

# 2021 Tufts Health Plan Medicare Preferred Prior Authorization Medical Necessity Guidelines

Effective: December 1, 2021

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Control #: H2256\_2021\_RXOPS187\_C

S0655\_2021\_RXOPS188\_C



# ABILIFY MYCITE

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## Products Affected

- ABILIFY MYCITE

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must meet the following: 1) have a documented diagnosis of bipolar I disorder, major depressive disorder or schizophrenia 2) the member must 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# AFINITOR

## Products Affected

- AFINITOR

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | <p>Afinitor or everolimus: 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).</p> <p>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).</p> <p>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.</p> <p>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.</p> <p>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.</p> |
| 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   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# AFINITOR DISPERZ

## Products Affected

- AFINITOR DISPERZ

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | Partial-onset Seizures Associated with Tuberous Sclerosis Complex (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). 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   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# AIMOVIG

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## Products Affected

- AIMOVIG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ALECENSA

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## Products Affected

- ALECENSA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of Anaplastic Lymphoma Kinase positive (ALK-positive), metastatic Non-small Cell Lung Cancer (NSCLC). |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ALUNBRIG

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## Products Affected

- ALUNBRIG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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). |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ARCALYST

## Products Affected

- ARCALYST

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Cryopyrin-associated periodic syndromes: The member must have a documented diagnosis of a Cryopyrin-Associated Periodic Syndrome, including Familial Cold Autoinflammatory Syndrome, or Muckle-Wells Syndrome. Deficiency of interleukin-1 receptor antagonist: The member must have a documented diagnosis of deficiency of interleukin-1 receptor antagonist and Arcalyst is being used for maintenance of remission in patients weighing 10kg or more. Recurrent Pericarditis (RP): The member must have a documented diagnosis of RP and Arcalyst is being used to reduce the risk of recurrence. |
| Age Restrictions             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ARMODAFINIL AND MODAFINIL

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## Products Affected

- *armodafinil*
- *modafinil*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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 shift-work sleep disorder. |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# AURYXIA

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## Products Affected

- AURYXIA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# AUSTEDO

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## Products Affected

- AUSTEDO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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.<br>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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# AYVAKIT

## Products Affected

- AYVAKIT

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Advanced Systemic Mastocytosis (AdvSM): The member must have a documented diagnosis of AdvSM, which includes aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).<br>Gastrointestinal Stromal Tumor (GIST): The member must have a documented diagnosis of PDGFRA Exon 18 mutation-positive unresectable or metastatic GIST. |
| Age Restrictions             | None  |
| Prescriber Restrictions      | The prescribing physician must be an allergist, immunologist, or oncologist.  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration.   |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# BALVERSA

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## Products Affected

- BALVERSA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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 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 prescribing physician must be an oncologist or urologist.  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration.  |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# BENLYSTA

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## Products Affected

- BENLYSTA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | 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. |
| <b>Required Medical Information</b> | 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).        |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be a rheumatologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# BERINERT

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## Products Affected

- BERINERT

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# BOSULIF

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## Products Affected

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

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# BRAFTOVI

## Products Affected

- BRAFTOVI

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma or wild-type BRAF CRC.  |
| <b>Required Medical Information</b> | Metastatic Colorectal Cancer: The member must have a documented diagnosis of metastatic colorectal cancer with a BRAF V600E mutation after prior therapy and will be taken combination with cetuximab.<br>Melanoma (unresectable or metastatic): 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). |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an oncologist.   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# BRIVIACT

## Products Affected

- BRIVIACT

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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 or more medications indicated for partial seizures (including but not limited to: 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), Vimpat, and/or zonisamide (Zonegran)). |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# BRUKINSA

## Products Affected

- BRUKINSA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of Mantle Cell Lymphoma (MCL) and has received at least one 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# CABOMETYX

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## Products Affected

- CABOMETYX

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Advanced Renal Cell Carcinoma (RCC): The member must have a documented diagnosis of advanced renal cell carcinoma (RCC). Differentiated Thyroid Cancer (DTC): The member must have a documented diagnosis of locally advanced or metastatic DTC that has progressed following prior VEGFR-targeted therapy and are radioactive iodine-refractory or ineligible. 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# CALQUENCE

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## Products Affected

- CALQUENCE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): The member must have a documented diagnosis of CLL or SLL. Mantle Cell Lymphoma (MCL): The member must have a documented diagnosis of MCL and has received at least one 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# CAPLYTA

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## Products Affected

- CAPLYTA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Caplyta will not be approved for members with dementia-related psychosis.          |
| Required Medical Information | The member must have a documented diagnosis of schizophrenia.                      |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# CAPRELSA

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## Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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 prescribing physician must be an endocrinologist or oncologist.  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# CARBAGLU

## Products Affected

- CARBAGLU

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# CERDELGA

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## Products Affected

- CERDELGA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of Gaucher Disease type 1 and documentation the member is a cytochrome P450 2D6 extensive metabolizer (EMs), intermediate metabolizer (IMs), or poor metabolizer (PMs). |
| Age Restrictions             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# CHOLBAM

## Products Affected

- CHOLBAM

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | 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.  |
| <b>Required Medical Information</b> | 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. |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | None   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# CINRYZE

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## Products Affected

- CINRYZE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# COMETRIQ

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## Products Affected

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

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# COPIKTRA

## Products Affected

- COPIKTRA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | None   |
| <b>Required Medical Information</b> | 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 prior therapies.<br>Follicular lymphoma (FL): The member must have a documented diagnosis of relapsed or refractory FL and has received at least two prior systemic therapies. |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be a hematologist or oncologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# COTELLIC

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## Products Affected

- COTELLIC

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# CRINONE

## Products Affected

- CRINONE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# DAURISMO

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## Products Affected

- DAURISMO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# DESOXYN/METHAMPHETAMINE ORAL TABLET

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## Products Affected

- DESOXYN
- *methamphetamine hcl*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# DIACOMIT

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## Products Affected

- DIACOMIT

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of seizures associated with Dravet syndrome and is concurrently taking clobazam. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# DICLOFENAC EPOLAMINE PATCH

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## Products Affected

- *diclofenac epolamine*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of acute pain due to one of the following: minor strain, sprain, or contusion. |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration.  |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# DIFICID

## Products Affected

- DIFICID

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# DOPTELET

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## Products Affected

- DOPTELET

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of one of the following:<br>1) Thrombocytopenia associated with chronic liver disease (CLD) and is scheduled to undergo a procedure<br>2) 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# DROXIDOPA

## Products Affected

- *droxidopa*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# DUPIXENT

## Products Affected

- DUPIXENT

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Dupixent will not be approved for the relief of acute bronchospasm or status asthmaticus.  |
| <b>Required Medical Information</b> | Atopic Dermatitis: The member must have a documented diagnosis of moderate-to-severe atopic dermatitis and an inadequate treatment response, intolerance, or contraindication to a high potency topical corticosteroid or a topical calcineurin inhibitor (i.e. tacrolimus, pimecrolimus). 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. 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. |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an allergist, dermatologist, immunologist, otolaryngologist or pulmonologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# EGRIFTA

