# 2019 Tufts Health Plan Medicare Preferred Prior Authorization Medical Necessity Guidelines

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Control # H2256_2019_RXOPS38_C
S0655_2019_RXOPS39_C

TUFTS Health Plan

# ABILIFY MYCITE

## Products Affected

- Abilify MyCite

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of schizophrenia, bipolar I disorder, or major depressive disorder and have documentation of worsening symptoms due to lack of adherence with oral aripiprazole. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a psychiatrist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# AFINITOR

## Products Affected

- Afinitor
- Afinitor Disperz

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Afinitor only: Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR+ BC): The member must have a documented diagnosis of Advanced HR+ BC, the member is postmenopausal, concurrently taking exemestane (Aromasin) and has a documented failure of letrozole (Femara) or anastrozole (Arimidex). Advanced Renal Cell Carcinoma (ARCC): The member must have a documented diagnosis of ARCC and the member has a demonstrated disease progression or intolerance following an appropriate trial with Nexavar (sorafenib) or Sutent (sunitinib). Neuroendocrine Tumors (NET): The member must have a documented diagnosis of progressive neuroendocrine tumors of pancreatic origin (pNET) or progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin, any of which are unresectable, locally advanced or metastatic. Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC): The member must have a documented presence of TSC and renal angiomyolipoma(s) greater than or equal to 3 cm in longest diameter. Afinitor Disperz only: Partial-onset Seizures Associated with TSC: The member must have a documented diagnosis of partial-onset seizures associated with TSC and is using Afinitor Disperz as an adjunct to other therapies (e.g., anticonvulsants). Afinitor and Afinitor Disperz: Subependymal Giant Cell Astrocytoma (SEGA): The member must have a documented diagnosis of SEGA associated with TSC and the member is not a candidate for surgical resection. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | None |

# AIMOVIG

## Products Affected

- Aimovig

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Initial: The member must have a documented diagnosis of migraine and the member has had an inadequate response after a 4-week trial of or has a contraindication to antidepressants, antiepileptic drugs (AEDs) or beta blockers. Subsequent: The member has had a clinically significant reduction in migraine days per month from baseline. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 6 months.  Subsequent approval: Life of Plan. |
| **Other Criteria** | None |

# ALECENSA

## Products Affected

- Alecensa

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Anaplastic Lymphoma Kinase (ALK)-positive, Metastatic Non-small Cell Lung Cancer (NSCLC): The member must have a documented diagnosis of ALK-positive, metastatic NSCLC as detected by an FDA-approved test and has progressed on or is intolerant to Xalkori (crizotinib). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ALUNBRIG

## Products Affected

- Alunbrig

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) and has had disease progression on or is intolerant to Xalkori (crizotinib). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# AMPYRA

## Products Affected

- Ampyra

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Multiple Sclerosis and the member is receiving concurrent therapy with a disease modifying agent (e.g. Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Rebif, Tecfidera, or Tysabri) if indicated, and the member is ambulatory with a baseline timed 25 foot walk between 8 and 45 seconds. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | Initial authorization is for twelve (12) weeks. |
| **Other Criteria** | Additional authorization may be provided if there is documented improvement in walking speed from pre-treatment baseline. Subsequent authorization is for an FDA-approved duration, balance of contract year or clinically appropriate duration. |

# APTIOM

## Products Affected

- Aptiom

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to two (2) or more medications indicated for adjunct partial seizures (e.g. Briviact, felbamate (Felbatol), Fycompa, gabapentin (Fanatrex, Gralise, Neurontin), lamotrigine (Lamictal, Lamictal XR, Lamictal ODT), Lyrica, levetiracetam (Keppra, Keppra XR, Roweepra, Spritam), oxcarbazepine (Oxtellar XR, Trileptal), tiagabine (Gabitril), topiramate (Topamax, Trokendi XR), Potiga, Vimpat, and/or zonisamide (Zonegran)). |
| **Age Restrictions** | The member must be four (4) years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ARCALYST

## Products Affected

- Arcalyst

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of a Cryopyrin-Associated Periodic Syndrome, including Familial Cold Autoinflammatory Syndrome, or Muckle-Wells Syndrome. |
| **Age Restrictions** | The member must be twelve (12) years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ARMODAFINIL AND MODAFINIL

## Products Affected

- *armodafinil*
- *modafinil*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Coverage will not be approved for generalized fatigue, jet lag, or sleep-deprivation not associated with a covered diagnosis. |
| **Required Medical Information** | The member must have a documented diagnosis of narcolepsy, excessive sleepiness associated with obstructive sleep apnea, or shiftwork sleep disorder. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# AUBAGIO

## Products Affected

- Aubagio

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of a relapsing form of multiple sclerosis (relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapse), or the member has a documented failure, contraindication or intolerance to Gilenya (fingolimod) or Tecfidera (dimethyl fumurate). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# AURYXIA

## Products Affected

- Auryxia

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Coverage will not be approved for the treatment of iron deficiency anemia in patients with CKD not on dialysis. |
| **Required Medical Information** | The member must have a documented diagnosis of hyperphosphatemia associated with chronic kidney disease (CKD) and receiving dialysis. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# AUSTEDO

## Products Affected

- Austedo

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Chorea Associated with Huntington's Disease: The member must have a documented diagnosis of chorea associated with Huntington's Disease. Tardive Dyskinesia: The member must have a documented diagnosis of Tardive Dyskinesia. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist or psychiatrist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# BALVERSA

## Products Affected

- Balversa

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations as detected by an FDA-approved companion diagnostic and the member progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescriber must be an oncologist or urologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# BENLYSTA

## Products Affected

- Benlysta

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Benlysta (belimumab) will not be approved as monotherapy, for members with severe active lupus nephritis or severe active central nervous system lupus, for members who are autoantibody negative or in combination with other biologics or intravenous cyclophosphamide. |
| **Required Medical Information** | The member must have a documented diagnosis of active, autoantibody-positive (e.g. ANA, anti-ds-DNA, anti-Sm) systemic lupus erythematosus (SLE) and is concurrently taking standard therapy for SLE (e.g., antimalarials, corticosteroids, or immunosuppressives). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a rheumatologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# BOSULIF

## Products Affected

- Bosulif Oral Tablet 100 MG, 400 MG, 500 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with a documented resistance or intolerance to prior therapy, including imatinib mesylate (Gleevec) or the member is newly diagnosed with chronic phase Ph+ CML. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# BRAFTOVI

## Products Affected

- Braftovi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma. |
| **Required Medical Information** | The member must have a documented diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation as detected by an FDA-approved test and will be taken in combination with Mektovi (binimetinib). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# BRIVIACT

## Products Affected

- Briviact

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to two (2) or more medications indicated for adjunct partial seizures (e.g. Aptiom, felbamate (Felbatol), Fycompa, gabapentin (Fanatrex, Gralise, Neurontin), lamotrigine (Lamictal, Lamictal XR, Lamictal ODT), Lyrica, levetiracetam (Keppra, Keppra XR), oxcarbazepine (Oxtellar XR, Trileptal), tiagabine (Gabitril), topiramate (Topamax, Trokendi XR), Potiga, Vimpat, and/or zonisamide (Zonegran)). |
| **Age Restrictions** | The member must be four (4) years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# CABOMETYX

## Products Affected

- Cabometyx

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Advanced Renal Cell Carcinoma (RCC): The member must have a documented diagnosis of advanced renal cell carcinoma (RCC). Hepatocellular Carcinoma (HCC): The member must have a documented diagnosis of HCC and has had a documented failure, contraindication, or intolerance with Nexavar (sorafenib). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# CALQUENCE

## Products Affected

- Calquence

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Mantle Cell Lymphoma (MCL): The member must have a documented diagnosis of MCL and has received at least one (1) prior therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# CAPRELSA

## Products Affected

- Caprelsa Oral Tablet 100 MG, 300 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescriber must be an endocrinologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# CARBAGLU

## Products Affected

- Carbaglu

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# CERDELGA

## Products Affected

- Cerdelga

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of type 1 Gaucher Disease and documentation the member is a cytochrome 2D6 extensive metabolizer (EMs), intermediate metabolizer (IMs), or poor metabolizer (PMs) as detected by an FDA-approved test. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# CHOLBAM

## Products Affected

- Cholbam

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Cholbam will not be approved for members with extrahepatic manifestations of either bile acid synthesis disorders due to single enzyme defects (SEDs) or peroxisomal disorders (PDs), including Zellweger spectrum disorders. |
| **Required Medical Information** | Bile Acid Synthesis Disorder: The member must have a documented diagnosis of bile acid synthesis disorders due to single enzyme defects (SEDs). Peroxisomal Disorders (PDs): The member must have a documented diagnosis of PDs, including Zellweger spectrum disorders, and exhibit manifestations of hepatic disease, steatorrhea, or complications from decreased fat soluble vitamin absorption and Cholbam is being used as adjunctive therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# CIALIS

## Products Affected

- Cialis

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Cialis is excluded from coverage for the treatment of Erectile Dysfunction. |
| **Required Medical Information** | The member must have a documented diagnosis or signs and symptoms of Benign Prostatic Hyperplasia (BPH) and has had a documented failure, adverse reaction, or contraindication to a 30-day trial of at least two (2) of the following medications: alfuzosin, doxazosin, dutasteride, dutasteride-tamsulosin, finasteride, tamsulosin, or terazosin. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# CINRYZE

## Products Affected

- Cinryze

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Hereditary Angioedema. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an allergist or immunologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# COMETRIQ

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of progressive, metastatic medullary thyroid cancer. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# COPIKTRA

