yes |

| PA Criteria | Criteria Details |
|---|---|
| **Required** | |

# 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 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 |

# 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 |
| **Prerequisite Therapy Required** | Yes |

# 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 |

# Ustekinumab

**Products Affected**

- Steqeyma Subcutaneous Solution Prefilled Syringe 90 MG/ML
- Yesintek Subcutaneous Solution Prefilled Syringe 90 MG/ML

| 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 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. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite** | |
| **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 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 |

# 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 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 |

# 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 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 |

# 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 |

# Verzenio (abemaciclib)

**Products Affected**
- Verzenio

| 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 |

# Vfend (voriconazole)

**Products Affected**

- Voriconazole Intravenous Reconstituted
- Voriconazole Oral Suspension
- Voriconazole Oral Tablet 200 MG

| 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 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 |

# Vizimpro (dacomitinib)

**Products Affected**
- Vizimpro

| 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 |

# Vonjos (pacritinib)

**Products Affected**
- Vonjo

| 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 |

# 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 |

# Votrient (pazopanib)

**Products Affected**

- PAZOPanib HCl Oral Tablet 200 MG

| 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 |

# 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 |
| **Prerequisite Therapy** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Required** | |

# Vraylar (cariprazine)

**Products Affected**

- Vraylar Oral Capsule 1.5 MG, 3 MG, 4.5 MG, 6 MG
- Vraylar Oral Capsule Therapy Pack

| 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite** | Yes |

| PA Criteria | Criteria Details |
|---|---|
| **Therapy Required** | |

# 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 |
| **Prerequisite Therapy Required** | No |

# Vyvanse (lisdexamphetamine)

**Products Affected**

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

# Welireg (belzurifan)

**Products Affected**
- Welireg

| 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 |

# 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 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 |

# 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): Trial and failure of one or more tumor necrosis factor (TNF) blocker. 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 |
| **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. |

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

# 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: 6 months Renewal: 1 year |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# 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 |

# 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 |

# 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. CIU (renewal request): Documentation of a reduction in exacerbation frequency and intensity. For nasal polyps, evidence of nasal polyps as as found on examination 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** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy** | Yes |

| PA Criteria | Criteria Details |
|---|---|
| **Required** | |

# Xospata (gilteritinib)

**Products Affected**
- Xospata

| 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 |

# 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) Oral Tablet Therapy Pack 20 MG, 40 MG
- Xpovio (80 MG Twice Weekly)

| 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 |

# 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 |
| **Prerequisite Therapy Required** | No |

# 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). Pediatric patients will not be required to first try and fail a cerebral stimulant or 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 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 |

# 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 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 |

# Zelboraf (vemurafenib)

**Products Affected**
- Zelboraf

| 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 |

# Zolinza (vorinostat)

**Products Affected**
- Zolinza

| 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 |

# Zydelig (idelalisib)

**Products Affected**
- Zydelig

| 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 |

# 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 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 |

# Zymfentra (infliximab-dyyb)

**Products Affected**

- Zymfentra (1 Pen)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Crohn's Disease (CD) and Ulcerative Colitis (UC): Documented diagnosis of moderately to severely active CD as evidenced by colonoscopy, CT scan, MRI, or capsule endoscopy. |
| **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 |

# 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 |

# Notice of Availability

| | |
|---|---|
| English | ATTENTION: If you speak English, free language assistance services are available to you. Appropriate auxiliary aids and services to provide information in accessible formats are also available free of charge. Call 1-855-592-7737 (TTY: 711) or speak to your provider. |
| Spanish<br>Español | ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. También están disponibles de forma gratuita ayuda y servicios auxiliares apropiados para proporcionar información en formatos accesibles. Llame al<br>1-855-592-7737 (TTY: 711) o hable con su proveedor. |
| Navajo<br>Diné | SHOOH: Diné bee yáníłti'gogo, saad bee aná'awo' bee áka'anída'awo'ít'áá jiik'eh ná hóló. Bee ahił hane'go bee nida'anishí t'áá ákodaat'éhígíí dóó bee áka'anída'wo'í áko bee baa hane'í bee hadadilyaa bich'į' ahoot'i'ígíí éí t'áá jiik'eh hóló. Kohjį' 1-855-592-7737 (TTY:711) hodíilnih doodago nika'análwo'í bich'į' hanidziih. |
| Vietnamese<br>Việt | LƯU Ý: Nếu bạn nói tiếng Việt, chúng tôi cung cấp miễn phí các dịch vụ hỗ trợ ngôn ngữ. Các hỗ trợ dịch vụ phù hợp để cung cấp thông tin theo các định dạng dễ tiếp cận cũng được cung cấp miễn phí. Vui lòng gọi theo số 1-855-592-7737 (Người khuyết tật: TTY: 711) hoặc trao đổi với người cung cấp dịch vụ của bạn. |
| German<br>Deutsch | ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlose Sprachassistenzdienste zur Verfügung. Entsprechende Hilfsmittel und Dienste zur Bereitstellung von Informationen in barrierefreien Formaten stehen ebenfalls kostenlos zur Verfügung. Rufen Sie 1-855-592-7737 (TTY: 711) an oder sprechen Sie mit Ihrem Provider. |
| Chinese<br>Simplified<br>简体中文 | 注意：如果您使用简体中文，我们将免费为您提供语言协助服务。我们还免费提供适当的辅助工具和服务，以提供无障碍格式版信息。请拨打 1-855-592-7737 (TTY: 711) 或咨询您的服务提供者。 |
| Chinese<br>Traditional<br>繁體中文 | 注意：如果您使用繁體中文，我們將免費為您提供語言協助服務。我們還免費提供適當的輔助工具和服務，以提供無障礙格式版資訊。請致電 1-855-592-7737 (TTY:711) 或諮詢您的服務提供者。 |
| Japanese<br>日本語 | 注: 日本語を話される場合、無料の言語支援サービスをご利用いただけます。アクセシブル（誰もが利用できるよう配慮された）な形式で情報を提供するための適切な補助支援やサービスも無料でご利用いただけます。1-855-592-7737（TTY：711）までお電話ください。または、ご利用の事業者にご相談ください。 |
| Filipino | ATTENTION: Kung marunong kang magsalita ng Filipino, makakagamit ka ng mga libreng serbisyo sa tulong sa wika. Ang mga angkop na karagdagang tulong at serbisyo upang magbigay ng impormasyon sa mga naa-access na format ay magagamit din nang libre. Tumawag sa 1-855-592-7737 (TTY: 711) o makipag-usap sa iyong provider. |
| Korean<br>한국어 | 주의: 한국어를 사용하는 경우 무료 언어 지원 서비스를 이용하실 수 있습니다. 접근 가능한 형식으로 정보를 제공하기 위한 적절한 보조 도구 및 서비스도 무료로 제공됩니다. 1-855-592-7737(TTY: 711)로 전화하거나 서비스 제공업체에 문의하세요. |