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## Products Affected

- EGRIFTA SV

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# EMFLAZA

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## Products Affected

- EMFLAZA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of Duchenne muscular dystrophy (DMD).                      |
| Age Restrictions             | None   |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# EMGALITY

## Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Initial Approval: The member must have a documented diagnosis of one of the following: 1) Migraine and the member has had an inadequate response, contraindication, or inability to tolerate an appropriate trial after 4-weeks with at least one drug from the following classes: antidepressants (including but not limited to: amitriptyline, venlafaxine), antiepileptic drugs (including but not limited to: divalproex sodium, topiramate) or beta blockers (including but not limited to: propranolol, timolol) 2) Episodic Cluster headache. Subsequent Approval: 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ENBREL

## Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION
- ENBREL SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE 25 MG/0.5ML, 50
- MG/ML
- ENBREL SUBCUTANEOUS SOLUTION  
RECONSTITUTED
- ENBREL SURECLICK

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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 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 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 months. |
| Age Restrictions             | None  |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ENSPRYNG

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## Products Affected

- ENSPRYNG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and are anti-aquaporin-4 (AQP4) antibody positive. |
| Age Restrictions             | None   |
| Prescriber Restrictions      | The prescribing physician must be a neurologist or ophthalmologist.  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# EPCLUSA

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## Products Affected

- EPCLUSA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# EPIDIOLEX

## Products Affected

- EPIDIOLEX

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS) or tuberous sclerosis complex (TSC). |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# ERIVEDGE

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## Products Affected

- ERIVEDGE

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ERLEADA

## Products Affected

- ERLEADA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of one of the following:<br>1) non-metastatic, castration-resistant prostate cancer 2) metastatic, castration-sensitive 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# ESBRIET

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## Products Affected

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

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of idiopathic pulmonary fibrosis (IPF). |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# EUCRISA

## Products Affected

- EUCRISA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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 (including but not limited to: tacrolimus, pimecrolimus). 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 (including but not limited to: tacrolimus, pimecrolimus). |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# EVENTITY

## Products Affected

- EVENTITY

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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 [including but not limited to: alendronate (Fosamax), calcitonin (Miacalcin), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel), zoledronic acid (Reclast)]. |
| Age Restrictions             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | Lifetime coverage duration of Eventity should be limited to 12 monthly doses.   |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# EVEROLIMUS

## Products Affected

- *everolimus oral tablet 2.5 mg, 5 mg, 7.5 mg*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | 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. 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. |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be a neurologist or oncologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# EVERYSDI

## Products Affected

- EVERYSDI

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of spinal muscular atrophy (SMA).       |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# FARYDAK

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## Products Affected

- FARYDAK

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of multiple myeloma and has received at least two 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# FASENRA

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## Products Affected

- FASENRA
- FASENRA PEN

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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             | None  |
| Prescriber Restrictions      | The prescribing physician 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# FINTEPLA

## Products Affected

- FINTEPLA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of seizures associated with Dravet syndrome. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# FIRDAPSE

## Products Affected

- FIRDAPSE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of Lambert-Eaton myasthenic syndrome (LEMS). |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# FORTEO

## Products Affected

- FORTEO

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Coverage for Forteo will not be authorized when cumulative use of it and/or other parathyroid hormone analogs is greater than 2 years.  |
| <b>Required Medical Information</b> | The requesting physician must provide documentation 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 have had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments (including but not limited to: alendronate (Fosamax), calcitonin (Miacalcin), denosumab (Prolia), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel) or zoledronic acid (Reclast)). |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | None  |
| <b>Coverage Duration</b>            | Cumulative lifetime therapy with Forteo should not exceed 2 years.  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# FOTIVDA

## Products Affected

- FOTIVDA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of relapsed or refractory advanced renal cell carcinoma following two or more prior systemic therapies. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# FYCOMPA

## Products Affected

- FYCOMPA

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | <p>Partial-onset Seizures: The member must have a documented diagnosis of partial-onset seizures and has had an insufficient response or intolerance to two or more medications indicated for partial seizures (including but not limited to: Aptiom, Briviact, felbamate (Felbatol), gabapentin (Fanatrex, Gralise, Neurontin), lamotrigine (Lamictal, Lamictal XR, Lamictal ODT), Lyrica, levetiracetam (Keppra, Keppra XR, Roweepra), oxcarbazepine (Oxtellar XR, Trileptal), tiagabine (Gabitril), topiramate (Topamax, Trokendi XR), Vimpat, and/or zonisamide (Zonegran)).</p> <p>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 or more medications indicated for primary generalized tonic-clonic seizures (including but not limited to: carbamazepine, felbamate, lamotrigine, levetiracetam, phenytoin, topiramate, and valproate)).</p> |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be a neurologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# GALAFOLD

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## Products Affected

- GALAFOLD

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# GATTEX

## Products Affected

- GATTEX

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# GAVRETO

## Products Affected

- GAVRETO

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | Non-small Cell Lung Cancer (NSCLC): The member must have a documented diagnosis of metastatic rearranged during transfection (RET) fusion-positive NSCLC. Thyroid Cancer: The member must have both 1) a documented diagnosis of advanced or metastatic medullary thyroid cancer or advanced or metastatic thyroid cancer 2) documentation of RET-mutant or RET fusion-positive cancer. |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an oncologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# GILOTRIF

## Products Affected

- GILOTRIF

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of one of the following:<br>1) Metastatic non-small cell lung cancer (NSCLC) and documented non-resistant epidermal growth factor receptor (EGFR) mutations 2) 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# GROWTH HORMONE REPLACEMENT THERAPY

## Products Affected

- GENOTROPIN
- GENOTROPIN MINIUICK
- 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  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | <p>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.</p> |
| Age Restrictions             | None  |

| <b>PA Criteria</b>             | <b>Criteria Details</b>  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | None   |
| <b>Coverage Duration</b>       | FDA-approved duration, balance of contract year or clinically appropriate duration |
| <b>Other Criteria</b>          | None   |
| <b>Indications</b>             | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>          |  |

# HAEGARDA

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## Products Affected

- HAEGARDA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# HARVONI

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## Products Affected

- HARVONI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# HETLIOZ

## Products Affected

- HETLIOZ
- HETLIOZ LQ

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Coverage will not be authorized for the diagnosis of insomnia.   |
| Required Medical Information | The member must have a documented diagnosis of Smith-Magenis Syndrome (SMS) and be experiencing nighttime sleep disturbances or 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# HIGH RISK MEDICATION: ANTIPARKINSON AGENTS

## Products Affected

- *benztropine mesylate*
- *trihexyphenidyl hcl*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-High Risk Medication (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. |
| Age Restrictions             | The Prior Authorization requirement only applies to members 65 years of age or older.  |
| Prescriber Restrictions      |  |
| 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.   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# HIGH RISK MEDICATION: CYCLOBENZAPRINE