## Products Affected

- Copiktra

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): The member must have a documented diagnosis of relapsed or refractory CLL or SLL and has received at least two (2) prior therapies. Follicular lymphoma (FL): The member must have a documented diagnosis of relapsed or refractory FL and has received at least two (2) prior systemic therapies. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# CORLANOR

## Products Affected

- Corlanor

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of stable, symptomatic chronic heart failure with a left ventricular ejection fraction of 35% or less, and is in sinus rhythm with resting heart rate at least 70 beats per minute (bpm) and is either on maximally tolerated doses of beta-blockers or has a contraindication to beta-blocker use. Pediatric Patients: The member must have a documented diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy. |
| **Age Restrictions** | For Stable Symptomatic Heart Failure due to Dilated Cardiomyopathy: The member must be 6 months to 18 years of age. |
| **Prescriber Restrictions** | The prescribing physician must be a cardiologist |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# COTELLIC

## Products Affected

- Cotellic

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Cotellic is not indicated for treatment of patients with wild-type BRAF melanoma. |
| **Required Medical Information** | The member must have a documented diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation and is being taken in combination with Zelboraf (vemurafenib). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# CRINONE

## Products Affected

- Crinone

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Crinone is excluded as part of an assisted reproductive technology (ART) treatment for infertile women with progesterone deficiency. |
| **Required Medical Information** | The member must have a documented diagnosis of secondary amenorrhea. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# DALFAMPRIDINE

## Products Affected

- *dalfampridine er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Multiple Sclerosis and the member is receiving concurrent therapy with a disease modifying agent (e.g. Aubagio, Avonex, Betaseron, Copaxone, Extavia, Gilenya, Rebif, Tecfidera, or Tysabri) if indicated, and the member is ambulatory with a baseline timed 25 foot walk between 8 and 45 seconds. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | Initial authorization is for twelve (12) weeks. |
| **Other Criteria** | Additional authorization may be provided if there is documented improvement in walking speed from pre-treatment baseline. Subsequent authorization is for an FDA-approved duration, balance of contract year or clinically appropriate duration. |

# DAURISMO

## Products Affected

- Daurismo

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of acute myelogenous leukemia (AML) and Daurismo is being used as first-line therapy in combination with low-dose cytarabine and the member meets one of the following: 1) is 75 years of age or older or 2) has comorbidities that make them ineligible for intensive induction chemotherapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# DESOXYN/METHAMPHETAMINE ORAL TABLET

## Products Affected

- Desoxyn
- *methamphetamine hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Desoxyn and methamphetamine oral tablets are not covered for narcolepsy and are excluded from coverage for exogenous obesity. |
| **Required Medical Information** | The member must have a documented diagnosis of ADHD. |
| **Age Restrictions** | The member must be 6 years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# DIFICID

## Products Affected

- Dificid

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Clostridium difficile-associated diarrhea with a treatment failure or inadequate response to metronidazole or vancomycin. |
| **Age Restrictions** | The member must be 18 years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# DOPTELET

## Products Affected

- Doptelet

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must meet one of the following criteria: 1) Documented diagnosis of thrombocytopenia associated with chronic liver disease (CLD) and is scheduled to undergo a procedure OR 2) Documented diagnosis of thrombocytopenia with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# DUPIXENT

## Products Affected

- Dupixent

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus. |
| **Required Medical Information** | Atopic Dermatitis: The member must have a documented diagnosis of moderate-to-severe atopic dermatitis and an inadequate treatment response, intolerance, or contraindication to BOTH a high potency topical corticosteroid and a topical calcineurin inhibitor (i.e. tacrolimus, Elidel).<br>Asthma: The member must have a documented diagnosis of moderate-to-severe asthma with an eosinophilic phenotype or is dependent on oral corticosteroids and documentation that underlying conditions or triggers for asthma or pulmonary disease are being maximally managed.<br>Rhinosinusitis (chronic) with nasal polyposis: The member must have a documented diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) and is inadequately controlled on current treatment alone. |
| **Age Restrictions** | Atopic Dermatitis and Asthma: The member must be 12 years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be an allergist, dermatologist, immunologist, otolaryngologist or pulmonologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# EGRIFTA

## Products Affected

- Egrifta

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of HIV-associated lipodystrophy with excess abdominal fat. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# EMFLAZA

## Products Affected

- Emflaza

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Duchenne muscular dystrophy (DMD). |
| **Age Restrictions** | The member must be 2 years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist or a provider who specializes in the treatment of DMD. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# EMGALITY

## Products Affected

- Emgality
- Emgality (300 MG Dose)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Initial: The member must have one of the following: 1) Documented diagnosis of migraine and the member has had an inadequate response after a 4-week trial of or has a contraindication to antidepressants, antiepileptic drugs (AEDs) or beta blockers OR 2) Documented diagnosis of episodic cluster headache. Subsequent: The member has had a clinically significant reduction in migraine days per month or the frequency of weekly cluster headache attacks from baseline. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 6 months.  Subsequent approval: Life of Plan. |
| **Other Criteria** | None |

# ENBREL

## Products Affected

- Enbrel Mini
- Enbrel Subcutaneous Solution Prefilled Syringe 25 MG/0.5ML, 50 MG/ML
- Enbrel Subcutaneous Solution Reconstituted
- Enbrel SureClick

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Ankylosing Spondylitis: The member must have a documented diagnosis of active ankylosing spondylitis. Plaque Psoriasis: The member must have a documented diagnosis of moderate-to-severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate treatment with one (1) of the following medications: cyclosporine, methotrexate, or acitretin (Soriatane). Rheumatoid Arthritis (RA) and Polyarticular Juvenile Idiopathic Arthritis (PJIA): The member must have a documented diagnosis of either disease and has a documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three (3) months. |
| **Age Restrictions** | Plaque Psoriasis: The member must be four (4) years of age or older. PJIA: The member must be two (2) years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be a dermatologist or rheumatologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# EPCLUSA

## Products Affected

- Epclusa

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Criteria will be applied consistent with current AASLD-IDSA guidance. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a gastroenterologist, hepatologist, or an infectious disease specialist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# EPIDIOLEX

## Products Affected

- Epidiolex

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS). |
| **Age Restrictions** | The member must be two (2) years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ERIVEDGE

## Products Affected

- Erivedge

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of metastatic basal cell carcinoma or locally advanced basal cell carcinoma that has recurred following surgery, or the member is not a candidate for surgery or radiation. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a dermatologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ERLEADA

## Products Affected

- Erleada

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of nonmetastatic, castration-resistant prostate cancer. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist or urologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ESBRIET

## Products Affected

- Esbriet Oral Capsule
- Esbriet Oral Tablet

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of idiopathic pulmonary fibrosis (IPF) and is not currently taking Ofev (nintedanib). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a pulmonologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# EUCRISA

## Products Affected

- Eucrisa

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Members 2 years to 17 years of age: The member must have a documented diagnosis of mild-to-moderate atopic dermatitis and an inadequate treatment response, intolerance, or contraindication to BOTH a low potency topical corticosteroid and a topical calcineurin inhibitor (i.e. tacrolimus, Elidel). Members 18 years of age or older: The member must have a documented diagnosis of mild-to-moderate atopic dermatitis and an inadequate treatment response, intolerance, or contraindication to BOTH a high potency topical corticosteroid and a topical calcineurin inhibitor (i.e. tacrolimus, Elidel). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a dermatologist or pediatrician. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# EVENITY

## Products Affected

- Evenity

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must be a postmenopausal woman with a documented diagnosis of osteoporosis with high risk of fracture, defined as a history of osteoporotic fracture or multiple risk factors for fracture, and the member has had an inadequate response to or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments [alendronate (Fosamax), calcitonin (Miacalcin), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel), zoledronic acid (Reclast)]. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Coverage of Evenity is limited to 1 year. |
| **Other Criteria** | None |

# EVZIO

## Products Affected

- Evzio

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Evzio may be approved for coverage if there is an FDA-confirmed shortage of Narcan (naloxone) nasal spray or the member or their caregiver(s) would be unable to utilize Narcan nasal spray due to significant visual, physical, or functional impairment. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# FARYDAK

## Products Affected

- Farydak

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of multiple myeloma and has received at least two (2) prior therapies including Velcade (bortezomib) and an immunomodulatory agent, and Farydak is being used in combination with dexamethasone and Velcade (bortezomib). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# FASENRA

## Products Affected

- Fasenra

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of severe asthma with an eosinophilic phenotype and documentation that underlying conditions or triggers for asthma or pulmonary disease are being maximally managed. |
| **Age Restrictions** | The member must be 12 years of age or older. |
| **Prescriber Restrictions** | The prescriber must be an asthma specialist (e.g., allergist, immunologist, pulmonologist). |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# FIRAZYR

## Products Affected

- Firazyr
- *icatibant acetate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Firazyr (icatibant) will not be approved for members with acquired angioedema or concurrently taking an angiotensin converting enzyme (ACE) inhibitor. |
| **Required Medical Information** | The member must have a documented diagnosis of Hereditary Angioedema (HAE) with a history of at least one severe attack in the past six (6) months. For HAE Types 1 & 2, the diagnosis must be confirmed by laboratory testing (e.g., low C4 level, reduced C1 esterase inhibitor level or function). |
| **Age Restrictions** | The member must be 18 years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be an allergist, hematologist or immunologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# FIRDAPSE

## Products Affected

- Firdapse

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Lambert-Eaton myasthenic syndrome (LEMS). |
| **Age Restrictions** | The member must be 18 years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# FORTEO

