

## ABIRATERONE

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**Products Affected**

- Abiraterone Acetate

- Abirtega

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Node-positive (N1), non-metastatic (M0) prostate cancer, very-high-risk prostate cancer, non-metastatic high-risk prostate cancer, non-metastatic prostate cancer with prostate-specific antigen (PSA) persistence/recurrence after radical prostatectomy |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy.  |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ACITRETIN

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## Products Affected

- Acitretin

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Prevention of non-melanoma skin cancers in high risk individuals, Lichen planus, Keratosis follicularis (Darier Disease)                             |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For psoriasis: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate or cyclosporine. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# ACTIMMUNE

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## Products Affected

- Actimmune INJ 100MCG/0.5ML

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses               | Mycosis fungoides, Sezary syndrome                                 |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# AIMOVIG

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## Products Affected

- Aimovig

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Initial: 3 months, Continuation: Plan Year  |
| Other Criteria               | N/A   |

# AKEEGA

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## Products Affected

- Akeega

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# ALECENSA

## Products Affected

- Alecensa

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC, ALK-positive anaplastic large-cell lymphoma (ALCL), Erdheim-Chester Disease (ECD) with ALK-fusion, inflammatory myofibroblastic tumors (IMT) with ALK translocation, ALK-positive large B-cell lymphoma |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic OR 2) the requested drug will be used as adjuvant treatment following tumor resection.   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ALOSETRON

## Products Affected

- Alosetron Hydrochloride

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For severe diarrhea-predominant irritable bowel syndrome (IBS): 1) The requested drug is being prescribed for a biological female or a person that self-identifies as a female, 2) chronic IBS symptoms lasting at least 6 months, 3) gastrointestinal tract abnormalities have been ruled out, AND 4) inadequate treatment response to one conventional therapy (e.g., antispasmodics, antidepressants, antidiarrheals). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ALPHA1-PROTEINASE INHIBITOR

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## Products Affected

- Prolastin-c

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For alpha1-proteinase inhibitor deficiency: Patient must have 1) clinically evident emphysema, AND 2) pretreatment serum alpha 1-proteinase inhibitor level less than 11 micromol/L (80 milligrams per deciliter [mg/dL] by radial immunodiffusion or 50 mg/dL by nephelometry). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |



# ALUNBRIG

## Products Affected

- Alunbrig

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), brain metastases from ALK-positive NSCLC, inflammatory myofibroblastic tumors (IMT) with ALK translocation, Erdheim-Chester disease (ECD) with ALK-fusion |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic, AND 2) the disease is anaplastic lymphoma kinase (ALK)-positive.  |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ALVAIZ

## Products Affected

- Alvaiz

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For chronic or persistent immune thrombocytopenia (ITP) (new starts): 1) Patient (pt) has experienced an inadequate treatment response or is intolerant to a prior therapy such as corticosteroids or immunoglobulins, AND 2) Untransfused platelet (plt) count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000-50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes pt to trauma). For ITP (continuation): plt count response to the requested drug: 1) Current plt count is less than or equal to 200,000/mcL, OR 2) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to a plt count sufficient to avoid clinically important bleeding. For thrombocytopenia associated with chronic hepatitis C (new starts): the requested drug is used for initiation and maintenance of interferon-based therapy. For thrombocytopenia associated with chronic hepatitis C (continuation): pt is receiving interferon-based therapy. For severe aplastic anemia (AA) (new starts): Pt had an insufficient response to immunosuppressive therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | HCV: 6mo, ITP/AA initial: 6mo, ITP reauth: Plan Year, AA reauth: APR-Plan Year, IPR-16 wks   |

|                       |  |
|-----------------------|--|
| <b>Other Criteria</b> | <p>For severe AA (continuation): 1) Current plt count is 50,000-200,000/mcL, OR 2) Current plt count is less than 50,000/mcL and pt has not received appropriately titrated therapy for at least 16 weeks, OR 3) Current plt count is less than 50,000/mcL and pt is transfusion-independent, OR 4) Current plt count is greater than 200,000/mcL to less than or equal to 400,000/mcL and dosing will be adjusted to achieve and maintain an appropriate target plt count. APR: adequate platelet response (greater than 50,000/mcL), IPR: inadequate platelet response (less than 50,000/mcL).</p> |
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# AMBRISENTAN

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## Products Affected

- Ambrisentan

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# ARCALYST

## Products Affected

- Arcalyst

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Prevention of gout flares in patients initiating or continuing urate-lowering therapy  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (new starts): 1) two or more gout flares within the previous 12 months, AND 2) inadequate response, intolerance, or contraindication to maximum tolerated doses of a non-steroidal anti-inflammatory drug (NSAID) and colchicine, AND 3) concurrent use with urate-lowering therapy. For prevention of gout flares in patients initiating or continuing urate-lowering therapy (e.g., allopurinol) (continuation): 1) patient must have achieved or maintained a clinical benefit (i.e., a fewer number of gout attacks or fewer flare days) compared to baseline, AND 2) continued use of urate-lowering therapy concurrently with the requested drug. For recurrent pericarditis: patient must have had an inadequate response, intolerance, or contraindication to maximum tolerated doses of a NSAID and colchicine. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# ARIKAYCE

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## Products Affected

- Arikayce

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# ARMODAFINIL

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## Products Affected

- Armodafinil

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For excessive sleepiness associated with narcolepsy: The diagnosis has been confirmed by sleep lab evaluation. For excessive sleepiness associated with obstructive sleep apnea (OSA): The diagnosis has been confirmed by polysomnography. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ASPARLAS

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## Products Affected

- Asparlas

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 21 years of age or younger    |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |



# AUBAGIO

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## Products Affected

- Teriflunomide

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# AUGTYRO

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## Products Affected

- Augtyro

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# AUSTEDO

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## Products Affected

- Austedo
- Austedo Xr
- Austedo Xr Patient Titration Kit

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses               | Tourette's syndrome  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# AUVELITY

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## Products Affected

- Auvelity

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For Major Depressive Disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# AYVAKIT

## Products Affected

- Ayvakit

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Myeloid and lymphoid neoplasms with eosinophilia, gastrointestinal stromal tumor (GIST) for residual, unresectable, tumor rupture, or recurrent/metastatic disease without platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation.   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For myeloid and lymphoid neoplasms with eosinophilia, the patient meets all of the following criteria: 1) The disease is FIP1L1- PDGFRA rearrangement-positive, AND 2) The disease harbors a PDGFRA D842V mutation, AND 3) The disease is resistant to imatinib. For GIST, the patient meets either of the following criteria: 1) The disease harbors PDGFRA exon 18 mutation, including a PDGFRA D842V mutation, OR 2) The requested drug will be used after failure on at least two Food and Drug Administration (FDA)-approved therapies in residual, unresectable, tumor rupture, or recurrent/metastatic disease without PDGFRA exon 18 mutation. For systemic mastocytosis: 1) The patient has a diagnosis of indolent systemic mastocytosis or advanced systemic mastocytosis (including aggressive systemic mastocytosis [ASM], systemic mastocytosis with associated hematological neoplasm [SM-AHN], and mast cell leukemia [MCL]) AND 2) The patient has a platelet count of greater than or equal to 50,000/microliter (mcL). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# BAFIERTAM

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## Products Affected

- Bafiertam

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# BALVERSA

## Products Affected

- Balversa

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For urothelial carcinoma: 1) disease has susceptible fibroblast growth factor receptor 3 (FGFR3) genetic alterations, AND 2) the requested drug will be used as subsequent therapy for any of the following: a) locally advanced, recurrent, or metastatic urothelial carcinoma, OR b) stage II-IV, recurrent, or persistent urothelial carcinoma of the bladder. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# BANZEL

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## Products Affected

- Rufinamide

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 1 year of age or older        |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |



# BENLYSTA

## Products Affected

- Benlysta INJ 200MG/ML

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | For patients new to therapy: severe active central nervous system lupus.   |
| Required Medical Information | For systemic lupus erythematosus (SLE): 1) patient is currently receiving a stable standard therapy regimen for SLE (for example, corticosteroid, antimalarial, or NSAIDs), OR 2) patient has experienced an intolerance or has a contraindication to standard therapy regimen for SLE. For lupus nephritis: 1) patient is currently receiving a stable standard therapy regimen for lupus nephritis (for example, corticosteroid, cyclophosphamide, mycophenolate mofetil, or azathioprine) OR 2) patient has experienced an intolerance or has a contraindication to standard therapy regimen for lupus nephritis. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# BERINERT