## Products Affected

- *cyclobenzaprine hcl*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | None   |
| <b>Required Medical Information</b> | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-High Risk Medication (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. |
| <b>Age Restrictions</b>             | The Prior Authorization requirement only applies to members 65 years of age or older.  |
| <b>Prescriber Restrictions</b>      | None   |
| <b>Coverage Duration</b>            | Initial Approval: 1 year. Subsequent Approval: Life of Plan.   |
| <b>Other Criteria</b>               | Non-HRM Alternatives include, but are not limited to: acetaminophen, NSAIDs, baclofen or tizanidine.   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# HIGH RISK MEDICATION: ESTROGEN-CONTAINING PRODUCTS

## Products Affected

- COMBIPATCH
- *dotti*
- *estradiol oral*
- *estradiol transdermal*
- FEMHRT
- FEMHRT LOW DOSE
- *fyavolv*
- *jinteli*
- MENEST
- MENOSTAR
- *norethindrone-eth estradiol*
- PREMARIN ORAL
- PREMPHASE
- PREMPRO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-High Risk Medication (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. |
| Age Restrictions             | The Prior Authorization requirement only applies to members 65 years of age or older.  |
| 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).   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# HIGH RISK MEDICATION: HYDROXYZINE

## Products Affected

- *hydroxyzine hcl*
- *hydroxyzine pamoate*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-High Risk Medication (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. |
| Age Restrictions             | The Prior Authorization requirement only applies to members 65 years of age or older.  |
| 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: levocetirizine (pruritus), duloxetine, escitalopram, venlafaxine ER (anxiety), alprazolam, temazepam (sedation).   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# HIGH RISK MEDICATION: ORAL HYPOGLYCEMICS

## Products Affected

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

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | None   |
| <b>Required Medical Information</b> | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-High Risk Medication (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. |
| <b>Age Restrictions</b>             | The Prior Authorization requirement only applies to members 65 years of age or older.  |
| <b>Prescriber Restrictions</b>      | None   |
| <b>Coverage Duration</b>            | Initial Approval: 1 year. Subsequent Approval: Life of Plan.   |
| <b>Other Criteria</b>               | Non-HRM Alternatives include, but are not limited to: glipizide, glipizide-metformin, tolazamide, or tolbutamide.  |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# HIGH RISK MEDICATION: PHENOBARBITAL

## Products Affected

- *phenobarbital*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-High Risk Medication (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. |
| Age Restrictions             | The Prior Authorization requirement only applies to members 65 years of age or older.  |
| 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)  |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# HIGH RISK MEDICATION: PROMETHAZINE

## Products Affected

- *promethazine hcl*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-High Risk Medication (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.                              |
| Age Restrictions             | The Prior Authorization requirement only applies to members 65 years of age or older.   |
| 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). |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# HIGH RISK MEDICATION: THIORIDAZINE

## Products Affected

- *thioridazine hcl*

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | None   |
| <b>Required Medical Information</b> | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-High Risk Medication (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. |
| <b>Age Restrictions</b>             | The Prior Authorization requirement only applies to members 65 years of age or older.  |
| <b>Prescriber Restrictions</b>      | None   |
| <b>Coverage Duration</b>            | Initial Approval: 1 year. Subsequent Approval: Life of Plan.   |
| <b>Other Criteria</b>               | Non-HRM Alternatives include, but are not limited to: olanzapine, quetiapine, risperidone, ziprasidone.  |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# HIGH RISK MEDICATION: TRICYCLIC ANTIDEPRESSANTS

## Products Affected

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

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | None   |
| <b>Required Medical Information</b> | The member must have a documented inadequate treatment response, intolerance or contraindication to one or more non-High Risk Medication (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. |
| <b>Age Restrictions</b>             | The Prior Authorization requirement only applies to members 65 years of age or older.  |
| <b>Prescriber Restrictions</b>      | None   |
| <b>Coverage Duration</b>            | Initial Approval: 1 year. Subsequent Approval: Life of Plan.   |
| <b>Other Criteria</b>               | 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.   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# HUMIRA

## Products Affected

- HUMIRA
- HUMIRA PEDIATRIC CROHNS START
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.4ML, 40 MG/0.8ML, 80 MG/0.8ML
- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PEDIATRIC UC START
- HUMIRA PEN-PS/UV/ADOL HS START
- HUMIRA PEN-PSOR/UEIT STARTER

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | <p>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 or more of the following agents: a) Corticosteroids (including but not limited to: methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (including but not limited to: 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 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 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 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.</p> |
| Age Restrictions             | None  |
| Prescriber Restrictions      | The prescribing physician must be a dermatologist, gastroenterologist, ophthalmologist, or rheumatologist.  |

| <b>PA Criteria</b>       | <b>Criteria Details</b>  |
|--------------------------|--|
| <b>Coverage Duration</b> | FDA-approved duration, balance of contract year or clinically appropriate duration |
| <b>Other Criteria</b>    | None   |
| <b>Indications</b>       | All FDA-approved Indications.  |
| <b>Off Label Uses</b>    |  |

# IBRANCE

## Products Affected

- IBRANCE

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | None   |
| <b>Required Medical Information</b> | The member must 1) 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 2) 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). |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an oncologist.   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# ICATIBANT

## Products Affected

- *icatibant acetate*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Icatibant will not be approved for members with acquired angioedema or concurrently taking an angiotensin converting enzyme (ACE) inhibitor.  |
| <b>Required Medical Information</b> | The member must have a documented diagnosis of Hereditary Angioedema (HAE) with a history of at least one severe attack in the past six 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). |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an allergist, hematologist, or immunologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# ICLUSIG

## Products Affected

- ICLUSIG

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Iclusig will not be approved for members with newly diagnosed chronic phase CML.   |
| <b>Required Medical Information</b> | 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. |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be a hematologist or oncologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# IDHIFA

## Products Affected

- IDHIFA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# IMBRUVICA

## Products Affected

- IMBRUVICA

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | 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 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 prior therapy. Marginal Zone Lymphoma (MZL): The member must have a documented diagnosis of MZL and has received at least one prior anti-CD20-based therapy. Waldenstrom Macroglobulinemia: The member must have a documented diagnosis of Waldenstrom macroglobulinemia. |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be a hematologist, oncologist, or transplant specialist.   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# INBRIJA

## Products Affected

- INBRIJA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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      | The prescribing physician must be a neurologist.  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# INCRELEX

## Products Affected

- INCRELEX

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | 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.   |
| <b>Required Medical Information</b> | 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. |
| <b>Age Restrictions</b>             | The member must be 2 to 18 years of age.   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an endocrinologist.  |
| <b>Coverage Duration</b>            | Initial authorization is for 6 months. Subsequent authorizations are for 1 year.   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# INGREZZA

## Products Affected

- INGREZZA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of tardive dyskinesia.                 |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# INLYTA

## Products Affected

- INLYTA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of advanced renal cell carcinoma and one of the following two requirements: 1) The member is using Inlyta as first line treatment in combination with avelumab or pembrolizumab 2) The member is using Inlyta as a single agent and has failed a trial of at least one systemic therapy (including but not limited to 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# INQOVI

## Products Affected

- INQOVI

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# INREBIC

## Products Affected

- INREBIC

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# INTRAVENOUS IMMUNE GLOBULIN