## Products Affected

- Forteo

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Coverage of Forteo will not be approved when used in combination with any of the other osteoporosis agents listed in the Required Medical Information section. |
| **Required Medical Information** | Coverage of Forteo may be authorized when the requesting physician has documented that the member is at high risk for fracture and has a T score less than or equal to -2.0 as evidenced via bone density scan or the requesting physician has documented that the member has had one or more osteoporotic fractures. For either condition previously listed, the member must also have had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments: alendronate (Fosamax), calcitonin (Miacalcin), denosumab (Prolia), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel) or zoledronic acid (Reclast). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Coverage of Forteo is limited to 24 months. |
| **Other Criteria** | None |

# FYCOMPA

## Products Affected

- Fycompa

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Partial-onset Seizures: The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to two (2) or more medications indicated for adjunct partial seizures (e.g. Aptiom, Briviact, felbamate (Felbatol), gabapentin (Fanatrex, Gralise, Neurontin), lamotrigine (Lamictal, Lamictal XR, Lamictal ODT), Lyrica, levetiracetam (Keppra, Keppra XR, Roweepra, Spritam), oxcarbazepine (Oxtellar XR, Trileptal), tiagabine (Gabitril), topiramate (Topamax, Trokendi XR), Potiga, Vimpat, and/or zonisamide (Zonegran)). Primary Generalized Tonic-clonic Seizures: The member must have a documented diagnosis of primary generalized tonic-clonic seizures and has had an insufficient response or intolerance to two (2) or more medications indicated for primary generalized tonic-clonic seizures (e.g. carbamazepine, felbamate, lamotrigine, levetiracetam, phenytoin, topiramate, and valproate). |
| **Age Restrictions** | The member must be 12 years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# GALAFOLD

## Products Affected

- Galafold

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a cardiologist, nephrologist, or a specialist in metabolic diseases or genetics. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# GATTEX

## Products Affected

- Gattex

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Short Bowel Syndrome (SBS) and is dependent on parenteral nutrition. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# GILENYA

## Products Affected

- Gilenya

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of a relapsing form of multiple sclerosis and the member has a documented failure, contraindication, or intolerance to Aubagio (teriflunomide) or Tecfidera (dimethyl fumurate). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# GILOTRIF

## Products Affected

- Gilotrif

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of metastatic non-small cell lung cancer (NSCLC) and documented non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test or a documented diagnosis of metastatic, squamous cell NSCLC and documentation that the disease has progressed following platinum-based chemotherapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# GROWTH HORMONE REPLACEMENT THERAPY

## Products Affected

- Genotropin
- Genotropin MiniQuick
- Humatrope
- Norditropin FlexPro
- Nutropin AQ NuSpin 10
- Nutropin AQ NuSpin 20
- Nutropin AQ NuSpin 5
- Omnitrope
- Saizen
- Saizenprep
- Serostim
- Zomacton
- Zorbtive

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All medically accepted indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Pediatric GHD, Initiation: Member must be evaluated and treated by a pediatric endocrinologist, have not attained epiphyseal closure as determined by X-ray, have failed to respond to at least TWO standard GH stimulation test, have documented gender-specific delayed bone age, have the height at initiation of therapy at greater than 2 standard deviations below normal mean for age and sex. Member must have one of the following: Chronic Renal Insufficiency prior to transplantation, Idiopathic Short Stature, Intrauterine Growth Retardation, Non-genetic GHD, Noonan Syndrome, Prader-Willi Syndrome, Short Stature Homeobox-containing gene (SHOX) deficiency, or Turner Syndrome. Pediatric GHD, Continuation: Documentation of the following is required: Medical history as it relates to growth, including any test results and growth chart, continuing care plan and an improvement in the annualized pre-treatment growth rate after the first six (6) months of therapy. Continuation of Therapy after Completion of Linear Growth: Member will be re-evaluated after GH treatments have been stopped for at least three (3) months to determine growth hormone status AND member must have failed to respond to at least one standard GH stimulation test. Acquired GHD: Member must have failed to respond to at least one standard GH stimulation test. AIDS Wasting Syndrome: Documented diagnosis of AIDS AND a weight loss of at least 10% from baseline weight OR a BMI of less than 20. Short Bowel Syndrome: Documented diagnosis of Short Bowel Syndrome from a gastroenterologist AND a documented dependence on IPN for nutritional support. |
| **Age Restrictions** | None |

| PA Criteria | Criteria Details |
|---|---|
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# HAEGARDA

## Products Affected

- Haegarda

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Hereditary Angioedema. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an allergist or immunologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# HARVONI

## Products Affected

- Harvoni

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Criteria will be applied consistent with current AASLD-IDSA guidance. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a gastroenterologist, hepatologist, or an infectious disease specialist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# HETLIOZ

## Products Affected

- Hetlioz

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Coverage will not be authorized for the diagnosis of insomnia. |
| **Required Medical Information** | The member must be completely blind and have a documented diagnosis of non-24-hour sleep-wake disorder (non-24). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist or sleep specialist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# HRM:ANTIPARKINSON AGENTS

## Products Affected

- *benztropine mesylate*
- *trihexyphenidyl hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: amantadine, carbidopa/levodopa, tolcapone. |

# HRM:ESTROGEN-CONTAINING PRODUCTS

## Products Affected

- Alora
- CombiPatch
- *dotti*
- Duavee
- *estradiol oral*
- *estradiol transdermal*
- Femhrt Low Dose
- *fyavolv*
- *jinteli*
- Menest
- Menostar
- *norethindrone-eth estradiol*
- Premarin Oral
- Premphase
- Prempro

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | This criterion applies to estrogen-containing oral and topical patch products only, with or without progesterone. |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: alendronate, calcitonin, Forteo, ibandronate, Prolia, raloxifene, risedronate, zoledronic acid (osteoporosis), estradiol vaginal cream, vaginal tab, vaginal ring (menopausal/vaginal symptoms). |

# HRM:FIRST GENERATION ANTIPSYCHOTICS

## Products Affected

- *thioridazine hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: olanzapine, quetiapine, risperidone, ziprasidone (some may require STPA for approval). |

# HRM:HYDROXYZINE

## Products Affected

- *hydroxyzine hcl*
- *hydroxyzine pamoate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: desloratadine, levocetirizine (pruritus), duloxetine, escitalopram, venlafaxine ER (anxiety), alprazolam, temazepam (sedation). |

# HRM:HYPNOTICS

## Products Affected

- *eszopiclone*
- *zaleplon*
- *zolpidem tartrate*
- *zolpidem tartrate er*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: Rozerem, Silenor, temazepam. |

# HRM:MISCELLANEOUS

## Products Affected

- *cyclobenzaprine hcl*
- *cyproheptadine hcl*
- *digitek oral tablet 250 mcg*
- *digox oral tablet 250 mcg*
- *digoxin oral solution*
- *digoxin oral tablet 250 mcg*
- *dipyridamole*
- *disopyramide phosphate*
- *doxepin hcl oral*
- *guanfacine hcl er*
- *indomethacin*
- *indomethacin er*
- Lanoxin Oral Tablet 250 MCG
- *megestrol acetate*
- *nifedipine*
- Norpace CR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: cyproheptadine (levocetirizine, desloratadine or physician attestation that the benefit outweighs the risk for beneficiaries age 65 or older), digoxin/Lanoxin 250 mcg (consider reducing dose to 0.125 mg daily or lower), dipyridamole immediate-release (anagrelide, Brilinta, clopidogrel, dipyridamole/aspirin), disopyramide (amiodarone, flecainide, mexiletine, propafenone, quinidine, sotalol), doxepin (citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine), guanfacine extended-release (amphetamine salt combo, dexmethylphenidate, dextroamphetamine, methamphetamine, methylphenidate), indomethacin (celecoxib, ibuprofen, naproxen, tramadol), megestrol tablets (covered without authorization for advanced carcinoma of the breast or endometrium), megestrol oral suspension (dronabinol) nifedipine immediate-release (isosorbide dinitrate, isosorbide mononitrate, Nitro-BID), Norpace CR (acebutolol, flecainide, mexiletine, propafenone, quinidine, sotalol), reserpine (Hypertension: ACE-Inhibitor or angiotensin-receptor blocker. Psychoses: olanzapine, quetiapine, risperidone, ziprasidone (some may require STPA for approval)). Cyclobenzaprine may be approved for relief of muscle spasm associated with acute, painful musculoskeletal conditions. |

# HRM:NITROFURANTOIN

## Products Affected

- *nitrofurantoin macrocrystal*
- *nitrofurantoin monohyd macro*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: ciprofloxacin, levofloxacin, sulfamethoxazole/trimethoprim, trimethoprim. |

# HRM:ORAL HYPOGLYCEMICS

## Products Affected

- *glyburide*
- *glyburide micronized*
- *glyburide-metformin*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: glimepiride, glipizide, glipizide-metformin, metformin, tolazamide, tolbutamide. |

# HRM:PHENOBARBITAL

## Products Affected

- *phenobarbital*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: buspirone (sedation), fosphenytoin, carbamazepine, lamotrigine, levetiracetam, topiramate, valproate (seizures). |

# HRM:PROMETHAZINE

## Products Affected

- *promethazine hcl*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: budesonide nasal, desloratadine, fluticasone nasal, flunisolide nasal, levocetirizine, triamcinolone nasal (allergic rhinitis), Anzemet, aprepitant, Cesamet, Emend, granisetron, perphenazine, ondansetron, prochlorperazine, Sancuso (emesis/motion sickness), buspirone (sedation), desloratadine, levocetirizine (urticaria). |