## Products Affected

- Berinert

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For treatment of acute angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# BESREMI

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## Products Affected

- Besremi

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# BETASERON

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## Products Affected

- Betaseron

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# BEXAROTENE

## Products Affected

- Bexarotene CAPS

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Mycosis fungoides (MF)/Sezary syndrome (SS), CD30-positive primary cutaneous anaplastic large cell lymphoma (ALCL), CD30-positive lymphomatoid papulosis (LyP) |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# BOSENTAN

## Products Affected

- Bosentan

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) if the request is for an adult patient, the patient meets both of the following: a) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units, and b) the patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to ambrisentan (Letairis). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# BOSULIF

## Products Affected

- Bosulif

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Philadelphia chromosome positive B-cell acute lymphoblastic leukemia (Ph+ B-ALL), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L, AND 3) Patient has experienced resistance or intolerance to imatinib, dasatinib, or nilotinib. For B-ALL including patients who have received hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I, G250E, V299L, and F317L. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# BRAFTOVI

## Products Affected

- Braftovi CAPS 75MG

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Adjuvant systemic therapy for cutaneous melanoma, appendiceal adenocarcinoma, recurrent NSCLC   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For colorectal cancer (including appendiceal adenocarcinoma): 1) Tumor is positive for BRAF V600E mutation, AND 2) The patient has either of the following: a) advanced or metastatic disease, b) unresectable metachronous metastases. For melanoma: 1) Tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with binimetinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer (NSCLC): 1) Tumor is positive for BRAF V600E mutation, AND 2) Disease is advanced, recurrent, or metastatic, AND 3) The requested drug will be used in combination with binimetinib. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |



# BRIVIACT

## Products Affected

- Briviact ORAL SOLN
- Briviact TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older). |
| Age Restrictions             | 1 month of age or older   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# BRIVIACT INJ

## Products Affected

- Briviact INJ

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older). |
| Age Restrictions             | 1 month of age or older   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# BRONCHITOL

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## Products Affected

- Bronchitol

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 18 years of age or older      |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# BRUKINSA

## Products Affected

- Brukinsa

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For mantle cell lymphoma and chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): the patient has experienced an intolerable adverse event or has a contraindication to Calquence (acalabrutinib). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# BUPRENORPHINE

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## Products Affected

- Buprenorphine Hcl SUBL

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | The requested drug is being prescribed for the treatment of opioid use disorder AND patient meets one of the following: 1) The patient is pregnant or breastfeeding, and the requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for treatment of opioid use disorder OR 2) The requested drug is being prescribed for induction therapy for transition from opioid use to treatment of opioid use disorder OR 3) The requested drug is being prescribed for maintenance therapy for treatment of opioid use disorder in a patient who is intolerant to naloxone. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# BUPRENORPHINE PATCH

## Products Affected

- Buprenorphine PTWK

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# CABOMETYX

## Products Affected

- Cabometyx

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Non-small cell lung cancer, Ewing sarcoma, osteosarcoma, gastrointestinal stromal tumor, endometrial carcinoma  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For renal cell carcinoma: The disease is advanced, relapsed, or stage IV (including brain metastases). For non-small cell lung cancer: 1) the disease is rearranged during transfection (RET) positive AND 2) the disease is recurrent, advanced, or metastatic. For hepatocellular carcinoma: the requested drug will be used as subsequent therapy. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture, AND 2) the disease has progressed after at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib). For Ewing sarcoma and osteosarcoma: the requested drug will be used as subsequent therapy. For differentiated thyroid cancer (DTC) (follicular, papillary, oncocyctic): 1) the disease is locally advanced or metastatic, AND 2) the disease has progressed after a vascular endothelial growth factor receptor (VEGFR)- targeted therapy, AND 3) the patient is refractory to radioactive iodine therapy (RAI) or ineligible for RAI. For endometrial carcinoma: 1) the disease is recurrent, AND 2) the requested drug will be used as subsequent therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# CALCIPOTRIENE

## Products Affected

- Calcipotriene CREA
- Calcipotriene OINT
- Calcipotriene SOLN
- Calcipotriene/betamethasone Dipropionate OINT
- Calcitrene
- Calcitriol OINT
- Enstilar

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For psoriasis: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a topical steroid. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# CALQUENCE

## Products Affected

- Calquence

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Waldenstrom macroglobulinemia (lymphoplasmacytic lymphoma), marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, splenic marginal zone lymphoma)  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug is being used for the treatment of relapsed, refractory, or progressive disease. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# CAPRELSA

## Products Affected

- Caprelsa

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses               | Thyroid carcinomas (follicular, oncocytic, papillary).             |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# CARAC

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## Products Affected

- Fluorouracil CREA 0.5%

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | Patients who are pregnant or may become pregnant. Patients with dihydropyrimidine dehydrogenase (DPD) enzyme deficiency.   |
| Required Medical Information | If being used as part of a compounded product, all active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 3 months   |
| Other Criteria               | N/A  |

# CARBAGLU

## Products Affected

- Carglumic Acid

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For N-acetylglutamate synthase (NAGS) deficiency: Diagnosis of NAGS deficiency was confirmed by enzymatic, biochemical, or genetic testing. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# CAYSTON

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## Products Affected

- Cayston

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For treatment of respiratory symptoms in cystic fibrosis patients: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of pseudomonas aeruginosa infection or colonization in the airways. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# CERDELGA

## Products Affected

- Cerdelga

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For type 1 Gaucher disease (GD1): 1) Diagnosis was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing, and 2) Patient's CYP2D6 metabolizer status has been established using an FDA-cleared test, and 3) Patient is a CYP2D6 extensive metabolizer, an intermediate metabolizer, or a poor metabolizer. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# CHANTIX AET

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## Products Affected

- Varenicline Starting Month
- Varenicline Tartrate

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 6 months   |
| Other Criteria               | This Prior Authorization requirement applies after the patient has received a cumulative 24 weeks of therapy in a Plan Year. |

## CHLORDIAZEPOXIDE - 65

### Products Affected

- Chlordiazepoxide Hcl CAPS 10MG, 5MG
- Chlordiazepoxide Hydrochloride CAPS 25MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For all indications: the prescriber must acknowledge the benefit of therapy with the prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) the requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), or b) serotonin-norepinephrine reuptake inhibitors (SNRIs). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Short-term relief anxiety-preop apprehens and anx-1 mo, Anxiety Disorder-4 mo, Alc Withdrawal-PlanYR  |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older.   |



# CLOBAZAM

## Products Affected

- Clobazam SUSP 2.5MG/ML
- Clobazam TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.              |
| Off-Label Uses               | Seizures associated with Dravet syndrome  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | Seizures associated with Lennox-Gastaut syndrome (LGS): 2 years of age or older |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# CLOMIPRAMINE

## Products Affected

- Clomipramine Hydrochloride

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Depression, panic disorder  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For obsessive-compulsive disorder (OCD) and panic disorder: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to any of the following: a serotonin and norepinephrine reuptake inhibitor (SNRI), a selective serotonin reuptake inhibitor (SSRI). For depression: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# CLORAZEPATE

## Products Affected

- Clorazepate Dipotassium TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Short-term relief anxiety-1 month, Anxiety Disorders-4 months, All other Diagnoses-Plan Year  |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older.   |

# CLOZAPINE ODT

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## Products Affected

- Clozapine Odt

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# COBENFY

## Products Affected

- Cobenfy
- Cobenfy Starter Pack

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# COLY-MYCIN

## Products Affected

- Colistimethate Sodium INJ

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The requested drug is being used intravenously (IV) or intramuscularly (IM). Administration will not be via nebulizer (Note: CMS endorsed compendia do not support inhalation/nebulization of colistimethate.). The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | Prescribed by or in consultation with an infectious disease specialist  |
| Coverage Duration            | Initial approval: 3 months. Renewal: Plan Year  |
| Other Criteria               | N/A   |

# COMETRIQ

## Products Affected

- Cometriq

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Non-small cell lung cancer (NSCLC), thyroid carcinomas (follicular, oncocytic, papillary).                           |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For non-small cell lung cancer (NSCLC): Disease is positive for rearranged during transfection (RET) rearrangements. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# COPIKTRA