## Products Affected

- BIVIGAM
- FLEBOGAMMA DIF
- GAMMAGARD
- GAMMAGARD S/D LESS IGA
- GAMMAKED
- GAMMAPLEX
- GAMUNEX-C
- OCTAGAM
- PANZYGA
- PRIVIGEN

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Coverage not approved for progressive MS   |
| <b>Required Medical Information</b> | <p>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., cicatricial 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.</p> |
| <b>Age Restrictions</b>             | None   |

| <b>PA Criteria</b>             | <b>Criteria Details</b>                |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | None                                   |
| <b>Coverage Duration</b>       | Initial authorization is for 6 months. |
| <b>Other Criteria</b>          | None                                   |
| <b>Indications</b>             | All Medically-accepted Indications.    |
| <b>Off Label Uses</b>          |  |

# IRESSA

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## Products Affected

- IRESSA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ISTURISA

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## Products Affected

- ISTURISA ORAL TABLET 1 MG, 10 MG, 5 MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# JAKAFI

## Products Affected

- JAKAFI

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Chronic Graft-versus-host Disease (GVHD): The member must have a documented diagnosis of chronic GVHD after failure of one or two lines of systemic therapy. 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             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | Initial authorization is for 6 months. Subsequent authorization is for Life of Plan.  |
| Other Criteria               | For Myelofibrosis: Subsequent authorization requires documentation of spleen size reduction or symptomatic improvement.   |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# JUXTAPID

## Products Affected

- JUXTAPID

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must 1) have a 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 and 2) 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# KALYDECO

## Products Affected

- KALYDECO

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | 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.   |
| <b>Required Medical Information</b> | 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. |
| <b>Age Restrictions</b>             | Granules: The member must be 4 months to 5 years of age.   |
| <b>Prescriber Restrictions</b>      | None   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# KERENDIA

## Products Affected

- KERENDIA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of chronic kidney disease associated with type 2 diabetes. |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration                     |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# KESIMPTA

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## Products Affected

- KESIMPTA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of relapsing forms of multiple sclerosis (MS), to include 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# KEVEYIS

## Products Affected

- KEVEYIS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# KINERET

## Products Affected

- KINERET

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Deficiency of Interleukin-1 Receptor Antagonist (DIRA): The member must have a documented diagnosis of DIRA. 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 months at optimal doses or an inability to take methotrexate. |
| Age Restrictions             | None  |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# 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  |
|------------------------------|---|
| 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 HR-positive, 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# KLISYRI

## Products Affected

- KLISYRI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of actinic keratosis of the face or scalp. |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration     |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# KORLYM

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## Products Affected

- KORLYM

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# KOSELUGO

## Products Affected

- KOSELUGO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of Neurofibromatosis type 1 and have symptomatic, inoperable plexiform neurofibromas. |
| Age Restrictions             | The member must be 2 to 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# KUVAN

## Products Affected

- KUVAN

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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 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. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# LAPATINIB

## Products Affected

- *lapatinib ditosylate*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | For estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2) overexpressing advanced or metastatic breast cancer, the member must meet ALL of the following criteria: 1) Documented diagnosis of HER2 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 HER2 receptor and is concurrently being treated with an aromatase inhibitor (including but not limited to: 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   |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# 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  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Advanced Endometrial Carcinoma: The member must have a documented diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation and it will be used in combination with Keytruda (pembrolizumab). Advanced Renal Cell Carcinoma (ARCC): The member must have a documented diagnosis of ARCC and has had one prior antiangiogenic therapy and is being used in combination with Afinitor (everolimus). 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# LIDOCAINE TRANSDERMAL PATCHES

## Products Affected

- *lidocaine external patch*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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.   |
| Indications                  | All Medically-accepted Indications.  |
| Off Label Uses               |  |

# LONSURF

## Products Affected

- LONSURF

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# LORBRENA

## Products Affected

- LORBRENA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# LUMAKRAS

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## Products Affected

- LUMAKRAS

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) and has received at least one prior systemic 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# LUPKYNIS

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## Products Affected

- LUPKYNIS

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | The requested drug will not be approved in combination with cyclophosphamide.  |
| Required Medical Information | The member must have a documented diagnosis of active lupus nephritis and the requested drug is being used in combination with a background immunosuppressive therapy regimen consisting of mycophenolate mofetil and corticosteroids. |
| Age Restrictions             | None   |
| Prescriber Restrictions      | The prescribing physician must be a nephrologist or rheumatologist.  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# LYNPARZA

## Products Affected

- LYNPARZA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | <p>Breast Cancer: The member has a diagnosis of deleterious or suspected deleterious germline BRCA-mutated, 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 prior endocrine therapy or contraindication to or inability to tolerate endocrine therapy. Ovarian Cancer: Lynparza is being used for one of the following 1) Maintenance treatment of deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy 2) Maintenance treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with bevacizumab and the member is in complete or partial response to first-line platinum-based chemotherapy and the member's cancer is associated with homologous recombination deficiency (HRD)-positive status 3) Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and the member is in complete or partial response to platinum-based chemotherapy 4) Treatment of deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer and the member has been treated with 3 or more prior lines of chemotherapy. Pancreatic Cancer: The member has a diagnosis of deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma and no disease progression after at least 16 weeks of first-line platinum-based chemotherapy. Prostate Cancer: The member has a documented diagnosis of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone.</p> |
| Age Restrictions             | None   |

| <b>PA Criteria</b>             | <b>Criteria Details</b>  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | The prescribing physician must be an oncologist.                                   |
| <b>Coverage Duration</b>       | FDA-approved duration, balance of contract year or clinically appropriate duration |
| <b>Other Criteria</b>          | None   |
| <b>Indications</b>             | All FDA-approved Indications.  |
| <b>Off Label Uses</b>          |  |

# MAVYRET

## Products Affected

- MAVYRET

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# MEDICATIONS FOR THE TREATMENT OF PULMONARY HYPERTENSION

## Products Affected

- ADEMPAS
- *alyq*
- *ambrisentan*
- *bosentan*
- OPSUMIT
- ORENITRAM
- *sildenafil citrate*
- *tadalafil (pah)*
- TRACLEER
- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLET THERAPY PACK
- VENTAVIS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | None   |
| <b>Required Medical Information</b> | 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. |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be a cardiologist or pulmonologist.   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# MEKINIST

## Products Affected

- MEKINIST

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Mekinist will not be approved as a single agent for members who have received prior BRAF-inhibitor therapy.  |
| <b>Required Medical Information</b> | Single Agent: The member must have a documented diagnosis of unresectable or metastatic melanoma with a BRAF V600E. In Combination with Tafenlar: The member must have a documented diagnosis of one of the following: 1) Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation. 2) Melanoma with a BRAF V600E or V600K mutation and involvement of lymph node(s) following complete resection. 3) Metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation. 4) Locally advanced or metastatic anaplastic thyroid cancer (ATC) with a BRAF V600E mutation with no satisfactory locoregional treatment options. |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an oncologist.   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# MEKTOVI

## Products Affected

- MEKTOVI

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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, 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# MIGLUSTAT

## Products Affected

- *miglustat*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of mild-to-moderate Gaucher disease type 1 and 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# MISCELLANEOUS INJECTABLES