# HRM:TRICYCLIC ANTIDEPRESSANTS

## Products Affected

- *amitriptyline hcl*
- *clomipramine hcl*
- *imipramine hcl*
- *imipramine pamoate*
- *trimipramine maleate*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-HRM alternative formulary drug listed in the OTHER CRITERIA field. Please provide the name(s) of the drug(s) to which the member has had an inadequate treatment response, intolerance or contraindication and the prescriber acknowledges that medication benefits outweigh potential risks in the member 65 years of age or older. |
| **Age Restrictions** | The Prior Authorization requirement only applies to members 65 years of age or older who are newly starting the prescribed medication. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial Approval: 1 year. Subsequent approval: Life of Plan. |
| **Other Criteria** | Non-HRM Alternatives include, but are not limited to: citalopram, duloxetine, escitalopram, venlafaxine (depression), fluoxetine, fluvoxamine, paroxetine, sertraline (depression/OCD). Imipramine is covered for the diagnosis of enuresis. |

# HUMIRA

## Products Affected

- Humira
- Humira Pediatric Crohns Start
- Humira Pen
- Humira Pen-CD/UC/HS Starter
- Humira Pen-Ps/UV/Adol HS Start

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Ankylosing Spondylitis: The member must have a documented diagnosis of active ankylosing spondylitis. Crohn's Disease and Ulcerative Colitis (UC): The member must have a documented diagnosis of either disease and an inadequate response to an appropriate trial with two (2) or more of the following agents: a) Corticosteroids (e.g., methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (e.g. balsalazide (Colazal), Dipentum, mesalamine (Asacol), Pentasa, Rowasa, sulfasalazine (Azulfidine)). c) 6-mercaptopurine (6-MP, Purinethol) or azathioprine. d) Methotrexate OR the member has demonstrated failure or intolerance to infliximab (Remicade). Hidradenitis Suppurativa: The member must have a documented diagnosis of moderate-to-severe hidradenitis suppurativa. Plaque Psoriasis: The member must have a documented diagnosis of moderate-to-severe chronic plaque psoriasis and has failed to respond to, or has been unable to tolerate treatment with one (1) of the following medications: cyclosporine, methotrexate, or acitretin (Soriatane). Psoriatic Arthritis: The member must have a documented diagnosis of active psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three (3) months. Rheumatoid Arthritis (RA) and Polyarticular Juvenile Idiopathic Arthritis (PJIA): The member must have a documented diagnosis of either disease and has a documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Uveitis: The member must have a documented diagnosis of non-infectious intermediate, posterior, and panuveitis. |
| **Age Restrictions** | Crohn's Disease: The member must be six (6) years of age or older. PJIA: The member must be two (2) years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be a dermatologist, gastroenterologist, ophthalmologist, or rheumatologist. |

| PA Criteria | Criteria Details |
|---|---|
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# IBRANCE

## Products Affected

- Ibrance

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must be a man or post-menopausal woman with a documented diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and Ibrance is being used in combination with an aromatase inhibitor OR the member must have a documented diagnosis of HR-positive, HER2- negative advanced or metastatic breast cancer with disease progression following endocrine therapy and documentation Ibrance (palbociclib) will be used in combination with Faslodex (fulvestrant). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ICLUSIG

## Products Affected

- Iclusig

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Iclusig will not be approved for members with newly diagnosed chronic phase CML. |
| **Required Medical Information** | Acute Lymphoblastic Leukemia (ALL): The member must be T315I positive or have a documented diagnosis of Philadelphia chromosome-positive ALL (Ph+ALL) for which no other tyrosine kinase inhibitor therapy is indicated. Chronic Myeloid Leukemia (CML): The member must be T315I positive or have a documented diagnosis of chronic phase, accelerated phase, or blast phase CML for which no other tyrosine kinase inhibitor therapy is indicated. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# IDHIFA

## Products Affected

- IDHIFA

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# IMBRUVICA

## Products Affected

- Imbruvica

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Chronic Graft versus Host Disease (cGVHD): The member must have a documented diagnosis of cGVHD and has had a documented inadequate response, contraindication, or inability to tolerate an appropriate trial with one (1) or more lines of systemic therapy. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): The member must have a documented diagnosis of CLL/SLL. Mantle Cell Lymphoma (MCL): The member must have a documented diagnosis of MCL and has received at least one (1) prior therapy. Marginal Zone Lymphoma (MZL): The member must have a documented diagnosis of MZL and has received at least one (1) prior anti-CD20-based therapy. Waldenstrom Macroglobulinemia: The member must have a documented diagnosis of Waldenstrom macroglobulinemia. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist, oncologist, or transplant specialist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# INBRIJA

## Products Affected

- Inbrija

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Parkinson's disease with off episodes and the member is being treated with carbidopa/levodopa. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# INCRELEX

## Products Affected

- Increlex

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Coverage of Increlex will not be authorized for conditions resulting in secondary forms of IGF-1 deficiency that include, but are not limited to: GH deficiency, malnutrition, hypothyroidism, or chronic steroid therapy. |
| **Required Medical Information** | The member must have a documented diagnosis of severe primary IGF-1 deficiency as defined by a height SD score less than or equal to -3.0, a basal IGF-1 SD score less than or equal to -3.0 , normal or elevated GH level OR GH gene deletion and has developed neutralizing antibodies to GH. Radiographs documenting open epiphyses are required for members who are Tanner stage III or greater. |
| **Age Restrictions** | The member must be aged 2 to 18 years. |
| **Prescriber Restrictions** | The prescribing physician must be an endocrinologist. |
| **Coverage Duration** | Initial authorization is for six (6) months. Subsequent authorizations are for one (1) year. |
| **Other Criteria** | None |

# INGREZZA

## Products Affected

- Ingrezza

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of tardive dyskinesia and has had a documented inadequate response, contraindication, or inability to tolerate an appropriate trial with conventional treatment options. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# INLYTA

## Products Affected

- Inlyta

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of advanced renal cell carcinoma and has failed a trial of at least one (1) first-line systemic therapy (e.g. Afinitor, Avastin, Nexavar, Sutent, Torisel, Votrient). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# INREBIC

## Products Affected

- Inrebic

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# INTRAVENOUS IMMUNE GLOBULIN

## Products Affected

- Flebogamma DIF
- Gammagard
- Gammagard S/D Less IgA
- Gammaked
- Gammaplex
- Gamunex-C
- Octagam
- Panzyga
- Privigen

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All medically accepted indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Coverage not approved for progressive MS |
| **Required Medical Information** | Documented diagnosis of one of the following: Primary humoral immunodeficiency (Congenital agammaglobulinemia, Common variable immunodeficiency, Wiskott-Aldrich syndrome, X-linked agammaglobulinemia, or Severe combined immunodeficiency). Recurrent severe infection and documented severe deficiency or absence of IgG subclass. Clinically significant functional deficiency of humoral immunity as evidenced by documented failure to produce antibodies to specific antigens and a history of recurrent infections. Immune thrombocytopenic purpura (ITP) (Acute and Chronic refractory ITP). Chronic Lymphocytic Leukemia with associated hypogammaglobulinemia. Symptomatic Human Immunodeficiency Virus (HIV) in patients less than 13 years of age, who are immunologically abnormal. Bone marrow transplantation. Solid organ transplantation. Kawasaki disease (mucocutaneous lymph node syndrome). Acute and chronic inflammatory demyelinating polyradiculoneuropathy. Guillain-Barre syndrome. Myasthenia gravis. Immune thrombocytopenic purpura in pregnancy. Multifocal motor neuropathy (MMN) and dermatomyositis. Autoimmune mucocutaneous blistering diseases (Pemphigus vulgaris, Bullous pemphigoid, Mucous membrane pemphigoid [a.k.a., cicatrical pemphigoid], or Epidermolysis bullosa Acquisita). Scleromyxedema is covered for patients whose treatment with more traditional measures has failed. Humoral or vascular allograft rejection. Hemolytic anemia. Polymyositis and Dermatomyositis. Sensitized renal transplant recipients. Sepsis. Kidney disease. CMV infection. von Willebrand disorder. Uveitis. Toxic shock syndrome. RSV infection. HIV-associated thrombocytopenia and treatment of post-transfusion Purpura. Chronic inflammatory demyelinating polyneuropathy. Hepatitis A, Measles (Rubeola). Rubella. Varicella in immunosuppressed patients when varicella zoster immunoglobulin is not available. |

| PA Criteria | Criteria Details |
|---|---|
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial authorization is for six (6) months. |
| **Other Criteria** | None |

# IRESSA

## Products Affected

- Iressa

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of metastatic non-small cell lung cancer (NSCLC) in tumors that have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ITRACONAZOLE

## Products Affected

- *itraconazole*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All medically accepted indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of onychomycosis of the fingernails or toenails, or tinea capitis, and the requesting physician has documented that the member has had an inadequate response, contraindication, or inability to tolerate terbinafine tablets or Lamisil oral granules, or the requesting physician has documented that the member has a case of one of the following fungal infections: Aspergillosis, Blastomycosis, Cryptococcus neoformans, Histoplasmosis, Tinea (corporis, pedis) resistant to aggressive topical therapy, Esophageal Candidiasis (oral solution only), or Oropharyngeal Candidiasis (oral solution only). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# JAKAFI

## Products Affected

- Jakafi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Myelofibrosis: The member must have a documented diagnosis of intermediate or high-risk myelofibrosis. Polycythemia Vera: The member must have a documented diagnosis of polycythemia vera with an inadequate response, contraindication, or inability to tolerate hydroxyurea. Steroid-Refractory Acute Graft-versus-host Disease (GVHD): The member must have a document diagnosis of steroid-refractory acute GVHD. |
| **Age Restrictions** | For steroid-refractory acute GVHD: The member must be 12 years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Initial authorization is for six (6) months.  Subsequent authorization is for Life of Plan. |
| **Other Criteria** | Subsequent authorization requires documentation of spleen size reduction or symptomatic improvement. |