## Products Affected

- Copiktra

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Hepatosplenic T-Cell lymphoma, breast implant-associated anaplastic large cell lymphoma (ALCL), peripheral T-Cell lymphoma   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), breast implant-associated anaplastic large cell lymphoma (ALCL), and peripheral T-Cell lymphoma: the patient has relapsed or refractory disease. For hepatosplenic T-Cell lymphoma: the patient has refractory disease. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |



# COSENTYX

## Products Affected

- Cosentyx

- Cosentyx Sensoready Pen
- Cosentyx Unoready

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, scalp, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Pyzchiva (ustekinumab-ttwe), Skyrizi (risankizumab-rzaa), Sotyktu (deucravacitinib), Stelara (ustekinumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce). For active ankylosing spondylitis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq (upadacitinib), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release). For active non-radiographic axial spondyloarthritis (new starts only): patient meets any of the following: 1) patient has experienced an inadequate treatment response to a non-steroidal anti-inflammatory drug (NSAID) OR 2) patient has experienced an intolerance or has a contraindication to NSAIDs. For an adult with active psoriatic arthritis (PsA) (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Enbrel (etanercept), Humira (adalimumab), Idacio (adalimumab-aacf), Pyzchiva (ustekinumab-ttwe), Rinvoq (upadacitinib)/Rinvoq LQ (upadacitinib), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib)/Xeljanz XR (tofacitinib extended-release), Yesintek (ustekinumab-kfce). |
| Age Restrictions             | N/A   |

|                                |   |
|--------------------------------|---|
| <b>Prescriber Restrictions</b> | N/A   |
| <b>Coverage Duration</b>       | Plan Year   |
| <b>Other Criteria</b>          | For moderate to severe hidradenitis suppurativa (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following products: adalimumab-aacf, Humira (adalimumab), Idacio (adalimumab-aacf). |

# COTELLIC

## Products Affected

- Cotellic

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Central nervous system (CNS) cancer (i.e., glioma, glioblastoma), adjuvant systemic therapy for cutaneous melanoma.   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For central nervous system (CNS) cancer (i.e., glioma, glioblastoma): 1) The tumor is positive for BRAF V600E activating mutation, AND 2) The requested drug will be used in combination with vemurafenib. For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used in combination with vemurafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# CYCLOPHOSPHAMIDE ORAL

## Products Affected

- Cyclophosphamide CAPS
- Cyclophosphamide TABS

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# CYSTAGON

## Products Affected

- Cystagon

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For nephropathic cystinosis: Diagnosis was confirmed by ANY of the following: 1) the presence of increased cystine concentration in leukocytes, OR 2) genetic testing, OR 3) demonstration of corneal cystine crystals by slit lamp examination. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# CYSTARAN

## Products Affected

- Cystaran

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For cystinosis: 1) Diagnosis was confirmed by ANY of the following: a) the presence of increased cystine concentration in leukocytes, OR b) genetic testing, OR c) demonstration of corneal cystine crystals by slit lamp examination, AND 2) the patient has corneal cystine crystal accumulation. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# DALFAMPRIDINE

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## Products Affected

- Dalfampridine Er

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For multiple sclerosis, patient must meet the following (for new starts): prior to initiating therapy, patient demonstrates sustained walking impairment. For multiple sclerosis (continuation): patient must have experienced an improvement in walking speed OR other objective measure of walking ability since starting the requested drug. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# DANZITEN

## Products Affected

- Danziten

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), pigmented villonodular synovitis/tenosynovial giant cell tumor   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I, Y253H, E255K/V, and F359V/C/I mutations. For acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If the patient has experienced resistance to an alternative tyrosine kinase inhibitor for ALL, patient is negative for T315I, Y253H, E255K/V, F359V/C/I and G250E mutations. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |



# DARAPRIM

## Products Affected

- Pyrimethamine TABS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Toxoplasmosis prophylaxis, Pneumocystis jirovecii pneumonia prophylaxis, cystoisosporiasis treatment and secondary prophylaxis   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For primary toxoplasmosis prophylaxis and Pneumocystis jirovecii pneumonia (PCP) prophylaxis: 1) The patient has experienced an intolerance or has a contraindication to trimethoprim-sulfamethoxazole (TMP-SMX) AND 2) The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 3 months. For secondary toxoplasmosis prophylaxis: The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 6 months. For cystoisosporiasis treatment: The patient has experienced an intolerance or has a contraindication to TMP-SMX. For secondary cystoisosporiasis prophylaxis: 1) The patient has experienced an intolerance or has a contraindication to TMP-SMX AND 2) The patient has had a CD4 cell count of less than 200 cells per cubic millimeter within the past 6 months. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Congen toxo tx: Plan Yr. Acqu toxo tx, prim toxo ppx, PCP ppx: 3mo. Sec toxo ppx, cysto tx/ppx: 6mo  |
| <b>Other Criteria</b>               | N/A  |

# DAURISMO

## Products Affected

- Daurismo

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Post-induction therapy/consolidation following response to previous therapy with the same regimen for acute myeloid leukemia (AML), relapsed/refractory AML as a component of repeating the initial successful induction regimen   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For acute myeloid leukemia (AML): 1) the requested drug must be used in combination with cytarabine, 2) the patient is 75 years of age or older OR has comorbidities that preclude intensive chemotherapy, AND 3) the requested drug will be used as treatment for induction therapy, post-induction/consolidation therapy, or relapsed or refractory disease. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# DEFERASIROX

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## Products Affected

- Deferasirox

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For chronic iron overload due to blood transfusions: pretreatment serum ferritin level is greater than 1000 mcg/L. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# DEMSEER

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## Products Affected

- Metyrosine

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to an alpha-adrenergic antagonist. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

## DHE NASAL

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### Products Affected

- Dihydroergotamine Mesylate NASAL SOLN

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin).           |
| Required Medical Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one triptan 5-HT <sub>1</sub> receptor agonist. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# DIACOMIT

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## Products Affected

- Diacomit

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 6 months of age or older      |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# DIAZEPAM AET

## Products Affected

- Diazepam CONC
- Diazepam INJ 5MG/ML
- Diazepam SOLN 5MG/5ML
- Diazepam TABS
- Diazepam Intensol

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Short-term relief anx-1 mo, skeletal muscle spasm-3 mo, Anx Disorders-4 mo, Other Diagnoses-PlanYR  |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older.   |

# DOPTELET AET

## Products Affected

- Doptelet

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For thrombocytopenia in patients with chronic liver disease: Untransfused platelet count prior to a scheduled procedure is less than 50,000/mcL. For chronic immune thrombocytopenia (ITP) (new starts): 1) Patient has experienced an inadequate treatment response or is intolerant to a prior therapy such as corticosteroids or immunoglobulins, AND 2) Patient has experienced an inadequate treatment response or intolerance to Alvaiz (eltrombopag), AND 3) Untransfused platelet count at any point prior to the initiation of the requested medication is less than 30,000/mcL OR 30,000 to 50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding (e.g., undergoing a medical or dental procedure where blood loss is anticipated, comorbidities such as peptic ulcer disease and hypertension, anticoagulation therapy, profession or lifestyle that predisposes patient to trauma). For ITP (continuation): platelet count response to the requested drug: 1) Current platelet count is less than or equal to 200,000/mcL, OR 2) Current platelet count is greater than 200,000/mcL and less than or equal to 400,000/mcL and dosing will be adjusted to a platelet count sufficient to avoid clinically important bleeding. |
| Age Restrictions             | 18 years of age or older   |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Chronic liver disease: 1 month, ITP initial: 6 months, ITP continuation: Plan Year   |
| Other Criteria               | N/A  |



# DRIZALMA

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## Products Affected

- Drizalma Sprinkle

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Cancer pain, chemotherapy-induced neuropathic pain   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | 1) The patient has tried duloxetine capsules OR 2) The patient is unable to take duloxetine capsules for any reason (e.g., difficulty swallowing capsules, requires nasogastric administration). |
| Age Restrictions             | Generalized Anxiety Disorder: 7 years of age or older  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# DRONABINOL

## Products Affected

- Dronabinol

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For nausea and vomiting associated with cancer chemotherapy: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one oral 5-HT3 receptor antagonist. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 6 months   |
| Other Criteria               | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.                                   |