## Products Affected

- ABELCET
- ACTHAR
- *acyclovir sodium*
- AMBISOME
- *amphotericin b*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# MULPLETA

## Products Affected

- MULPLETA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# MYCAPSSA

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## Products Affected

- MYCAPSSA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of acromegaly who have responded to and tolerated treatment with octreotide or lanreotide injections. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# MYFEMBREE

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## Products Affected

- MYFEMBREE

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must be premenopausal and have a documented diagnosis of uterine leiomyomas (fibroids) associated with heavy menstrual bleeding. |
| Age Restrictions             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | Coverage of Myfembree is limited to 24 months.  |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# MYTESI

## Products Affected

- MYTESI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of non-infectious diarrhea associated with HIV or AIDS and is currently taking antiretroviral therapy. |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# NATPARA

## Products Affected

- NATPARA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | 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. |
| <b>Required Medical Information</b> | 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.                         |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an endocrinologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# NAYZILAM

## Products Affected

- NAYZILAM

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of a seizure disorder requiring acute treatment. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# NERLYNX

## Products Affected

- NERLYNX

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Extended Adjuvant Treatment of Early-stage Breast Cancer: 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. Advanced or Metastatic Breast Cancer: The member must have a documented diagnosis of advanced or metastatic HER2-positive breast cancer, is using Nerlynx in combination with capecitabine, and has received two or more prior anti-HER2 based regimens. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# NEXAVAR

## Products Affected

- NEXAVAR

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# NEXLETOL

## Products Affected

- NEXLETOL

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | None   |
| <b>Required Medical Information</b> | The member must meet the following criteria: 1) Member has an elevated LDL-C level while being treated with maximally tolerated statin therapy or has an elevated LDL-C level and a contraindication/intolerance to statin therapy. 2) The member must have a documented diagnosis of one of the following: a) Heterozygous Familial Hypercholesterolemia (HeFH) b) atherosclerotic cardiovascular disease |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The medication must be prescribed by or in consultation with a cardiologist, endocrinologist, lipidologist, or neurologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# NEXLIZET

## Products Affected

- NEXLIZET

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must meet the following criteria: 1) Member has an elevated LDL-C level while being treated with maximally tolerated statin therapy or has an elevated LDL-C level and a contraindication/intolerance to statin therapy. 2) The member must have a documented diagnosis of one of the following: a) Heterozygous Familial Hypercholesterolemia (HeFH) b) atherosclerotic cardiovascular disease. |
| Age Restrictions             | None  |
| Prescriber Restrictions      | The medication must be 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               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# NINLARO

## Products Affected

- NINLARO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# NITISINONE

## Products Affected

- *nitisinone*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of hereditary tyrosinemia type-1 (HT-1). |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# NITYR

## Products Affected

- NITYR

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of hereditary tyrosinemia Type-1 (HT-1). |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# NORTHERA

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## Products Affected

- NORTHERA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# NOURIANZ

## Products Affected

- NOURIANZ

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of Parkinson's disease and Nourianz is being used as adjunctive treatment to levodopa/carbidopa in those experiencing "off" episodes. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# NUBEQA

## Products Affected

- NUBEQA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# NUCALA

## Products Affected

- NUCALA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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 of the following immunosuppressants: azathioprine, cyclophosphamide, or methotrexate. Hypereosinophilic Syndrome (HES): The member must have a documented diagnosis of HES for at least 6 months without an identifiable non-hematologic secondary cause. |
| Age Restrictions             | None   |
| Prescriber Restrictions      | The prescribing physician must be an asthma specialist (e.g., allergist, immunologist, pulmonologist), hematologist, or rheumatologist.  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# NUEDEXTA

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## Products Affected

- NUEDEXTA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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            | Coverage duration is limited to 1 year.  |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# NUPLAZID

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## Products Affected

- NUPLAZID

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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 must be 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# OCALIVA

## Products Affected

- OCALIVA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ODOMZO

## Products Affected

- ODOMZO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of locally advanced basal cell carcinoma and one of the following: 1) Documentation of disease recurrence following surgery or radiation therapy or 2) 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# OFEV

## Products Affected

- OFEV

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of one of the following: 1) idiopathic pulmonary fibrosis (IPF) 2) systemic sclerosis-associated interstitial lung disease (SSc-ILD) or 3) chronic fibrosing interstitial lung diseases (ILD) with a progressive phenotype. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ONGENTYS

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## Products Affected

- ONGENTYS

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of Parkinson's Disease and has had a documented failure, contraindication, or intolerance to entacapone. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# ONUREG

## Products Affected

- ONUREG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of acute myeloid leukemia and has achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ORALAIR

## Products Affected

- ORALAIR

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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 grass species contained in this product. |
| Age Restrictions             | The member must be 5 to 65 years of age.  |
| Prescriber Restrictions      | The medication must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist.  |
| Coverage Duration            | Coverage duration is limited to 1 year.   |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ORFADIN

## Products Affected

- ORFADIN

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of hereditary tyrosinemia type-1 (HT-1). |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# ORGOVYX

## Products Affected

- ORGOVYX

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of advanced 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# ORIAHNN

## Products Affected

- ORIAHNN

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must be premenopausal and have a documented diagnosis of uterine leiomyomas (fibroids) associated with heavy menstrual bleeding. |
| Age Restrictions             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ORILISSA

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## Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# ORKAMBI

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## Products Affected

- ORKAMBI ORAL PACKET
- ORKAMBI ORAL TABLET

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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 that the member has the F508del mutation on both alleles of the CFTR gene. |
| Age Restrictions             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ORLADEYO

## Products Affected

- ORLADEYO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# OXERVATE

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## Products Affected

- OXERVATE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of neurotrophic keratitis.             |
| Age Restrictions             | None   |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# PALYNZIQ

## Products Affected

- PALYNZIQ

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# PEMAZYRE

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## Products Affected

- PEMAZYRE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of unresectable, locally advanced or metastatic Cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement and has been previously treated. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# PIQRAY

## Products Affected

- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# POMALYST

## Products Affected

- POMALYST

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | Kaposi Sarcoma: The member must have a documented diagnosis Kaposi sarcoma (KS) or AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART). Multiple Myeloma: The member must have a documented diagnosis of multiple myeloma and has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (including but not limited to: 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# PRALUENT

## Products Affected

- PRALUENT

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | The member must meet the 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. |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | The medication must be prescribed by or in consultation with a cardiologist, endocrinologist, lipidologist, or neurologist.   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | 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.   |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# PREVYMIS

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## Products Affected

- PREVYMIS

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# PROLIA

## Products Affected

- PROLIA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | None   |
| <b>Required Medical Information</b> | Coverage of Prolia (denosumab) for the treatment of osteoporosis in men and postmenopausal women may be authorized when the following criteria are met: 1) 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 2) the member has had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments [including but not limited to: alendronate (Fosamax), calcitonin (Miacalcin), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel), zoledronic acid (Reclast)] or 3) 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 also be authorized for 1) men at high risk of fracture who are receiving androgen deprivation therapy for non-metastatic prostate cancer or 2) treatment for glucocorticoid-induced osteoporosis in men and women at high risk for fracture. |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | None   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# PROMACTA