# JUXTAPID

## Products Affected

- Juxtapid

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a laboratory-confirmed documented diagnosis of homozygous familial hypercholesterolemia (HoFH) based on one of the following tests: a) LDLR DNA Sequence Analysis. b) LDLR Deletion/Duplication Analysis for large gene rearrangement testing (only if the Sequence Analysis is negative). c) APOB and PCSK9 testing if both of the above tests are negative but a strong clinical picture exists. The member must be concurrently taking lipid-lowering medications or has a documented contraindication to lipid-lowering medications and has had a documented inadequate response to an appropriate trial with or a contraindication to a PCSK9 Inhibitor. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# KALYDECO

## Products Affected

- Kalydeco

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Kalydeco is not effective in patients with cystic fibrosis who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. |
| **Required Medical Information** | The member must have a documented diagnosis of cystic fibrosis (CF) and have one mutation in the CFTR gene that is responsive to Kalydeco based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared cystic fibrosis mutation test should be used to detect the presence of a CFTR mutation followed by verification with bidirectional sequencing when recommended by the mutation test instructions for use. |
| **Age Restrictions** | Granules: The member must be 6 months to five 5 years of age. Tablets: The member must be 6 years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# KEVEYIS

## Products Affected

- Keveyis

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# KINERET

## Products Affected

- Kineret

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Neonatal-Onset Multisystem Inflammatory Disease (NOMID): The member must have a documented diagnosis of NOMID. Rheumatoid Arthritis (RA): The member must have a documented diagnosis of moderately-to-severely active RA and has documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. |
| **Age Restrictions** | For RA, the member must be 18 years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be a pediatrician or rheumatologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# KISQALI

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Premenopausal or Perimenopausal Women: The member must have a documented diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and Kisqali is being used in combination with an aromatase inhibitor as initial endocrine-based therapy. Postmenopausal Women: The member must have a documented diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and Kisqali is being used in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy or Kisqali is being used in combination with fulvestrant following disease progression on endocrine therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# KORLYM

## Products Affected

- Korlym

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of hyperglycemia secondary to hypercortisolism with endogenous Cushing's syndrome and type 2 diabetes mellitus OR glucose intolerance AND has failed surgery OR is not a candidate for surgery. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# KUVAN

## Products Affected

- Kuvan

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a specialist in metabolic diseases or a geneticist. |
| **Coverage Duration** | Initial authorization is for eight (8) weeks. Subsequent authorization is for Life of Plan. |
| **Other Criteria** | Coverage may be authorized for continuing therapy if the member has demonstrated at least a 30% reduction in phenylalanine levels compared to baseline. |

# LENVIMA

## Products Affected

- Lenvima (10 MG Daily Dose)
- Lenvima (12 MG Daily Dose)
- Lenvima (14 MG Daily Dose)
- Lenvima (18 MG Daily Dose)
- Lenvima (20 MG Daily Dose)
- Lenvima (24 MG Daily Dose)
- Lenvima (4 MG Daily Dose)
- Lenvima (8 MG Daily Dose)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Advanced Renal Cell Carcinoma (ARCC): The member must have a documented diagnosis of ARCC and has had one (1) prior antiangiogenic therapy and is being used in combination with Afinitor(everolimus). Endometrial Carcinoma: 1) The member must have a documented diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) 2) have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation and 3) Lenvima must be used in combination with pembrolizumab. Hepatocellular carcinoma (HCC): The member must have a documented diagnosis of unresectable hepatocellular carcinoma. Thyroid Cancer: The member must have a documented diagnosis of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# LIDOCAINE TRANSDERMAL PATCHES

## Products Affected

- *lidocaine external patch*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All medically accepted indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | For Postherpetic Neuralgia or Diabetic Neuropathy, the member must have had a failure, adverse reaction, or contraindication to gabapentin. Lidocaine transdermal patches may be approved for members who are not candidates for opioid or other oral pain management therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | Coverage will be authorized for new members if their pain is currently well-controlled on lidocaine transdermal patches. |

# LONSURF

## Products Affected

- Lonsurf

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Metastatic Colorectal Cancer (mCRC): The member must have a documented diagnosis of mCRC and has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) biological therapy, and if rat sarcoma viral oncogene (RAS) wild-type, an anti-epidermal growth factor receptor (EGFR) therapy. Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma: The member must have a documented diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and has been previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# LORBRENA

## Products Affected

- Lorbrena

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) and has demonstrated disease progression on Xalkori (crizotinib) and at least one other ALK inhibitor for metastatic disease, or the member has progressed on Alecensa (alectinib) or Zykadia (ceritinib) as the first ALK inhibitor therapy for metastatic disease. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# LYNPARZA

## Products Affected

- Lynparza

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Breast Cancer: The member must have a documented diagnosis of deleterious or suspected deleterious germline BRCA-mutated (as detected by an FDA-approved test), HER2-negative metastatic breast cancer and has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. If hormone receptor-positive the member should have documented prior endocrine therapy or contraindication to or inability to tolerate endocrine therapy. Advanced Ovarian Cancer: The member must have a documented diagnosis of deleterious or suspected deleterious germline BRCA-mutated (as detected by an approved test) advanced ovarian cancer and has been treated with at least three (3) prior lines of chemotherapy or advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Recurrent Ovarian Cancer: The member must have a documented diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in a complete or partial response to platinum-based chemotherapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# MAVENCLAD

## Products Affected

- Mavenclad (10 Tabs)
- Mavenclad (4 Tabs)
- Mavenclad (5 Tabs)
- Mavenclad (6 Tabs)
- Mavenclad (7 Tabs)
- Mavenclad (8 Tabs)
- Mavenclad (9 Tabs)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Mavenclad will not be approved for members with clinically isolated syndrome (CIS). |
| **Required Medical Information** | The member must have a documented diagnosis of a relapsing form of multiple sclerosis, including relapsing-remitting disease as well as active secondary progressive disease, and the member has a documented failure, contraindication, or intolerance to another disease modifying agent. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# MAVYRET

## Products Affected

- Mavyret

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Criteria will be applied consistent with current AASLD-IDSA guidance. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a gastroenterologist, hepatologist, or an infectious disease specialist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# MAYZENT

## Products Affected

- Mayzent Oral Tablet 0.25 MG, 2 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of a relapsing form of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# MEDICATIONS FOR THE TREATMENT OF PULMONARY HYPERTENSION

## Products Affected

- Adempas
- *alyq*
- *ambrisentan*
- *bosentan*
- Letairis
- Opsumit
- Orenitram
- REVATIO ORAL SOLUTION
- *sildenafil citrate*
- *tadalafil (pah)*
- Tracleer
- Uptravi Oral Tablet
- Uptravi Oral Tablet Therapy Pack
- Ventavis

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of pulmonary arterial hypertension (WHO group I: see below) as confirmed by right heart catheterization. World Health Organization (WHO) Classification of Pulmonary Hypertension - Group 1: a) Idiopathic PAH (primary pulmonary hypertension). b) Heritable PAH. c) Drug- and toxin-induced PAH. d) PAH associated with other diseases and conditions (APAH), such as: i) Connective tissue diseases ii) HIV infection iii) Portal hypertension iv) Congenital heart disease v) Schistosomiasis vi) Chronic hemolytic anemia. e) Persistent pulmonary hypertension of the newborn OR chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) AND the pulmonary hypertension has progressed despite surgical treatment and/or maximal medical treatment of the underlying condition AND the medication used for treatment is consistent with its FDA-approved functional class (see Other Criteria). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a cardiologist or pulmonologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Adempas-WHO Class II-IV (Pulmonary Arterial Hypertension): Alyq-NYHA Class II-IV: Letairis and ambrisentan-WHO Class II-IV: Opsumit-WHO Class II-IV: Orenitram-WHO Class II-IV: Revatio-NYHA Class II-IV: sildenafil-NYHA Class II-IV: tadalafil-NYHA class II-IV: Tracleer and bosentan-NYHA Class II-IV: Uptravi - WHO Group I: Ventavis-NYHA Class III-IV |

# MEKINIST

## Products Affected

- Mekinist

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Mekinist will not be approved as a single agent for members who have received prior BRAF-inhibitor therapy. |
| **Required Medical Information** | Single Agent: The member must have a documented diagnosis of unresectable ormetastatic melanoma with a BRAF V600E mutation as confirmed by an FDA-approved test. In combination with Tafinlar, the member must have one of the following documented diagnoses as detected by an FDA-approved test: Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, or as adjuvant treatment of melanoma with a BRAF V600E or V600K mutation and involvement of lymph node(s) following complete resection, or metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, or locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# MEKTOVI

## Products Affected

- Mektovi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation as detected by an FDA-approved test, and will be taken in combination with Braftovi (encorafenib). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# MIGLUSTAT

## Products Affected

- *miglustat*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of mild-to-moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g. allergy, hypersensitivity, poor venous access). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# MISCELLANEOUS INJECTABLES

## Products Affected

- Abelcet
- Acthar
- *acyclovir sodium*
- AmBisome
- *amphotericin b*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Diagnosis of an FDA-approved indication not otherwise excluded from Part D. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# MULPLETA

## Products Affected

- Mulpleta

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of thrombocytopenia with chronic liver disease and is scheduled to undergo a procedure. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# MYTESI

## Products Affected

- Mytesi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of non-infectious diarrhea associated with HIV or AIDS and be on antiretroviral therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# NATPARA

## Products Affected

- Natpara

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Natpara will not be approved for members who are well-controlled on calcium supplements and active forms of vitamin D alone, or for members with hypoparathyroidism caused by calcium-sensing receptor mutations or acute postsurgical hypoparathyroidism. |
| **Required Medical Information** | The member must have a documented diagnosis of hypocalcemia secondary to hypoparathyroidism. Before starting Natpara, the prescriber must confirm sufficient 25-hydroxyvitamin D stores and that serum calcium is above 7.5 mg/dL. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an endocrinologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# NERLYNX