# DUPIXENT

## Products Affected

- Dupixent INJ 200MG/1.14ML, 300MG/2ML

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For atopic dermatitis (AD), initial therapy: 1) Patient has moderate-to-severe disease, AND 2) Patient has had an inadequate treatment response to either a topical corticosteroid or a topical calcineurin inhibitor, OR topical corticosteroids and topical calcineurin inhibitors are not advisable for the patient. For AD, continuation of therapy: Patient achieved or maintained positive clinical response. For oral corticosteroid dependent asthma, initial therapy: Patient has inadequate asthma control despite current treatment with both of the following medications: 1) High-dose inhaled corticosteroid AND 2) Additional controller (i.e., long acting beta2-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For moderate-to-severe asthma, initial therapy: Patient has a baseline blood eosinophil count of at least 150 cells per microliter and their asthma remains inadequately controlled despite current treatment with both of the following medications: 1) Medium-to-high-dose inhaled corticosteroid, AND 2) Additional controller (i.e., LABA, LAMA, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For chronic rhinosinusitis with nasal polyposis (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) For 18 years of age or older, patient has experienced an inadequate treatment response to Xhance (fluticasone). |
| Age Restrictions             | Atopic Dermatitis: 6 months of age or older, Asthma: 6 years of age or older, Chronic Rhinosinusitis with Nasal Polyposis: 12 years of age or older, Chronic Obstructive Pulmonary Disease and Prurigo Nodularis: 18 years of age or older, Eosinophilic Esophagitis: 1 year of age or older   |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | N/A  |
| <b>Coverage Duration</b>       | AD, initial: 4 months, PN, initial: 6 months, All others: Plan Year  |
| <b>Other Criteria</b>          | <p>For eosinophilic esophagitis (EoE), initial therapy: 1) Diagnosis has been confirmed by esophageal biopsy characterized by greater than or equal to 15 intraepithelial esophageal eosinophils per high power field, AND 2) Patient is exhibiting clinical manifestations of the disease (for example, dysphagia), AND 3) Patient weighs at least 15 kilograms, AND 4) Patient experienced an inadequate treatment response, intolerance, or patient has a contraindication to a topical corticosteroid. For EoE, continuation of therapy: Patient achieved or maintained a positive clinical response. For prurigo nodularis (PN), initial therapy: Patient has had an inadequate treatment response to a topical corticosteroid OR topical corticosteroids are not advisable for the patient. For PN, continuation of therapy: Patient achieved or maintained a positive clinical response. For chronic obstructive pulmonary disease (COPD), initial therapy: 1) Patient is either of the following: a) currently receiving standard inhaled triple therapy (i.e., inhaled glucocorticoid, LAMA, and LABA) or b) currently receiving a LAMA and LABA, and has a contraindication to inhaled glucocorticoid, AND 2) Patient has an absolute blood eosinophil count of at least 300 cells per microliter prior to initiating therapy. For COPD, continuation of therapy: Patient achieved or maintained a positive clinical response.</p> |

# ELIGARD

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## Products Affected

- Eligard

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses               | Recurrent androgen receptor positive salivary gland tumors         |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# EMSAM

## Products Affected

- Emsam

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For Major Depressive Disorder (MDD): 1) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion OR 2) The patient is unable to swallow oral formulations. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ENDARI

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## Products Affected

- Endari
- L-glutamine PACK

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 5 years of age or older       |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# EPCLUSA

## Products Affected

- Epclusa

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Criteria will be applied consistent with current AASLD-IDSA guidance   |
| Other Criteria               | N/A  |



# EPIDIOLEX

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## Products Affected

- Epidiolex

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 1 year of age or older        |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# EPO

## Products Affected

- Procrit

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Anemia due to myelodysplastic syndromes (MDS), anemia in rheumatoid arthritis (RA), anemia due to hepatitis C treatment (ribavirin in combination with either interferon alfa or peginterferon alfa)  |
| <b>Exclusion Criteria</b>           | Patients receiving chemotherapy with curative intent. Patients with myeloid cancer.   |
| <b>Required Medical Information</b> | Requirements regarding hemoglobin (Hgb) values exclude values due to a recent transfusion. For initial approval: 1) for all uses except anemia due to chemotherapy or myelodysplastic syndrome (MDS): patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%), AND 2) for all uses except surgery: pretreatment (no erythropoietin treatment in previous month) Hgb is less than 10 g/dL, AND 3) for MDS: pretreatment serum erythropoietin level is 500 international units/L or less. For reauthorizations (patient received erythropoietin treatment in previous month) in all uses except surgery: 1) patient has received at least 12 weeks of erythropoietin therapy, AND 2) patient responded to erythropoietin therapy, AND 3) current Hgb is less than 12 g/dL, AND 4) for all uses except anemia due to chemotherapy or MDS: patient has adequate iron stores (for example, a transferrin saturation [TSAT] greater than or equal to 20%). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 16 weeks  |
| <b>Other Criteria</b>               | Coverage includes use in anemia in patients whose religious beliefs forbid blood transfusions. Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual (e.g., used for treatment of anemia for a patient with chronic renal failure who is undergoing dialysis, or furnished from physician's supply incident to a physician service).  |

# EPRONTIA

## Products Affected

- Eprontia

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom (if 4 years of age or older), Xcopri (if 18 years of age or older), Spritam (if 4 years of age or older). For monotherapy treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response or intolerance to a generic topiramate immediate release product, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) If the patient is 6 years of age or older, the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Spritam. For the preventative treatment of migraines: 1) The patient has experienced an inadequate treatment response or intolerance to a generic topiramate immediate release product, OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| Age Restrictions             | Epilepsy: 2 years of age or older, Migraine: 12 years of age or older  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# ERGOTAMINE

## Products Affected

- Ergotamine Tartrate/caffeine

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin). |
| Required Medical Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least ONE triptan 5-HT1 agonist.            |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# ERIVEDGE

## Products Affected

- Erivedge

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Adult medulloblastoma   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For adult medulloblastoma: patient has received prior systemic therapy AND has tumor(s) with mutations in the sonic hedgehog pathway. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

## ERLEADA

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### Products Affected

- Erleada

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# ERLOTINIB

## Products Affected

- Erlotinib Hydrochloride TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Recurrent non-small cell lung cancer (NSCLC), recurrent chordoma, relapsed or stage IV renal cell carcinoma (RCC), brain metastases from non-small cell lung cancer (NSCLC), recurrent pancreatic cancer  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For non-small cell lung cancer (NSCLC) (including brain metastases from NSCLC): 1) the disease is recurrent, advanced, or metastatic, AND 2) the patient has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease. For pancreatic cancer: the disease is locally advanced, unresectable, recurrent, or metastatic. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ESBRIET

## Products Affected

- Pirfenidone

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For idiopathic pulmonary fibrosis (new starts only): 1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern, OR 2) HRCT study of the chest reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported either by a lung biopsy or by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# ETANERCEPT

## Products Affected

- Enbrel INJ 25MG/0.5ML, 50MG/ML
- Enbrel Mini
- Enbrel Sureclick

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Hidradenitis suppurativa, non-radiographic axial spondyloarthritis  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e. at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). For hidradenitis suppurativa (new starts only): patient has severe, refractory disease. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |

|                       |     |
|-----------------------|-----|
| <b>Other Criteria</b> | N/A |
|-----------------------|-----|

# EVEROLIMUS

## Products Affected

- Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG
- Everolimus TBSO

- Torpenz

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Classic Hodgkin lymphoma, thymomas and thymic carcinomas, previously treated Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, soft tissue sarcoma (perivascular epithelioid cell tumors (PEComa) and lymphangi leiomyomatosis subtypes), gastrointestinal stromal tumors, neuroendocrine tumors of the thymus, well differentiated grade 3 neuroendocrine tumors, thyroid carcinoma (papillary, oncocyctic, and follicular), endometrial carcinoma, uterine sarcoma, breast cancer (in combination with fulvestrant or tamoxifen), histiocytic neoplasms (Rosai-Dorfman Disease, Erdheim-Chester Disease, Langerhans Cell Histiocytosis), meningiomas.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For breast cancer: 1) The disease is recurrent unresectable, advanced, or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, AND 2) The requested drug is prescribed in combination with exemestane, fulvestrant, or tamoxifen, AND 3) The requested drug is used for subsequent treatment. For renal cell carcinoma: The disease is relapsed, advanced, or stage IV. For subependymal giant cell astrocytoma (SEGA): The requested drug is given as adjuvant treatment. For gastrointestinal stromal tumor: 1) The disease is residual, recurrent, unresectable, or metastatic/tumor rupture, AND 2) The disease has progressed after use of at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib). For Erdheim-Chester Disease (ECD), Rosai-Dorfman Disease, and Langerhans Cell Histiocytosis (LCH): the patient must have a phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha (PIK3CA) mutation. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |

|                          |           |
|--------------------------|-----------|
| <b>Coverage Duration</b> | Plan Year |
| <b>Other Criteria</b>    | N/A       |