## Products Affected

- PROMACTA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Chronic Immune (idiopathic) Thrombocytopenic Purpura (ITP): The member must have a documented diagnosis of Chronic ITP and has had an insufficient response or intolerance to corticosteroids, immunoglobulins, or splenectomy. Severe Aplastic Anemia: 1) The member must have a documented diagnosis of severe aplastic anemia and 2) will be taken in combination with, or in those who have had an insufficient response with, standard immunosuppressive therapy. Thrombocytopenia with Chronic Hepatitis C: The member must have a documented diagnosis of thrombocytopenia with chronic hepatitis C infection. |
| Age Restrictions             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# QINLOCK

## Products Affected

- QINLOCK

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# RAVICTI

## Products Affected

- RAVICTI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# REMICADE

## Products Affected

- REMICADE

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | Ankylosing Spondylitis: The member must have a documented diagnosis of active ankylosing spondylitis. Crohn's Disease, Pediatric Ulcerative Colitis, or Ulcerative Colitis (UC): The member must have a documented diagnosis of one of the aforementioned diseases and an inadequate response to an appropriate trial with two or more of the following agents: a) Corticosteroids (including but not limited to: methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (including but not limited to: balsalazide (Colazal), Dipentum, mesalamine (Asacol), Pentasa, Rowasa, sulfasalazine (Azulfidine)). c) 6-mercaptopurine (6-MP, Purinethol) or azathioprine. d) Methotrexate. Plaque Psoriasis: The member must have a documented diagnosis of severe chronic plaque psoriasis and has failed to respond to or has been unable to tolerate treatment with one of the following medications: cyclosporine, methotrexate, or acitretin (Soriatane). 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 months. Rheumatoid Arthritis (RA): The member must have a documented diagnosis of RA and has documented inadequate response after three months at optimal doses or an inability to take methotrexate. |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | None  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |

| PA Criteria    | Criteria Details |
|----------------|------------------|
| Off Label Uses |                  |

# RETEVMO

## Products Affected

- RETEVMO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | Non-Small Cell Lung Cancer: The member must have a documented diagnosis of metastatic RET fusion-positive non-small cell lung cancer (NSCLC). RET-mutant Medullary Thyroid Cancer: The member must have a documented diagnosis of advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy. RET Fusion-Positive Thyroid Cancer: The member must have a documented diagnosis of advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). |
| Age Restrictions             | None   |
| Prescriber Restrictions      | The prescribing physician must be on oncologist.   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# 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   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Coverage of topical acne products will not be authorized for cosmetic purposes.  |
| <b>Required Medical Information</b> | For all retinoids, the member must have a documented diagnosis of acne vulgaris, comedones (white heads), or actinic keratosis. Tazorac or tazarotene 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 or tazarotene is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature. |
| <b>Age Restrictions</b>             | This criterion only applies to members age 26 or older. Authorization is not required for members 25 years of age or younger.  |
| <b>Prescriber Restrictions</b>      | None   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off Label Uses</b>               |  |

# REVLIMID

## Products Affected

- REVLIMID

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | Follicular Lymphoma (FL): The member must have a documented diagnosis of previously treated follicular lymphoma and Revlimid is being used in combination with a rituximab product. Mantle Cell Lymphoma (MCL): The member must have a documented diagnosis of MCL and the member's disease has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib). Marginal Zone Lymphoma (MZL): The member must have a documented diagnosis of previously treated marginal zone lymphoma and Revlimid is being used in combination with a rituximab product. 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 low- or intermediate-1-risk MDS associated with the 5q-deletion cytogenetic abnormality. |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be a hematologist or oncologist.   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# REZUROCK

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## Products Affected

- REZUROCK

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of chronic graft-versus-host disease and has a failure, contraindication, or intolerance to at least two prior lines of systemic therapy. |
| Age Restrictions             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# RINVOQ

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## Products Affected

- RINVOQ

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of Rheumatoid Arthritis who have had an inadequate response after three months at optimal doses or intolerance to methotrexate. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ROZLYTREK

## Products Affected

- ROZLYTREK

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# RUBRACA

## Products Affected

- RUBRACA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Rubraca will not be approved for concurrent use with other chemotherapy agents.  |
| Required Medical Information | Ovarian Cancer: The member must have a documented diagnosis of deleterious germline and/or somatic BRCA mutation associated epithelial ovarian, fallopian tube, or primary peritoneal cancer and has been treated with two 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. Prostate Cancer: The member must have a documented diagnosis of deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor directed therapy and a taxane-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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# RUZURGI

## Products Affected

- RUZURGI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# RYDAPT

## Products Affected

- RYDAPT

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Rydapt will not be approved as single-agent induction therapy for the treatment of patients with AML.  |
| Required Medical Information | Acute Myeloid Leukemia (AML): The member must have a documented diagnosis of AML that is FLT3 mutation-positive and Rydapt is being used as first-line therapy in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Mast Cell Leukemia (MCL): The member must have a documented diagnosis of MCL. Systemic Mastocytosis: The member must have a documented diagnosis of aggressive systemic mastocytosis (ASM) or systemic mastocytosis with associated hematological neoplasm (SM-AHN). |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# SAPROPTERIN

## Products Affected

- *sapropterin dihydrochloride*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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 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. |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# SIGNIFOR

## Products Affected

- SIGNIFOR

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# SIRTURO

## Products Affected

- SIRTURO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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 other drugs to which the member'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 other drugs to which the member's MDR-TB isolate is likely to be susceptible. |
| Age Restrictions             | None  |
| Prescriber Restrictions      | None  |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| Other Criteria               | None  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# SKYRIZI

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## Products Affected

- SKYRIZI
- SKYRIZI (150 MG DOSE)
- SKYRIZI PEN

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | 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). |
| Age Restrictions             | None   |
| Prescriber Restrictions      | The prescribing physician must be a dermatologist.   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# SOMAVERT

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## Products Affected

- SOMAVERT

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# SPRYCEL

## Products Affected

- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | Chronic Myeloid Leukemia (CML): 1) The member must have a documented diagnosis of Philadelphia chromosome-positive (Ph+) CML in chronic phase or 2) The member has a documented diagnosis of chronic, 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). For Pediatric Members: The member must have a documented diagnosis of Ph+CML in chronic phase or the member has Ph+ALL and Sprycel is being used in combination with 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# STELARA

## Products Affected

- STELARA

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | <p>Crohn's disease: 1) The member must have a documented diagnosis of moderately to severely active Crohn's disease and 2) the member had an inadequate response, intolerance, or contraindication to Humira. Plaque Psoriasis: 1) The member must have a documented diagnosis of moderate to severe plaque psoriasis with at least 5% of body surface area (BSA) affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the member had an inadequate response, intolerance, or contraindication to Enbrel or Humira. Psoriatic Arthritis: 1) The member must have a documented diagnosis of active psoriatic arthritis (PsA) and 2) the member had an inadequate response, intolerance, or contraindication to Enbrel, Humira or Xeljanz/Xeljanz XR. 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 or more of the following agents: a) Corticosteroids (including but not limited to: methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (including but not limited to: balsalazide (Colazal), Dipentum, mesalamine (Asacol), Pentasa, Rowasa, sulfasalazine (Azulfidine)). c) 6-mercaptopurine (6-MP, Purinethol) or azathioprine. d) methotrexate.</p> |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be a dermatologist, gastroenterologist or rheumatologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |

| PA Criteria    | Criteria Details |
|----------------|------------------|
| Off Label Uses |                  |