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| French<br>Français | ATTENTION : Si vous parlez Français, des services d'assistance linguistique gratuits sont à votre disposition. Des aides et services auxiliaires appropriés pour fournir des informations dans des formats accessibles sont également disponibles gratuitement. Appelez le 1-855-592-7737 (TTY : 711) ou parlez à votre fournisseur. |
| Tagalog | PAALALA: Kung nagsasalita ka ng Tagalog, magagamit mo ang mga libreng serbisyong tulong sa wika. Magagamit din nang libre ang mga naaangkop na auxiliary na tulong at serbisyo upang magbigay ng impormasyon sa mga naa-access na format. Tumawag sa 1-855-592-7737 (TTY: 711) o makipag-usap sa iyong provider. |
| Russian<br>РУССКИЙ | ВНИМАНИЕ: Если вы говорите на русский, вам доступны бесплатные услуги языковой поддержки. Соответствующие вспомогательные средства и услуги по предоставлению информации в доступных форматах также предоставляются бесплатно. Позвоните по телефону 1-855-592-7737 (TTY: 711) или обратитесь к своему поставщику услуг. |
| Urdu<br>اردو | توجہ دیں: اگر آپ اردو بولتے ہیں تو، مفت لسانی اعانت کی خدمات آپ کے لیے دستیاب ہیں۔ مناسب ضمنی امداد اور خدمات بھی قابل رسائی فارمیٹس میں معلومات فراہم کرنے کے لیے بلا معاوضہ دستیاب ہیں۔ 1-855-592-7737 (TTY: 711) پر کال کریں یا اپنے فراہم کنندہ سے بات کریں۔ |
| Nepali<br>नेपाली | ध्यान दिनुहोस्: तपाईं नेपाली बोल्नुहुन्छ भने तपाईंका लागि निःशुल्क भाषा सहायता सेवाहरू उपलब्ध छन्। पहुँचयोग्य ढाँचाहरूमा जानकारी प्रदान गर्न उपयुक्त सहायक सहायताहरू र सेवाहरू पनि निःशुल्क उपलब्ध छन्। 1-855-592-7737 (TTY: 711) मा फोन गर्नुहोस् वा आफ्नो प्रदायकसँग कुरा गर्नुहोस्। |
| Bengali<br>বাংলা | মনোযোগ দিন: আপনি যদি বাংলায় কথা বলেন, তাহলে বিনামূল্যে ভাষা সহায়তা পরিষেবা আপনার জন্য উপলব্ধ। অ্যাক্সেসযোগ্য ফর্ম্যাটে তথ্য প্রদানের জন্য উপযুক্ত সহায়ক সহায়তা এবং পরিষেবাগুলিও বিনামূল্যে পাওয়া যায়। 1-855-592-7737 (TTY: 711) নম্বরে কল করুন অথবা আপনার প্রদানকারীর সাথে কথা বলুন। |
| Hindi<br>हिंदी | ध्यान दें: यदि आप हिंदी बोलते हैं तो आपके लिए निःशुल्क भाषा सहायता सेवाएँ उपलब्ध हैं। सुलभ प्रारूपों में जानकारी प्रदान करने के लिए उपयुक्त सहायक सहायताएँ और सेवाएँ भी निःशुल्क उपलब्ध हैं। 1-855-592-7737 (TTY: 711) पर कॉल करें या अपने प्रदाता से बात करें। |
| Arabic<br>اللغة العربية | تنبيه: إذا كنت تتحدث العربية، فمتاح لك خدمات لغوية بالمجان. ومتاح بالمجان أيضًا مساعدات وخدمات إضافية مناسبة لتقديم المعلومات بتنسيقات يسهل الحصول عليها. اتصل بالرقم 1-855-592-7737 (TTY: 711) (خدمة الهاتف النصي) أو تحدث إلى مزود الخدمة المعني بك. |
| Turkish<br>Türkçe | DİKKATİNİZE: Türkçe biliyorsanız, ücretsiz dil destek hizmetlerinden faydalanabilirsiniz. Ayrıca ücretsiz olarak, uygun yardımcı araçlarla ve hizmetlerle erişilebilir formatlarda bilgi de sağlanmaktadır. 1-855-592-7737 (TTY (İşitme ve Konuşma Engelli Destek Hattı): 711) numaralı telefondan bize ulaşabilir veya hizmet sağlayıcınız ile görüşebilirsiniz. |