## EXKIVITY

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### Products Affected

- Exkivity

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# FANAPT

## Products Affected

- Fanapt

- Fanapt Titration Pack

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For treatment of schizophrenia: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. For acute treatment of manic or mixed episodes associated with bipolar I disorder: 1) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) The patient experienced an inadequate treatment response, intolerance, or has a contraindication to brand Vraylar. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# FASENRA

## Products Affected

- Fasenra

- Fasenra Pen

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For severe asthma, initial therapy: 1) Either a) Patient has baseline blood eosinophil count of at least 150 cells per microliter OR b) Patient is dependent on systemic corticosteroids, AND 2) Patient has a history of severe asthma despite current treatment with both of the following medications: a) medium-to-high-dose inhaled corticosteroid AND b) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For severe asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For eosinophilic granulomatosis with polyangiitis (EGPA), initial therapy: patient has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10 percent. For EGPA, continuation of therapy: patient has a beneficial response to treatment with the requested drug, as demonstrated by any of the following: 1) a reduction in the frequency of relapses, 2) a reduction in the daily oral corticosteroid dose, OR 3) no active vasculitis. |
| Age Restrictions             | Asthma: 6 years of age or older, EGPA: 18 years of age or older   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# FENTANYL PATCH

## Products Affected

- Fentanyl PT72

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# FETZIMA

## Products Affected

- Fetzima

- Fetzima Titration Pack

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For major depressive disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to TWO of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# FINTEPLA

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## Products Affected

- Fintepla

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 2 years of age or older       |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# FIRMAGON

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## Products Affected

- Firmagon INJ 120MG/VIAL, 80MG

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# FLUCYTOSINE

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## Products Affected

- Flucytosine CAPS 250MG, 500MG

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | 6 weeks                       |
| Other Criteria               | N/A                           |

# FORTEO

## Products Affected

- Teriparatide INJ 620MCG/2.48ML

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For postmenopausal osteoporosis: patient has ONE of the following: 1) history of fragility fracture, OR 2) pre-treatment T-score of less than or equal to -2.5 or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment Fracture Risk Assessment Tool (FRAX) fracture probability AND patient has ANY of the following: a) indicators for higher fracture risk (e.g., advanced age, frailty, glucocorticoid therapy, very low T-scores, or increased fall risk), OR b) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy OR c) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For primary or hypogonadal osteoporosis in men: patient has ONE of the following: 1) history of osteoporotic vertebral or hip fracture, OR 2) pre-treatment T-score of less than or equal to -2.5, or pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability AND patient has ANY of the following: a) patient has failed prior treatment with or is intolerant to a previous injectable osteoporosis therapy, OR b) patient has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate. For glucocorticoid-induced osteoporosis: patient has had an oral bisphosphonate trial of at least 1-year duration unless patient has a contraindication or intolerance to an oral bisphosphonate, AND patient meets ANY of the following: 1) patient has a history of fragility fracture, OR 2) pre-treatment T-score of less than or equal to -2.5, OR 3) pre-treatment T-score greater than -2.5 and less than -1 with a high pre-treatment FRAX fracture probability. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |

|                          |   |
|--------------------------|---|
| <b>Coverage Duration</b> | Initial: 24 months, Continuation: Plan Year   |
| <b>Other Criteria</b>    | Continuation of therapy: If the patient has received greater than or equal to 24 months of therapy with any parathyroid hormone analog: 1) The patient remains at or has returned to having a high risk for fracture, AND 2) The benefit of therapy with this prescribed medication outweighs the potential risks for this patient. Patient has high FRAX fracture probability if the 10-year probability is either greater than or equal to 20 percent for any major osteoporotic fracture or greater than or equal to 3 percent for hip fracture. If glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day, the estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture and 1.2 for hip fracture. |

# FOTIVDA

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## Products Affected

- Fotivda

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For renal cell carcinoma: 1) The disease is advanced, relapsed, refractory or Stage IV, AND 2) The patient has received two or more prior systemic therapies. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# FRUZAQLA

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## Products Affected

- Fruzaqla

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |



# FYCOMPA

## Products Affected

- Fycompa

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam. For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Spritam. |
| Age Restrictions             | Partial-onset seizures (i.e., focal-onset seizures): 4 years of age or older.<br>Primary generalized tonic-clonic seizures: 12 years of age or older   |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# GATTEX

## Products Affected

- Gattex

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For short bowel syndrome (SBS) initial therapy: 1) for an adult patient, the patient has been dependent on parenteral support for at least 12 months OR 2) for a pediatric patient, the patient is dependent on parenteral support. For SBS continuation: requirement for parenteral support has decreased from baseline while on therapy with the requested drug. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | Prescribed by or in consultation with a gastroenterologist, gastrointestinal surgeon, or nutritional support specialist.   |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# GAVRETO

## Products Affected

- Gavreto

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Recurrent rearranged during transfection (RET) rearrangement-positive non-small cell lung cancer, RET mutation-positive medullary carcinoma   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For non-small cell lung cancer, patient must meet all of the following: 1) The disease is recurrent, advanced, or metastatic, AND 2) The tumor is rearranged during transfection (RET) fusion-positive or RET rearrangement-positive. |
| <b>Age Restrictions</b>             | Non-small cell lung cancer: 18 years of age or older, Thyroid cancer: 12 years of age or older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# GILENYA

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## Products Affected

- Fingolimod Hydrochloride

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# GILOTRIF

## Products Affected

- Gilotrif

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For non-small cell lung cancer (NSCLC), patient meets either of the following: 1) has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease AND a) has experienced an intolerable adverse event or contraindication to erlotinib, gefitinib or osimertinib, OR 2) has metastatic squamous NSCLC that progressed after platinum-based chemotherapy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# GLATIRAMER

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## Products Affected

- Glatiramer Acetate
- Glatopa

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# GOMEKLI

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## Products Affected

- Gomekli

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 2 years of age or older       |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# GROWTH HORMONE

## Products Affected

- Genotropin

- Genotropin Miniquick

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | Pediatric patients with closed epiphyses  |
| Required Medical Information | Pediatric growth hormone deficiency (GHD): Patient (pt) is a neonate or was diagnosed with GHD as a neonate OR meets any of the following: 1) younger than 2.5 years old (yo) with pre-treatment (pre-tx) height (ht) more than 2 standard deviations (SD) below mean and slow growth velocity OR 2) 2.5 yo or older AND one of the following: a) pre-tx 1-year ht velocity more than 2 SD below mean OR b) pre-tx ht more than 2 SD below mean and 1-year ht velocity more than 1 SD below mean, AND patient meets any of the following: 1) failed 2 pre-tx growth hormone (GH) stimulation tests (peak below 10 ng/mL), OR 2) pituitary/central nervous system (CNS) disorder (e.g., genetic defects, acquired structural abnormalities, congenital structural abnormalities) and pre-tx insulin-like growth factor-1 (IGF-1) more than 2 SD below mean. Turner syndrome (TS): 1) Confirmed by karyotyping AND 2) pre-tx ht is less than the 5th percentile for age. Small for gestational age (SGA): 1) Birth weight (wt) less than 2500g at gestational age (GA) greater than 37 weeks, OR birth wt or length below 3rd percentile for GA or at least 2 SD below mean for GA, AND 2) did not manifest catch-up growth by age 2. |
| Age Restrictions             | SGA: 2 years of age or older  |
| Prescriber Restrictions      | Prescribed by or in consultation with an endocrinologist, nephrologist, infectious disease specialist, gastroenterologist/nutritional support specialist, or geneticist.  |
| Coverage Duration            | Plan Year   |



|                       |   |
|-----------------------|---|
| <b>Other Criteria</b> | <p>Adult GHD: Pt meets any of the following: 1) failed 2 pre-tx GH stimulation tests, OR 2) pre-tx IGF-1 more than 2 SD below mean AND failed 1 pre-tx GH stimulation test, OR 3) organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with 3 or more pituitary hormone deficiencies AND pre-tx IGF-1 more than 2 SD below mean, OR 4) genetic or structural hypothalamic-pituitary defects, OR 5) childhood-onset GHD with congenital (genetic or structural) abnormality of the hypothalamus/pituitary/CNS. For pediatric GHD, TS, SGA, and adult GHD, continuation of therapy: Patient is experiencing improvement.</p> |
|-----------------------|---|