# STIVARGA

## Products Affected

- STIVARGA

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | 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 RAS wild type, an antiepidermal growth factor receptor (EGFR) therapy. |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an oncologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# SUNITINIB

## Products Affected

- *sunitinib malate*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | 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. Recurrent Renal Cell Carcinoma (RCC): The member must have a documented diagnosis of recurrent RCC following nephrectomy and Sunitinib is being used as adjuvant therapy. |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an oncologist.  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# SUNOSI

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## Products Affected

- SUNOSI

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# SUTENT

## Products Affected

- SUTENT

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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. Recurrent Renal Cell Carcinoma (RCC): The member must have a documented diagnosis of recurrent RCC following nephrectomy and Sutent is being used as adjuvant 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# SYMDEKO

## Products Affected

- SYMDEKO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of cystic fibrosis (CF), who are homozygous for the F508del mutation or 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             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TABRECTA

## Products Affected

- TABRECTA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of metastatic non-small cell lung cancer (NSCLC) with a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TADALAFIL

## Products Affected

- *tadalafil*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Tadalafil is excluded from coverage for the treatment of Erectile Dysfunction.  |
| <b>Required Medical Information</b> | 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 of the following medications: alfuzosin, doxazosin, dutasteride, dutasteride-tamsulosin, finasteride, tamsulosin, or terazosin. |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | None  |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# TAFINLAR

## Products Affected

- TAFINLAR

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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. In Combination with Mekinist: The member must have a documented diagnosis of one of the following: 1) Unresectable or metastatic melanoma with a BRAF V600E or V600K mutation. 2) Melanoma with a BRAF V600E or V600K mutation and involvement of lymph node(s) following complete resection. 3) Metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation. 4) 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# TAGRISSO

## Products Affected

- TAGRISSO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of 1) metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations OR 2) metastatic EGFR T790M mutation-positive NSCLC whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy (including but not limited to: Gilotrif, Iressa, Tarceva) or 3) NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations and Tagrisso is being used as adjuvant therapy after tumor resection. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TAKHZYRO

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## Products Affected

- TAKHZYRO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TALTZ

## Products Affected

- TALTZ

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Ankylosing Spondylitis: The member must have a documented diagnosis of active ankylosing spondylitis and has had an inadequate response, contraindication, or inability to tolerate Humira or Enbrel. Plaque Psoriasis: The member must have a documented diagnosis of moderate-to-severe plaque psoriasis and has had an inadequate response, contraindication, or inability to tolerate Humira, Enbrel, or Skyrizi. Psoriatic Arthritis: The member must have a documented diagnosis of active psoriatic arthritis and has had an inadequate response, contraindication, or inability to tolerate Humira, Enbrel, or Xeljanz/Xeljanz XR. Non-radiographic Axial Spondyloarthritis: The member must have a documented diagnosis of active non-radiographic axial spondyloarthritis with objective signs of inflammation. |
| Age Restrictions             | None  |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# TALZENNA

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## Products Affected

- TALZENNA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TARGRETIN GEL

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## Products Affected

- TARGRETIN EXTERNAL

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of cutaneous T-cell lymphoma with refractory or persistent disease after other therapies or with an intolerance to other therapies. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# TASIGNA

## Products Affected

- TASIGNA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML): The member must have a documented diagnosis of Ph+ CML in chronic phase and Tasigna is being used as initial therapy. Resistant or Intolerant Ph+ CML-CP and CML-AP: The member must have a documented diagnosis of Ph+ CML in chronic phase or 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TAZVERIK

## Products Affected

- TAZVERIK

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have one of the following requirements: 1) The member must have a documented diagnosis of metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. 2) The member must have a documented diagnosis of relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation and has received at least two prior systemic therapies. 3) The member must have a documented diagnosis of relapsed or refractory follicular lymphoma who have no satisfactory alternative 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TEGSEDI

## Products Affected

- TEGSEDI

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# TEPMETKO

## Products Affected

- TEPMETKO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TERIPARATIDE

## Products Affected

- *teriparatide (recombinant)*

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Exclusion Criteria</b>           | Coverage for teriparatide will not be authorized when cumulative use of it and/or other parathyroid hormone analogs is greater than 2 years.  |
| <b>Required Medical Information</b> | The requesting physician must provide documentation 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 have had an inadequate response to, or is unable to tolerate therapy with at least one of the traditional osteoporosis treatments (including but not limited to: alendronate (Fosamax), calcitonin (Miacalcin), denosumab (Prolia), ibandronate (Boniva), raloxifene (Evista), risedronate (Actonel) or zoledronic acid (Reclast)). |
| <b>Age Restrictions</b>             | None  |
| <b>Prescriber Restrictions</b>      | None  |
| <b>Coverage Duration</b>            | Cumulative lifetime therapy with teriparatide should not exceed 2 years.  |
| <b>Other Criteria</b>               | None  |
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off Label Uses</b>               |   |

# TETRABENAZINE

## Products Affected

- *tetrabenazine*

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# TIBSOVO

## Products Affected

- TIBSOVO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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. Acute Myeloid Leukemia (AML): The member must have a documented diagnosis of AML with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, 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.<br>Cholangiocarcinoma: The member must have a documented diagnosis of locally advanced or metastatic cholangiocarcinoma who have been previously treated. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TRANSMUCOSAL IMMEDIATE-RELEASE FENTANYL (TIRF)

## Products Affected

- ACTIQ
- *fentanyl citrate*
- LAZANDA NASAL SOLUTION 100 MCG/ACT, 400 MCG/ACT
- SUBSYS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | The Transmucosal Immediate-Release Fentanyl (TIRF) products will not be covered for any non-cancer pain indication.  |
| <b>Required Medical Information</b> | 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.   |
| <b>Age Restrictions</b>             | None.  |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an oncologist or a pain management specialist.   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | 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. |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# TRIKAFTA

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## Products Affected

- TRIKAFTA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of cystic fibrosis (CF) with at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration.  |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TRUSELTIQ

## Products Affected

- TRUSELTIQ (100MG DAILY DOSE)
- TRUSELTIQ (125MG DAILY DOSE)
- TRUSELTIQ (50MG DAILY DOSE)
- TRUSELTIQ (75MG DAILY DOSE)

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# TUKYSA

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## Products Affected

- TUKYSA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must 1) have a documented diagnosis of advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting and 2) be taking in combination with trastuzumab and capecitabine. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TURALIO