## Products Affected

- Nerlynx

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of early stage human epidermal growth receptor type 2 (HER2) overexpressed/amplified breast cancer and has had previous adjuvant treatment with Herceptin-based therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# NEXAVAR

## Products Affected

- NexAVAR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Advanced Renal Cell Carcinoma (ARCC): The member must have a documented diagnosis of ARCC. Hepatocellular Carcinoma (HCC): The member must have a documented diagnosis of biopsy-proven, unresectable HCC. Thyroid Carcinoma (TC): The member must have a documented diagnosis of locally recurrent or metastatic, progressive, differentiated TC refractory to radioactive iodine treatment. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a nephrologist, oncologist, or urologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# NINLARO

## Products Affected

- Ninlaro

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of multiple myeloma and Ninlaro is being used in combination with Revlimid (lenalidomide) and dexamethasone in patients who have received at least one (1) prior therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# NITYR

## Products Affected

- Nityr

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of genetic (hereditary) tyrosinemia Type-1. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# NORTHERA

## Products Affected

- Northera

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of neurogenic orthostatic hypotension (NOH). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# NUBEQA

## Products Affected

- Nubeqa

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of non-metastatic castration-resistant prostate cancer. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist or urologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# NUCALA

## Products Affected

- Nucala

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Severe Asthma with an Eosinophilic Phenotype: The member must have a documented diagnosis of severe asthma with an eosinophilic phenotype and documentation that underlying conditions or triggers for asthma or pulmonary disease are being maximally managed. Eosinophilic granulomatosis with polyangiitis: The member must have a documented diagnosis of eosinophilic granulomatosis with polyangiitis and has had an inadequate response to an appropriate trial with at least one (1) of the following immunosuppressants: azathioprine, cyclophosphamide, or methotrexate. |
| **Age Restrictions** | Severe Asthma: The member must be 6 years of age or older. |
| **Prescriber Restrictions** | The prescriber must be an asthma specialist (e.g., allergist, immunologist, pulmonologist) or rheumatologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# NUEDEXTA

## Products Affected

- Nuedexta

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Nuedexta will not be approved for management of heroin detoxification or neuropathic pain. |
| **Required Medical Information** | The member must have a documented diagnosis of pseudobulbar affect (PBA). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | One (1) year. |
| **Other Criteria** | None |

# NUPLAZID

## Products Affected

- Nuplazid

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Parkinson's disease and have hallucinations and delusions associated with Parkinson's disease psychosis. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The medication is being prescribed by or in consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# OCALIVA

## Products Affected

- Ocaliva

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Ocaliva will not be authorized for the treatment of non-alcoholic steatohepatitis. |
| **Required Medical Information** | The member must have a documented diagnosis of primary biliary cholangitis (PBC) and Ocaliva is being used in combination with ursodiol if the member has had an inadequate response to treatment with ursodiol alone. Ocaliva may be approved as monotherapy if the member is unable to tolerate ursodiol. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ODOMZO

## Products Affected

- Odomzo

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of locally advanced basal cell carcinoma and one of the following: a) Documentation of disease recurrence following surgery or radiation therapy or b) Documentation that the member is not a candidate for surgery or radiation therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# OFEV

## Products Affected

- Ofev

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of idiopathic pulmonary fibrosis (IPF) and is not currently taking Esbriet (pirfenidone). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a pulmonologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ORALAIR

## Products Affected

- Oralair

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have documentation of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five (5) grass species contained in this product. |
| **Age Restrictions** | The member must be 10 to 65 years of age. |
| **Prescriber Restrictions** | The medication is being prescribed by or in consultation with an allergist, immunologist, or pulmonologist. |
| **Coverage Duration** | One (1) year. |
| **Other Criteria** | None |

# ORFADIN

## Products Affected

- Orfadin

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of genetic (hereditary) tyrosinemia type-1. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ORILISSA

## Products Affected

- Orilissa Oral Tablet 150 MG, 200 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of endometriosis with moderate-to-severe pain. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ORKAMBI

## Products Affected

- Orkambi Oral Packet
- Orkambi Oral Tablet

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Orkambi will not be covered for individuals that are not homozygous for the F508del mutation. |
| **Required Medical Information** | The member must have a documented diagnosis of cystic fibrosis (CF) and have documentation from an FDA-approved CF mutation test that the member has the F508del mutation on both alleles of the CFTR gene. |
| **Age Restrictions** | The member must be two (2) years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# OXERVATE

## Products Affected

- Oxervate

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of neurotrophic keratitis. |
| **Age Restrictions** | The member must be 2 years of age or older. |
| **Prescriber Restrictions** | The medication must be prescribed by or in consultation with an ophthalmologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# PALYNZIQ

## Products Affected

- Palynziq

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of phenylketonuria (PKU) and has uncontrolled blood phenylalanine concentrations greater than 600 micromol per liter on existing management. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a specialist in metabolic diseases or a geneticist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# PIQRAY

## Products Affected

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

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must meet the following criteria: 1) The member must be a man or postmenopausal woman. 2) The member must have a documented diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer. 3) The member has progressed on or after an endocrine-based regimen. 4) Piqray is being used in combination with fulvestrant. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# POMALYST

## Products Affected

- Pomalyst

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of multiple myeloma and has received at least two (2) prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (Kyprolis, Ninlaro, or Velcade) and has demonstrated disease progression on or within 60 days of completion of the last therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# PRALUENT

## Products Affected

- Praluent

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must meet following criteria: 1) Documented value and date of baseline LDL cholesterol. 2) Documented lipid-lowering treatments and responses. 3) Member has an elevated LDL-C level while being treated with a high-potency statin (see Other Criteria), or has an elevated LDL-C level and a contraindication/intolerance to statin therapy. 4) The member must have a documented diagnosis of one of the following: a) Primary hyperlipidemia including Heterozygous Familial Hypercholesterolemia (HeFH) as confirmed by a genetic test or Meets Simon-Broome or WHO/Dutch Lipid Clinic Network Criteria (see Other Criteria). b) Cardiovascular disease. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The medication is being prescribed by or in consultation with a cardiologist, endocrinologist, lipidologist, or neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | High-potency statin treatment: atorvastatin greater than or equal to 40 mg or rosuvastatin greater than or equal to 20 mg daily. Simon-Broome Diagnostic Criteria for definite FH: Total cholesterol greater than 290 mg/dL or LDL-C greater than 190 mg/dL and tendon xanthomas in the patient, first (parent, sibling or child) or second degree relative (grandparent, uncle or aunt). Dutch Lipid Clinical Network Criteria for definite FH: Total score greater than 8 points. |

# PREVYMIS

## Products Affected

- Prevymis

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have documentation of having had, or is scheduled to receive, an allogeneic hematopoietic stem cell transplant (HSCT) and the member is at risk for cytomegalovirus (CMV) infection. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# PROLIA AND XGEVA

## Products Affected

- Prolia
- Xgeva

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Coverage of Prolia (denosumab) for the treatment of osteoporosis in men and postmenopausal women may be authorized when the following criteria are met: The member is at high risk of fracture defined as a history of osteoporotic fracture or multiple risk factors for fracture and a T score less than or equal to -2.0 as evidenced via bone density scan or the member has had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments [alendronate (Fosamax), calcitonin (Miacalcin), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel), zoledronic acid (Reclast)] or the member is a female at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and is using Prolia (denosumab) as a treatment to increase bone mass. Coverage of Prolia may be authorized for men at high risk of fracture who are receiving androgen deprivation therapy for nonmetastatic prostate cancer. Coverage for Xgeva (denosumab) may be authorized for prevention of skeletal-related events in patients with multiple myeloma or with bone metastases from solid tumors, or the member is being treated for unresectable giant cell tumor of bone (GCTB) or surgical resection of GCTB is likely to result in severe morbidity, or for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# PROMACTA

## Products Affected

- Promacta Oral Packet
- Promacta Oral Tablet

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Chronic Immune (idiopathic) Thrombocytopenic purpura (ITP) and has had an insufficient response or intolerance to corticosteroids, immunoglobulins, or splenectomy. Coverage may also be authorized for the treatment of thrombocytopenia in patients with chronic hepatitis C infection. Coverage may be authorized for the treatment of severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy or as first line in combination with standard immunosuppressive therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# RAVICTI

## Products Affected

- Ravicti

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Ravicti will not be approved for members with acute hyperammonemia. |
| **Required Medical Information** | The member must have a documented diagnosis of a urea cycle disorder. |
| **Age Restrictions** | The member must be two (2) months of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# RETINOIDS FOR THE TOPICAL TREATMENT OF ACNE VULGARIS AND PSORIASIS

## Products Affected

- *adapalene*
- *adapalene-benzoyl peroxide*
- Atralin
- *avita*
- Fabior
- Retin-A
- Retin-A Micro
- Retin-A Micro Pump
- *tazarotene*
- Tazorac
- *tretinoin external*
- *tretinoin microsphere*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All medically accepted indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Coverage of topical acne products will not be authorized for cosmetic purposes. |
| **Required Medical Information** | For all retinoids, the member must have a documented diagnosis of acne vulgaris, comedones (white heads), or actinic keratosis. Tazorac may also be covered if the member has a physician-documented diagnosis of plaque psoriasis or documented diagnosis of skin cancer provided effective treatment with Tazorac is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature. |
| **Age Restrictions** | This criterion only applies to members age 26 or older. Authorization is not required for members 25 years of age or younger. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# REVLIMID