# HAEGARDA

## Products Affected

- Haegarda

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For the prophylaxis of angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing, OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month. |
| Age Restrictions             | 6 years of age or older  |
| Prescriber Restrictions      | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# HARVONI

## Products Affected

- Harvoni

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Criteria applied consistent w/ current AASLD-IDSA guidance. Reminder for 8wk option if appropriate.  |
| Other Criteria               | N/A  |

# HETLIOZ

## Products Affected

- Tasimelteon

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For Non-24-Hour Sleep-Wake Disorder: 1) For initial therapy and continuation of therapy the patient must meet both of the following: a) diagnosis of total blindness in both eyes (e.g., nonfunctioning retinas) and b) unable to perceive light in either eye, AND 2) If currently on therapy with the requested drug, patient must meet at least one of the following: a) increased total nighttime sleep or b) decreased daytime nap duration. For nighttime sleep disturbances in Smith-Magenis Syndrome (SMS): 1) For initial therapy and continuation therapy, the patient has a confirmed diagnosis of SMS, AND 2) If currently on therapy with the requested drug, the patient experienced improvement in the quality of sleep since starting therapy. |
| Age Restrictions             | Non-24: 18 years of age or older, SMS: 16 years of age or older  |
| Prescriber Restrictions      | Prescribed by or in consultation with a sleep disorder specialist, neurologist, or psychiatrist  |
| Coverage Duration            | Initiation: 6 months, Renewal: Plan Year   |
| Other Criteria               | N/A  |

## HIGH RISK MEDICATION - 65

### Products Affected

- Chlordiazepoxide/amitriptyline
- Dicyclomine Hcl SOLN
- Dicyclomine Hydrochloride CAPS
- Dicyclomine Hydrochloride INJ
- Dicyclomine Hydrochloride TABS
- Dihydroergotamine Mesylate INJ
- Dipyridamole TABS
- Disopyramide Phosphate CAPS
- Guanfacine Hydrochloride
- Guanfacine Hydrochloride Er
- Ketorolac Tromethamine TABS
- Meprobamate
- Methscopolamine Bromide TABS
- Perphenazine/amitriptyline
- Thioridazine Hydrochloride
- Trimethobenzamide Hydrochloride

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) |

## HRM - ANTICONVULSANTS - 65

### Products Affected

- Phenobarbital ELIX 20MG/5ML
- Phenobarbital TABS 100MG, 15MG, 16.2MG, 30MG, 32.4MG, 60MG, 64.8MG, 97.2MG
- Phenobarbital Sodium INJ 130MG/ML, 65MG/ML

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Epilepsy  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) |

## HRM - HYPNOTICS - 65

### Products Affected

- Eszopiclone
- Zaleplon
- Zolpidem Tartrate TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For insomnia: 1) The patient meets one of the following: a) the patient has a contraindication to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) OR b) The non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND the patient experienced an inadequate treatment response OR intolerance to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 2) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient AND 3) If the patient is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, quetiapine, sertraline, clonazepam, escitalopram, alprazolam) with the requested drug, the prescriber has determined that taking multiple central nervous system (CNS) active medications is medically necessary for the patient [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls.]. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prior authorization applies to greater than cumulative 90 days of therapy per year.   |

## HRM - SCOPOLAMINE - 65

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### Products Affected

- Scopolamine PT72 1MG/3DAYS

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Excessive salivation   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.). |



## HRM-ANTIPARKINSON - 65

### Products Affected

- Benztropine Mesylate TABS
- Trihexyphenidyl Hcl SOLN
- Trihexyphenidyl Hydrochloride

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. EPS (extrapyramidal symptoms): 1) The patient has not tried the non-HRM alternative drug amantadine AND 2) The patient has a contraindication to the non-HRM alternative drug amantadine OR 3) The patient has tried the non-HRM alternative drug amantadine AND 4) The patient experienced an inadequate treatment response OR intolerance to the non-HRM alternative drug amantadine. Parkinson's: 1) The patient has tried two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)   |

## HRM-CYPROHEPTADINE - 65

### Products Affected

- Cyproheptadine Hcl SYRP
- Cyproheptadine Hydrochloride TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Pruritus, spasticity due to spinal cord injury  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.). Prior Authorization applies to greater than cumulative 30 days of therapy per year.  |

## HRM-DOXEPIN - 65

### Products Affected

- Doxepin Hcl CAPS 75MG
- Doxepin Hcl CONC
- Doxepin Hydrochloride CAPS 100MG, 10MG, 150MG, 25MG, 50MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone. For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)  |

## HRM-HYDROXYZINE - 65

### Products Affected

- Hydroxyzine Hcl TABS 50MG
- Hydroxyzine Hydrochloride SYRP
- Hydroxyzine Hydrochloride TABS 10MG, 25MG
- Hydroxyzine Pamoate CAPS

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety. For all indications: 1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. AND 2) If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, cyclobenzaprine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.]. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.).   |

## HRM-HYDROXYZINE INJ - 65

### Products Affected

- Hydroxyzine Hcl INJ 25MG/ML

- Hydroxyzine Hydrochloride INJ

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | <p>Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For Alcohol Withdrawal Syndrome: 1) The patient has not tried one of the following alternative drugs: clorazepate or lorazepam AND 2) The patient has a contraindication to one of the following alternative drugs: clorazepate or lorazepam OR 3) The patient has tried one of the following alternative drugs: clorazepate or lorazepam AND 4) The patient experienced an inadequate treatment response OR intolerance to one of the following alternative drugs: clorazepate or lorazepam. For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety.</p> |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | <p>This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)</p>   |

## HRM-PROMETHAZINE - 65

### Products Affected

- Promethazine Hcl INJ
- Promethazine Hcl SUPP 12.5MG
- Promethazine Hydrochloride SUPP 25MG
- Promethazine Hydrochloride TABS
- Promethazine Hydrochloride Plain
- Promethegan

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prior authorization applies to greater than cumulative 30 days of therapy per year.   |

## HRMS - ANTIDEPRESSANTS

### Products Affected

- Amitriptyline Hcl TABS 100MG, 150MG, 25MG, 75MG
- Amitriptyline Hydrochloride TABS 100MG, 10MG, 50MG
- Desipramine Hydrochloride
- Imipramine Hcl TABS 25MG, 50MG
- Imipramine Hydrochloride TABS 10MG
- Imipramine Pamoate

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Neuropathic pain, chronic tension-type headache prophylaxis (amitriptyline only)  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | This Prior Authorization only applies to patients 65 years of age or older. (The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)   |

## HRMS - CARBINOXAMINE

### Products Affected

- Carbinoxamine Maleate SOLN
- Carbinoxamine Maleate TABS 4MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)   |



## HRMS - CLEMASTINE- 65

### Products Affected

- Clemastine Fumarate TABS 2.68MG
- Clemasz

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)   |

# HRMS - TCAS

## Products Affected

- Protriptyline Hcl
- Trimipramine Maleate CAPS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For depression: 1) The patient tried two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: SSRIs (selective serotonin reuptake inhibitors), SNRIs (serotonin-norepinephrine reuptake inhibitors), bupropion, mirtazapine, or trazodone AND 3) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)   |

## HRM-SKELETAL MUSCLE RELAXANTS - 65

### Products Affected

- Chlorzoxazone TABS 500MG
- Cyclobenzaprine Hydrochloride TABS 10MG, 5MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | 1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient AND<br>2) If the patient is using one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, hydroxyzine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.]. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 3 months   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prior authorization applies to greater than cumulative 90 days of therapy per year.  |

# HUMIRA

## Products Affected

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pen
- Humira Pen-cd/uc/hs Starter INJ 80MG/0.8ML
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter INJ 0