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## Products Affected

- TURALIO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# TYKERB

## Products Affected

- TYKERB

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | For estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2) overexpressing advanced or metastatic breast cancer, the member must meet ALL of the following criteria: 1) Documented diagnosis of HER2 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 HER2 receptor and is concurrently being treated with an aromatase inhibitor (including but not limited to: 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# TYMLOS

## Products Affected

- TYMLOS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Coverage for Tymlos will not be authorized when cumulative use of it and/or other parathyroid hormone analogs is greater than 2 years.   |
| <b>Required Medical Information</b> | The requesting physician must provide documentation 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 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). |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | None   |
| <b>Coverage Duration</b>            | Coverage of Tymlos is limited to 24 months.  |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# UKONIQ

## Products Affected

- UKONIQ

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of 1) relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen or 2) relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# VALTOCO

## Products Affected

- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE
- VALTOCO 20 MG DOSE
- VALTOCO 5 MG DOSE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of a seizure disorder requiring acute treatment. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# VENCLEXTA

## Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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 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. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): The member must have a documented diagnosis of CLL/SLL. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# VERZENIO

## Products Affected

- VERZENIO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | For Monotherapy: 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 with disease progression following endocrine therapy and prior chemotherapy. For Combination Therapy with Faslodex (fulvestrant): The member must have a documented diagnosis of 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 a documented diagnosis of 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# VITRAKVI

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## Products Affected

- VITRAKVI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# VIZIMPRO

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## Products Affected

- VIZIMPRO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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. |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# VOSEVI

## Products Affected

- VOSEVI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# VOTRIENT

## Products Affected

- VOTRIENT

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# VYNDAMAX

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## Products Affected

- VYNDAMAX

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# VYNDAQEL

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## Products Affected

- VYNDAQEL

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# VYVANSE

## Products Affected

- VYVANSE

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | ADHD: The member must have a documented diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) and has failed or has had an inability to tolerate 2 or more generic medications indicated for ADHD.BED: The member must have a documented diagnosis of Moderate to Severe Binge Eating Disorder (BED). |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# WAKIX

## Products Affected

- WAKIX

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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 either excessive daytime sleepiness (EDS) or cataplexy both of which must also be associated with narcolepsy. |
| Age Restrictions             | None   |
| Prescriber Restrictions      | None   |
| Coverage Duration            | FDA-approved duration, balance of contract year or clinically appropriate duration.  |
| Other Criteria               | None   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# WELIREG

## Products Affected

- WELIREG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of von Hippel-Lindau disease and require therapy for associated renal cell carcinoma, CNS hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# XALKORI

## Products Affected

- XALKORI

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of 1) metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive or the member has documented ROS1-positive tumors or 2) relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# XCOPRI

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## Products Affected

- XCOPRI
- XCOPRI (250 MG DAILY DOSE)
- XCOPRI (350 MG DAILY DOSE)

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must have a documented diagnosis of partial-onset seizures.             |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# XELJANZ

## Products Affected

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET
- XELJANZ XR

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA): The member must have a documented diagnosis of active pcJIA and has had an inadequate response or inability to take methotrexate at maximal doses for three months. 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 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 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 or more of the following agents: a) Corticosteroids (including but not limited to: methylprednisolone, prednisolone, prednisone). b) 5-Aminosalicylates (including but not limited to: 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# XERMELO

## Products Affected

- XERMELO

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# XGEVA

## Products Affected

- XGEVA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | Coverage for Xgeva (denosumab) may be authorized if one of the following is met: 1) for prevention of skeletal-related events in patients with multiple myeloma or with bone metastases from solid tumors 2) 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 3) 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# XIFAXAN 550 MG

## Products Affected

- XIFAXAN ORAL TABLET 550 MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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             | None   |
| 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.   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# XOLAIR

## Products Affected

- XOLAIR

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | Xolair will not be approved for the relief of acute bronchospasm or status asthmaticus.  |
| Required Medical Information | Asthma: The member must 1) have a documented diagnosis of moderate-to-severe persistent asthma 2) has had a failure of a treatment regimen that included two or more of the following medications: inhaled corticosteroids, oral corticosteroids, leukotriene modifiers and inhaled long-acting bronchodilators, or is unable to tolerate these medications. 3) shows a definitive sensitivity on allergy testing to one or more perennial allergens and 4) 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. CIU: 1) The member has a documented diagnosis of chronic idiopathic urticaria (CIU) and 2) the physician has documented that the member remains symptomatic despite H1 antihistamine treatment. Nasal polyps: The member must have a documented diagnosis of nasal polyps with inadequate response to nasal corticosteroids. |
| Age Restrictions             | None   |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# XOSPATA

## Products Affected

- XOSPATA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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. |
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# XPOVIO

## Products Affected

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY)
- XPOVIO (60 MG ONCE WEEKLY)
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY)
- XPOVIO (80 MG TWICE WEEKLY)

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | In combination with dexamethasone: 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. In combination with (Velcade) bortezomib and dexamethasone: The member must have a documented diagnosis of multiple myeloma and has received at least one prior therapy. Relapsed or Refractory Diffuse Large B-cell Lymphoma (DLBCL): The member must have a documented diagnosis of DLBCL, not otherwise specified, including DLBCL arising from follicular lymphoma, and has received at least 2 lines of systemic 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# XTANDI

## Products Affected

- XTANDI

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Exclusion Criteria           | None  |
| Required Medical Information | The member must have a documented diagnosis of castration-resistant prostate cancer or metastatic castration-sensitive 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# XURIDEN

## Products Affected

- XURIDEN

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# YONSA

## Products Affected

- YONSA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# ZEJULA

## Products Affected

- ZEJULA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | The member must meet one of the two following requirements: 1) The member must have a documented diagnosis of advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and is experiencing complete or partial response to platinum-based chemotherapy. 2) The member must have a documented diagnosis of advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation, or genomic instability and who have progressed more than six months after response to the last 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# ZELBORAF

## Products Affected

- ZELBORAF

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Exclusion Criteria</b>           | Zelboraf is not indicated for treatment of patients with wild-type BRAF melanoma.  |
| <b>Required Medical Information</b> | Erdheim-Chester Disease (ECD): The member must have a documented diagnosis of 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. |
| <b>Age Restrictions</b>             | None   |
| <b>Prescriber Restrictions</b>      | The prescribing physician must be an oncologist.   |
| <b>Coverage Duration</b>            | FDA-approved duration, balance of contract year or clinically appropriate duration   |
| <b>Other Criteria</b>               | None   |
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off Label Uses</b>               |  |

# ZOLINZA

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## Products Affected

- ZOLINZA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ZYDELIG

## Products Affected

- ZYDELIG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Exclusion Criteria           | None   |
| Required Medical Information | Chronic Lymphocytic Leukemia (CLL): The member must have a documented diagnosis of relapsed CLL and Zydelig is being used 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 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

# ZYKADIA

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## Products Affected

- ZYKADIA

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| 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). |
| 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  |
| Indications                  | All FDA-approved Indications.   |
| Off Label Uses               |   |

# ZYTIGA

## Products Affected

- *abiraterone acetate*

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| 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 abiraterone 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   |
| Indications                  | All FDA-approved Indications.  |
| Off Label Uses               |  |

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