## Products Affected

- Revlimid

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Mantle Cell Lymphoma (MLL): The member must have a documented diagnosis of MLL and the member's disease has relapsed or progressed after two (2) prior therapies, one of which included Velcade (bortezomib). Multiple Myeloma: The member must have a documented diagnosis of multiple myeloma and Revlimid is being used in combination with dexamethasone or as maintenance therapy in a member following autologous hematopoietic stem cell transplantation. Myelodysplastic Syndrome (MDS): The member must have a documented diagnosis of transfusion-dependent anemia due to MDS associated with the 5q-deletion cytogenetic abnormality. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ROZLYTREK

## Products Affected

- Rozlytrek

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Non-small Cell Lung Cancer (NSCLC): The member must have a documented diagnosis of metastatic NSCLC with ROS1-positive tumors. Solid Tumors: The member must have a documented diagnosis of solid tumors that 1) have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, 2) are metastatic or where surgical resection is likely to result in severe morbidity, and 3) have progressed following treatment or have no satisfactory alternative therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# RUBRACA

## Products Affected

- Rubraca

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Rubraca will not be approved for concurrent use with other chemotherapy agents. |
| **Required Medical Information** | Advanced Ovarian Cancer (monotherapy): The member must have a documented diagnosis of deleterious germline and/or somatic BRCA mutation associated advanced ovarian cancer as detected by an FDA-approved test and has been treated with two (2) or more prior lines of chemotherapy. Recurrent Ovarian Cancer (maintenance): The member must have a documented diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and is in a complete or partial response to platinum-based chemotherapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# RUZURGI

## Products Affected

- Ruzurgi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Lambert-Eaton myasthenic syndrome (LEMS). |
| **Age Restrictions** | The member must be 6 years to less than 17 years of age. |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# RYDAPT

## Products Affected

- Rydapt

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML. |
| **Required Medical Information** | The member must have a newly-documented diagnosis of acute myeloid leukemia (AML) that is FLT3 mutation-positive as detected by an FDA-approved test, and is being used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Rydapt is covered for members with a documented diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# SIGNIFOR

## Products Affected

- Signifor

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Cushing's disease and pituitary surgery is not an option or has not been curative. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an endocrinologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# SIRTURO

## Products Affected

- Sirturo

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) and Sirturo is being used in combination with at least three (3) other drugs to which the patient's MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, treatment may be initiated with Sirturo in combination with at least four (4) other drugs to which the patient's MDR-TB isolate is likely to be susceptible. |
| **Age Restrictions** | The member must be 18 years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# SOMAVERT

## Products Affected

- Somavert

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of acromegaly and has had a failure of, or is unable to tolerate, a treatment regimen that includes octreotide, and the member is not a candidate for surgery and/or radiation, or has had an inadequate response to surgery and/or radiation. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an endocrinologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# SPRYCEL

## Products Affected

- Sprycel Oral Tablet 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Chronic Myeloid (or Myelogenous) Leukemia (CML): The member must have a documented diagnosis of accelerated, or myeloid or lymphoid blast phase Ph+ CML and documented resistance or intolerance to prior therapy, including imatinib mesylate (Gleevec). Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL): The member must have a documented diagnosis of Ph+ALL and documented resistance or intolerance to prior therapy, including imatinib mesylate (Gleevec). Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase (Ph+ CP-CML): The member must have a documented diagnosis of Ph+ CP-CML. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist or hematologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# STIVARGA

## Products Affected

- Stivarga

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Gastrointestinal Stromal Tumors (GIST): The member must have a documented diagnosis of GIST and documented failure, contraindication, or intolerance to both imatinib mesylate (Gleevec) and Sutent (sunitinib malate). Hepatocellular Carcinoma: The member must have a documented diagnosis of hepatocellular carcinoma and had a documented failure, contraindication, or intolerance to Nexavar (sorafenib). Metastatic Colorectal Cancer (MCC): The member must have a documented diagnosis of MCC and has been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an antivascular endothelial growth factor (VEGF) therapy, and, if KRAS wild type, an antiepidermal growth factor receptor (EGFR) therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# SUNOSI

## Products Affected

- Sunosi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Coverage will not be approved for generalized fatigue, jet lag, or sleep-deprivation not associated with a covered diagnosis. |
| **Required Medical Information** | The member must have a documented diagnosis of excessive daytime sleepiness associated with either narcolepsy or obstructive sleep apnea (OSA). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# SUTENT

## Products Affected

- Sutent

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Advanced Renal Cell Carcinoma (ARCC): The member must have a documented diagnosis of ARCC. Gastrointestinal Stromal Tumor (GIST): The member must have a documented diagnosis of GIST and has a demonstrated disease progression or intolerance following an appropriate trial with imatinib mesylate (Gleevec). Progressive Neuroendocrine Tumors (pNET): The member must have a documented diagnosis of unresectable, locally advanced, or metastatic pNET located in the pancreas. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# SYMDEKO

## Products Affected

- Symdeko

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of cystic fibrosis (CF) and have one mutation in the CFTR gene that is responsive to Symdeko based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bidirectional sequencing when recommended by the mutation test instructions for use. |
| **Age Restrictions** | The member must be six (6) years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TADALAFIL

## Products Affected

- *tadalafil*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Tadalafil is excluded from coverage for the treatment of Erectile Dysfunction. |
| **Required Medical Information** | The member must have a documented diagnosis or signs and symptoms of Benign Prostatic Hyperplasia (BPH) and has had a documented failure, adverse reaction, or contraindication to a 30-day trial of at least two (2) of the following medications: alfuzosin, doxazosin, dutasteride, dutasteride-tamsulosin, finasteride, tamsulosin, or terazosin. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TAFINLAR

## Products Affected

- Tafinlar

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Tafinlar is not indicated for the treatment of patients with wild-type BRAF mutations. |
| **Required Medical Information** | Single Agent: The member must have a documented diagnosis of unresectable or metastatic melanoma with a BRAF V600E mutation as confirmed by an FDA-approved test. In combination with Mekinist, the member must have one of the following documented diagnoses as detected by an FDA-approved test: Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, or as adjuvant treatment of melanoma with a BRAF V600E or V600K mutation and involvement of lymph node(s) following complete resection, or metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, or locally advanced or metastatic anaplastic thyroid cancer (ATC) with a BRAF V600E mutation with no satisfactory locoregional treatment options. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TAGRISSO

## Products Affected

- Tagrisso

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of metastatic non-small cell lung cancer (NSCLC) and epidermal growth factor receptor (EGFR) T790M mutation-positive as detected by an FDA-approved test, and a documented failure, contraindication, or intolerance to prior tyrosine kinase inhibitor therapy (e.g., Gilotrif, Iressa, Tarceva) OR EGFR exon 19 deletions or exon 21 L858R mutation-positive disease as detected by an FDA-approved test. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TAKHZYRO

## Products Affected

- Takhzyro

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of Hereditary Angioedema. |
| **Age Restrictions** | The member must be 12 years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be an allergist or immunologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TALZENNA

## Products Affected

- Talzenna

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of deleterious or suspected deleterious germline BRCA-mutated, HER2-negative locally advanced or metastatic breast cancer as detected by an FDA-approved test. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TASIGNA

## Products Affected

- Tasigna

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Newly-diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML): The member must have a documented diagnosis of Ph+ CML in chronic phase. Resistant or Intolerant Ph+ CML-CP and CML-AP: The member must have a documented diagnosis of Ph+ CML in chronic phase or in accelerated phase and documented resistance or intolerance to prior therapy, including imatinib mesylate (Gleevec). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TECFIDERA

## Products Affected

- TECFIDERA ORAL STARTER PACK
- Tecfidera Oral Capsule Delayed Release

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of a relapsing form of multiple sclerosis (MS) or the member has a documented failure, contraindication, or intolerance to at least one (1) of the following MS immunomodulator agents: Aubagio (teflunomide) or Gilenya (fingolimod). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TEGSEDI

## Products Affected

- Tegsedi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TETRABENAZINE

## Products Affected

- *tetrabenazine*

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of chorea associated with Huntington's Disease. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TIBSOVO

## Products Affected

- Tibsovo

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Relapsed or Refractory Acute Myeloid Leukemia (AML): The member must have a documented diagnosis of relapsed or refractory AML with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. Acute Myeloid Leukemia (AML): The member must have a documented diagnosis of AML with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test, Tibsovo is being used as first-line therapy, and the member meets one of the following: 1) is 75 years of age or older or 2) has comorbidities that make them ineligible for intensive induction chemotherapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF)

## Products Affected

- Abstral
- Actiq
- *fentanyl citrate*
- Fentora
- Lazanda Nasal Solution 100 MCG/ACT, 300 MCG/ACT, 400 MCG/ACT
- Subsys

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | The Transmucosal Immediate-Release Fentanyl (TIRF) products will not be covered for any non-cancer pain indication. |
| **Required Medical Information** | The Transmucosal Immediate-Release Fentanyl (TIRF) products may be covered for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. |
| **Age Restrictions** | None. |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist or a pain management specialist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of, but not limited to, morphine oral 60 mg daily or more, fentanyl transdermal 25 mcg/hour or more, oxycodone oral 30 mg daily or more, hydromorphone oral 8 mg daily or more, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking fentanyl transmucosal. |

# TURALIO

## Products Affected

- Turalio

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and the condition is not amenable to improvement with surgery. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TYKERB

## Products Affected

- Tykerb

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | For estrogen receptor (ER)-positive, human epidermal growth factor receptor-2 (HER-2) overexpressing advanced or metastatic breast cancer, the member must meet ALL of the following criteria: 1. Documented diagnosis of HER-2 overexpressing advanced or metastatic breast cancer. 2. The member has failed prior therapy with an anthracycline and a taxane chemotherapeutic agent. 3. The member has failed prior therapy with Herceptin (trastuzumab). 4. The member is concurrently treated with capecitabine (Xeloda). Hormone receptor positive metastatic breast cancer in post-menopausal women: The member must have a documented diagnosis of hormone receptor positive metastatic breast cancer that overexpresses the HER-2 receptor and is concurrently being treated with an aromatase inhibitor (e.g. anastrozole, exemestane, or letrozole). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# TYMLOS