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, scalp, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |

|                          |  |
|--------------------------|--|
| <b>Coverage Duration</b> | Plan Year  |
| <b>Other Criteria</b>    | For non-infectious intermediate, posterior and panuveitis (new starts only): 1) patient has experienced an inadequate treatment response or intolerance to a corticosteroid OR 2) the patient has a contraindication that would prohibit a trial of corticosteroids. |

## HYPNOTIC-BENZODIAZEPINES - 65

### Products Affected

- Triazolam
- Temazepam CAPS 15MG, 22.5MG, 7.5MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For short-term treatment of insomnia: 1) Prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older. Prior authorization applies to greater than cumulative 90 days of therapy per year.   |

# IBRANCE

## Products Affected

- Ibrance

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Unresectable well-differentiated/dedifferentiated liposarcoma of the retroperitoneum, recurrent hormone receptor-positive human epidermal growth factor receptor 2 (HER2)-negative breast cancer   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For breast cancer: 1) the disease is advanced, recurrent, or metastatic, AND 2) the patient has hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative disease, AND 3) the requested drug will be used in combination with an aromatase inhibitor or fulvestrant, AND 4) the patient has experienced an intolerable adverse event to Kisqali (ribociclib) OR Verzenio (abemaciclib) or has a contraindication to Kisqali (ribociclib) AND Verzenio (abemaciclib). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# ICATIBANT

## Products Affected

- Icatibant Acetate

- Sajazir

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For the treatment of acute angioedema attacks due to hereditary angioedema (HAE): 1) the patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR 2) the patient has HAE with normal C1 inhibitor confirmed by laboratory testing and one of the following: a) the patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation, b) the patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month. |
| Age Restrictions             | 18 years of age or older  |
| Prescriber Restrictions      | Prescribed by or in consultation with an immunologist, allergist, or rheumatologist   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# ICLUSIG

## Products Affected

- Iclusig

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Myeloid and/or lymphoid neoplasms with eosinophilia and FGFR1 or ABL1 rearrangement in the chronic phase or blast phase, Gastrointestinal Stromal Tumors  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: 1) Patient has accelerated or blast phase CML and no other kinase inhibitor is indicated, OR 2) Patient has chronic phase CML and has experienced resistance or intolerance to at least 2 prior kinase inhibitors AND at least one of those was imatinib, dasatinib, or nilotinib, OR 3) Patient is positive for the T315I mutation. For acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For gastrointestinal stromal tumors (GIST): 1) Disease meets any of the following: A) residual, B) unresectable, C) recurrent, D) metastatic/tumor rupture, AND 2) Disease has progressed after use of at least two Food and Drug Administration (FDA) approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# IDACIO

## Products Affected

- Adalimumab-aacf (2 Pen)
- Adalimumab-aacf (2 Syringe)
- Adalimumab-aacf Starter Pack/cd/uc/hs (6 Pen)
- Adalimumab-aacf Starter Pack/psoriasis/uveitis (4 Pen)
- Idacio (2 Pen)
- Idacio (2 Syringe)
- Idacio Starter Package For Crohns Disease
- Idacio Starter Package For Plaque Psoriasis

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For moderately to severely active rheumatoid arthritis (new starts only): 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX) OR 2) patient has experienced an inadequate treatment response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. For active ankylosing spondylitis and non-radiographic axial spondyloarthritis (new starts only): patient has experienced an inadequate treatment response or intolerance to a non-steroidal anti-inflammatory drug (NSAID) OR the patient has a contraindication that would prohibit a trial of NSAIDs. For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, scalp, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |

|                          |  |
|--------------------------|--|
| <b>Coverage Duration</b> | Plan Year  |
| <b>Other Criteria</b>    | For non-infectious intermediate, posterior and panuveitis (new starts only): 1) patient has experienced an inadequate treatment response or intolerance to a corticosteroid OR 2) the patient has a contraindication that would prohibit a trial of corticosteroids. |

## IDHIFA

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### Products Affected

- Idhifa

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Newly-diagnosed acute myeloid leukemia   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation: 1) patient has newly-diagnosed AML and is not a candidate for intensive induction therapy, OR 2) the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug, OR 3) patient has relapsed or refractory AML. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# IMATINIB

## Products Affected

- Imatinib Mesylate

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Desmoid tumors, pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT), recurrent chordoma, cutaneous melanoma, Kaposi sarcoma, chronic graft versus host disease (cGVHD), T-cell acute lymphoblastic leukemia with ABL-class translocation, aggressive systemic mastocytosis for well-differentiated systemic mastocytosis (WDSM) or when eosinophilia is present with FIP1L1-PDGFR A fusion gene, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1, FIP1L1-PDGFR A, or PDGFR B rearrangement in the chronic phase or blast phase.   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), including patients who have received a hematopoietic stem cell transplant: Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML: Patient did not fail (excluding failure due to intolerance) prior therapy with a tyrosine kinase inhibitor. For cutaneous melanoma: 1) Disease is metastatic or unresectable AND 2) Disease is positive for c-KIT activating mutations AND 3) Requested medication will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# IMBRUVICA

## Products Affected

- Imbruvica CAPS
- Imbruvica SUSP
- Imbruvica TABS 140MG, 280MG, 420MG

| PA Criteria        | Criteria Details   |
|--------------------|--|
| Indications        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses     | Hairy cell leukemia, lymphoplasmacytic lymphoma, primary central nervous system (CNS) lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphoma, diffuse large B-cell lymphoma, post-transplant lymphoproliferative disorders, high-grade B-cell lymphoma, mantle cell lymphoma, marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, splenic marginal zone lymphoma) |
| Exclusion Criteria | N/A  |

|                                     |   |
|-------------------------------------|---|
| <b>Required Medical Information</b> | For mantle cell lymphoma: 1) the requested drug will be used as subsequent therapy AND the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Calquence (acalabrutinib), OR 2) the requested drug will be used in combination with rituximab as pretreatment to induction therapy with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen, OR 3) the requested drug will be used as aggressive induction therapy. For marginal zone lymphoma (including extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma): the requested drug will be used as second-line or subsequent therapy. For hairy cell leukemia: the requested drug will be used as a single agent for disease progression. For primary CNS lymphoma: 1) the disease is relapsed or refractory OR 2) the requested drug is used for induction therapy as a single agent. For diffuse large B-cell lymphoma, high-grade B-cell lymphoma, human immunodeficiency virus (HIV)-related B-cell lymphoma: The requested drug will be used as a single agent and as second-line or subsequent therapy for relapsed or refractory disease. For post-transplant lymphoproliferative disorders: the requested drug will be used in patients who have received prior chemoimmunotherapy. For chronic lymphocytic leukemia/small lymphocytic lymphoma: the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Calquence (acalabrutinib). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# IMKELDI

## Products Affected

- Imkeldi

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Recurrent chordoma, cutaneous melanoma, Kaposi sarcoma  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For all indications: The patient is unable to use imatinib tablets. For chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), including patients who have received a hematopoietic stem cell transplant: Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML: Patient did not fail (excluding failure due to intolerance) prior therapy with a tyrosine kinase inhibitor. For cutaneous melanoma: 1) Disease is metastatic or unresectable AND 2) Disease is positive for c-KIT activating mutations AND 3) Requested medication will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |



# IMPAVIDO

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## Products Affected

- Impavido

| PA Criteria                  | Criteria Details                     |
|------------------------------|--------------------------------------|
| Indications                  | All FDA-approved Indications.        |
| Off-Label Uses               | N/A                                  |
| Exclusion Criteria           | Pregnancy. Sjogren-Larsson-Syndrome. |
| Required Medical Information | N/A                                  |
| Age Restrictions             | 12 years of age or older             |
| Prescriber Restrictions      | N/A                                  |
| Coverage Duration            | 28 days                              |
| Other Criteria               | N/A                                  |

# INBRIJA

## Products Affected

- Inbrija

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For initial treatment of off episodes in Parkinson's disease: 1) The patient is currently being treated with oral carbidopa/levodopa, AND 2) The patient does not have any of the following: asthma, chronic obstructive pulmonary disease (COPD), or other chronic underlying lung disease. For continuation treatment of off episodes in Parkinson's disease: The patient is experiencing improvement on the requested drug. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# INCRELEX