## Products Affected

- Tymlos

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Coverage for Tymlos will not be authorized when cumulative use of it and/or other parathyroid hormone analogs is greater than 2 years. |
| **Required Medical Information** | Coverage of Tymlos may be authorized when the requesting physician has documented that the member is at high risk for fracture and has a T score less than or equal to -2.0 as evidenced via bone density scan or the requesting physician has documented that the member has had one or more osteoporotic fractures. For either condition previously listed, the member must also have had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments: alendronate (Fosamax), calcitonin (Miacalcin), denosumab (Prolia), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel) or zoledronic acid (Reclast). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | Coverage of Tymlos is limited to 24 months. |
| **Other Criteria** | None |

# VENCLEXTA

## Products Affected

- Venclexta
- Venclexta Starting Pack

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): The member must have a documented diagnosis of AML and Venclexta is being used as first-line therapy in combination with azacitidine, decitabine, or low-dose cytarabine or the member has comorbidities that make them ineligible for intensive induction chemotherapy. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): The member must have a documented diagnosis of CLL/SLL as detected by an FDA-approved test and has received at least one (1) prior therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# VERZENIO

## Products Affected

- Verzenio

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | For monotherapy, the member must have documented hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy. For combination therapy with Faslodex (fulvestrant), the member must have documented HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. For combination therapy with an aromatase inhibitor, the member must be postmenopausal with documented hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# VIMPAT

## Products Affected

- Vimpat Oral Solution
- Vimpat Oral Tablet

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to at least two (2) other medications indicated for adjunct partial seizures (e.g. Aptiom, Briviact, felbamate (Felbatol), Fycompa, gabapentin (Fanatrex, Gralise, Neurontin), lamotrigine (Lamictal, Lamictal XR, Lamictal ODT), Lyrica, levetiracetam (Keppra, Keppra XR, Roweepra, Spritam), oxcarbazepine (Oxtellar XR, Trileptal), tiagabine (Gabitril), topiramate (Topamax, Trokendi XR), Potiga, and/or zonisamide (Zonegran)). |
| **Age Restrictions** | The member must be four (4) years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be a neurologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# VITRAKVI

## Products Affected

- Vitrakvi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of metastatic or surgically unresectable neurotrophic receptor tyrosine kinase (NTRK) gene fusion-positive solid tumors with no known acquired resistance mutation and with no satisfactory alternative treatments or the member has progressed following treatment. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# VIZIMPRO

## Products Affected

- Vizimpro

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of metastatic non-small cell lung cancer (NSCLC) in tumors that have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# VOSEVI

## Products Affected

- Vosevi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Criteria will be applied consistent with current AASLD-IDSA guidance. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a gastroenterologist, hepatologist, or an infectious disease specialist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# VOTRIENT

## Products Affected

- Votrient

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Advanced Renal Cell Carcinoma (ARCC): The member must have a documented diagnosis of ARCC. Advanced Soft Tissue Sarcoma (ASTS): The member must have a documented diagnosis of ASTS and has received prior chemotherapy, including anthracycline treatment, or was unsuited for such therapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# VYNDAQEL

## Products Affected

- Vyndaqel

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a cardiologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# XALKORI

## Products Affected

- Xalkori

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive or the member has documented ROS1-positive tumors as detected by an FDA-approved test. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# XELJANZ

## Products Affected

- Xeljanz
- Xeljanz XR

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Psoriatic Arthritis: The member must have a documented diagnosis of psoriatic arthritis and has had an inadequate response or inability to take methotrexate or sulfasalazine at maximal doses for three (3) months. Rheumatoid Arthritis (RA): The member must have a documented diagnosis of moderately-to-severely active RA and has a documented inadequate response after three (3) months at optimal doses or an inability to take methotrexate. Ulcerative Colitis (UC): The member must have a documented diagnosis of moderate-to-severely active UC and has had an inadequate response to an appropriate trial with two (2) or more of the following agents: a) Corticosteroids (e.g., methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (e.g. balsalazide (Colazal), Dipentum, mesalamine (Asacol), Pentasa, Rowasa, sulfasalazine (Azulfidine)). c) 6-mercaptopurine (6-MP, Purinethol) or azathioprine. d) methotrexate |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a gastroenterologist or rheumatologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# XERMELO

## Products Affected

- Xermelo

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of carcinoid syndrome diarrhea that is inadequately controlled by somastatin analog (SSA) therapy alone and Xermelo is being used in combination with an SSA (e.g. Sandostatin LAR). |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a gastroenterologist, hematologist, or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# XIFAXAN 550 MG

## Products Affected

- Xifaxan Oral Tablet 550 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Coverage will not be authorized for treatment of Irritable Bowel Syndrome with constipation (IBS-C). |
| **Required Medical Information** | Hepatic Encephalopathy: The member must have a documented diagnosis of hepatic encephalopathy and has had an inadequate response or a contraindication to lactulose. Irritable Bowel Syndrome with Diarrhea (IBS-D): The member must have a documented diagnosis of IBS-D. |
| **Age Restrictions** | Hepatic Encephalopathy: The member must be 18 years of age or older. |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | Xifaxan 200 mg tablets do not require authorization. |

# XOLAIR

## Products Affected

- Xolair

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Coverage may be authorized when all of the following criteria are met: 1. The member has had a failure of a treatment regimen that included two (2) or more of the following medications: inhaled corticosteroids, oral corticosteroids, leukotriene modifiers and inhaled long-acting bronchodilators, or is unable to tolerate these medications. 2. The member shows a definitive sensitivity on allergy testing to one or more perennial allergens. 3. The member has a pre-treatment serum IgE level equal to or greater than 30 IU/mL and less than or equal to 1,300 IU/mL. Chronic Idiopathic Urticaria (CIU): Coverage of Xolair may be authorized if the member has a diagnosis of CIU for at least 6 weeks and the physician has documented that the member remains symptomatic despite H1 antihistamine treatment. |
| **Age Restrictions** | Chronic Idiopathic Urticaria (CIU): 12 years of age or older. Moderate-to-severe persistent asthma: 6 years of age or older. |
| **Prescriber Restrictions** | The prescribing physician must be an allergist, dermatologist, immunologist or pulmonologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# XOSPATA

## Products Affected

- Xospata

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# XPOVIO

## Products Affected

- Xpovio (100 MG Once Weekly)
- Xpovio (60 MG Once Weekly)
- Xpovio (80 MG Once Weekly)
- Xpovio (80 MG Twice Weekly)

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must meet ALL of the following criteria: 1) Documented diagnosis of relapsed or refractory multiple myeloma. 2) Has received at least four prior therapies. 3) The member's disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody 3) Xpovio is being used in combination with dexamethasone. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration. |
| **Other Criteria** | None |

# XTANDI

## Products Affected

- Xtandi

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of castration-resistant prostate cancer. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist or urologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# XURIDEN

## Products Affected

- Xuriden

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of hereditary orotic aciduria. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | None |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# YONSA

## Products Affected

- Yonsa

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and is being used in combination with methylprednisolone. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist or urologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ZEJULA

## Products Affected

- Zejula

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and is experiencing complete or partial response to platinum-based chemotherapy. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ZELBORAF

## Products Affected

- Zelboraf

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | Zelboraf is not indicated for treatment of patients with wild-type BRAF melanoma. |
| **Required Medical Information** | Erdheim-Chester Disease (ECD): The member must have a documented diagnosis of Erdheim-Chester disease (ECD) with a BRAF V600 mutation. Unresectable or Metastatic Melanoma: The member must have a documented diagnosis of unresectable or metastatic melanoma that is BRAF V600E mutation-positive as detected by an FDA-approved test. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ZEPATIER

## Products Affected

- Zepatier

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Criteria will be applied consistent with current AASLD-IDSA guidance. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a gastroenterologist, hepatologist, or an infectious disease specialist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ZOLINZA

## Products Affected

- Zolinza

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of cutaneous T-cell lymphoma (Stage IIB and higher) and progressive, persistent or recurrent disease and documented current or prior treatment or treatment failure with at least two (2) systemic chemotherapeutic agents for cutaneous T-cell lymphoma. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ZYDELIG

## Products Affected

- Zydelig

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | Chronic Lymphocytic Leukemia (CLL): The member must have a documented diagnosis of relapsed CLL and Zydelig will be given in combination with Rituxan (rituximab). Follicular B-cell non-Hodgkin Lymphoma and Small Lymphocytic Lymphoma (SLL): The member must have a documented diagnosis of either disease and documented use of at least two (2) prior systemic therapies. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be a hematologist or oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ZYKADIA

## Products Affected

- Zykadia

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

# ZYTIGA

## Products Affected

- Zytiga Oral Tablet 250 MG, 500 MG

| PA Criteria | Criteria Details |
|---|---|
| **Covered Uses** | All FDA-approved indications not otherwise excluded from Part D. |
| **Exclusion Criteria** | None |
| **Required Medical Information** | The member must have a documented diagnosis of metastatic castration-resistant prostate cancer (CRPC) or metastatic high-risk castration-sensitive prostate cancer and Zytiga is being used in combination with prednisone. |
| **Age Restrictions** | None |
| **Prescriber Restrictions** | The prescribing physician must be an oncologist or urologist. |
| **Coverage Duration** | FDA-approved duration, balance of contract year or clinically appropriate duration |
| **Other Criteria** | None |

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