## Products Affected

- Increlex

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | Pediatric patients with closed epiphyses  |
| Required Medical Information | For growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency or growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH, patient meets all of the following prior to beginning therapy with the requested drug (new starts only): 1) height 3 or more standard deviations (SD) below the mean for children of the same age and gender AND 2) basal IGF-1 level 3 or more SD below the mean for children of the same age and gender AND 3) provocative growth hormone test showing a normal or elevated growth hormone level. For growth failure due to severe primary IGF-1 deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH, continuation of therapy: patient is experiencing improvement. |
| Age Restrictions             | 2 years of age or older   |
| Prescriber Restrictions      | Prescribed by or in consultation with an endocrinologist  |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# INLYTA

## Products Affected

- Inlyta

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.                  |
| Off-Label Uses               | Thyroid carcinoma (papillary, oncocytic, or follicular), alveolar soft part sarcoma |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For renal cell carcinoma: the disease is advanced, relapsed, or Stage IV.           |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# INQOVI

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## Products Affected

- Inqovi

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# INREBIC

## Products Affected

- Inrebic

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and janus kinase 2 (JAK2) rearrangement, accelerated or blast phase myeloproliferative neoplasms |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase.                            |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# INSULIN SUPPLIES

## Products Affected

- Alcohol Prep Pads PADS 70%
- Bd Insulin Syringe Safetyglide/1ml/29g X 1/2"
- B-d Insulin Syringe Ultrafine Ii/0.3ml/31g X 5/16"
- Bd Insulin Syringe Ultra-fine/0.5ml/30g X 12.7mm
- Bd Insulin Syringe Ultra-fine/1ml/31g X 8mm
- Bd Pen Needle/original/ultra-fine/29g X 12.7mm
- Bd Veo Insulin Syringe Ultra-fine/0.3ml/31g X 6mm
- Curity Gauze Pads 2"x2" 12 Ply

| PA Criteria                  | Criteria Details                                  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.                     |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The requested product is being used with insulin. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

## IR BEFORE ER

### Products Affected

- Hydrocodone Bitartrate Er T24A
- Methadone Hcl INJ
- Methadone Hcl ORAL SOLN
- Methadone Hcl TABS
- Methadone Hydrochloride CONC
- Morphine Sulfate Er TBCR 100MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through palliative care OR the patient meets all of the following: 1) The requested drug is being prescribed for pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid AND 2) The patient can safely take the requested dose based on their history of opioid use [Note: This drug should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.] AND 3) The patient has been evaluated and the patient will be monitored for the development of opioid use disorder AND 4) This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days OR the patient has taken an immediate-release opioid for at least one week. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# IRESSA

## Products Affected

- Gefitinib

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent non-small cell lung cancer (NSCLC)   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic, AND 2) the patient must have a sensitizing epidermal growth factor receptor (EGFR) mutation. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# ISOTRETINOIN

## Products Affected

- Accutane
- Amnesteem
- Claravis
- Isotretinoin CAPS
- Zenatane

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Refractory acne vulgaris, severe refractory rosacea, neuroblastoma, cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides, Sezary syndrome), high risk for developing skin cancer (squamous cell cancers), transient acantholytic dermatosis (Grover's Disease), keratosis follicularis (Darier Disease), lamellar ichthyosis, pityriasis rubra pilaris. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# ITOVEBI

## Products Affected

- Itovebi

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# ITRACONAZOLE

## Products Affected

- Itraconazole CAPS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Coccidioidomycosis, Coccidioidomycosis prophylaxis in HIV infection,, Cryptococcosis, Microsporidiosis, Talaromycosis (formerly Penicilliosis), Histoplasmosis prophylaxis in HIV infection, Invasive fungal infection prophylaxis in liver transplant, chronic granulomatous disease (CGD), and hematologic malignancy, Sporotrichosis, Pityriasis versicolor, Tinea versicolor, Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis, primary treatment for allergic bronchopulmonary aspergillosis, primary treatment for chronic cavitary or subacute invasive (necrotizing) pulmonary aspergillosis |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | The requested drug will be used orally. For the treatment of onychomycosis due to dermatophytes (Tinea unguium), the diagnosis has been confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy). For primary treatment of allergic bronchopulmonary aspergillosis, the requested drug is initiated in combination with systemic corticosteroids.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Disseminated/CNS histo, histo/CM/CGD ppx, chronic cavitary/necrotizing PA: 12 mths. Others: 6 mths   |
| <b>Other Criteria</b>               | N/A  |

# IVERMECTIN TAB

## Products Affected

- Ivermectin TABS

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Ascariasis, Cutaneous larva migrans, Mansonelliasis, Scabies, Gnathostomiasis, Pediculosis                         |
| Exclusion Criteria           | N/A  |
| Required Medical Information | The requested drug is not being prescribed for the prevention or treatment of coronavirus disease 2019 (COVID-19). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 1 month  |
| Other Criteria               | N/A  |

# IVIG

## Products Affected

- Gammaked INJ 10GM/100ML, 1GM/10ML, 20GM/200ML, 5GM/50ML
- Gamunex-c
- Octagam INJ 10GM/100ML, 10GM/200ML, 1GM/20ML, 2.5GM/50ML, 20GM/200ML, 2GM/20ML, 30GM/300ML, 5GM/100ML, 5GM/50ML
- Privigen

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For B-cell chronic lymphocytic leukemia (CLL): 1) serum IgG less than 500 mg/dL OR 2) a history of recurrent bacterial infections. For bone marrow transplant/hematopoietic stem cell transplant (BMT/HSCT): 1) IVIG is requested within the first 100 days post-transplant OR 2) serum IgG less than 400 mg/dL. For pediatric human immunodeficiency virus (HIV) infection: 1) serum IgG less than 400 mg/dL OR 2) history of recurrent bacterial infections. For dermatomyositis and polymyositis: 1) at least one standard first-line treatment (corticosteroid or immunosuppressant) has been tried but was unsuccessful or not tolerated OR 2) patient is unable to receive standard therapy because of a contraindication or other clinical reason. For pure red cell aplasia (PRCA): PRCA is secondary to parvovirus B19 infection. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.   |

# IWILFIN

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## Products Affected

- Iwilfin

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# JAKAFI

## Products Affected

- Jakafi

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Lower-risk myelofibrosis, accelerated or blast phase myeloproliferative neoplasms, acute lymphoblastic leukemia (ALL), chronic myelomonocytic leukemia (CMML)-2, myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) with neutrophilia, essential thrombocythemia, myeloid, lymphoid or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement, T-cell prolymphocytic leukemia  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For polycythemia vera: 1) patient had an inadequate response or intolerance to hydroxyurea and Besremi (ropeginterferon alfa-2b-njft), OR 2) patient has high risk disease. For acute lymphoblastic leukemia: patient has a cytokine receptor-like factor 2 (CRLF2) mutation or a mutation associated with activation of the Janus kinase/signal transducers and activators of transcription (JAK/STAT) pathway. For CMML-2: the requested drug is used in combination with a hypomethylating agent. For myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) with neutrophilia: the requested drug is used as a single agent or in combination with a hypomethylating agent. For essential thrombocythemia: patient had an inadequate response or loss of response to hydroxyurea, interferon therapy, or anagrelide. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and JAK2 rearrangement: the disease is in chronic or blast phase. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |



# JAYPIRCA

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## Products Affected

- Jaypirca

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL): The patient meets both of the following: 1) The patient has received prior treatment with a Bruton Tyrosine Kinase (BTK) inhibitor, for example Calquence (acalabrutinib), AND 2) The patient has received prior treatment with a B-cell lymphoma 2 (BCL-2) inhibitor. For mantle cell lymphoma: the patient has received prior treatment for a BTK inhibitor, for example Calquence (acalabrutinib). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# KALYDECO

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## Products Affected

- Kalydeco

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# KESIMPTA

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## Products Affected

- Kesimpta

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# KETOCONAZOLE

## Products Affected

- Ketoconazole TABS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Cushing's syndrome   |
| <b>Exclusion Criteria</b>           | Acute or chronic liver disease. Concurrent use with drugs that are contraindicated with ketoconazole tablets: dofetilide, quinidine, pimozide, cisapride, methadone, disopyramide, dronedarone, ranolazine, ergot alkaloids, irinotecan, lurasidone, oral midazolam, alprazolam, triazolam, felodipine, nisoldipine, tolvaptan, eplerenone, lovastatin, simvastatin, or colchicine.                          |
| <b>Required Medical Information</b> | The potential benefits outweigh the risks of treatment with oral ketoconazole. For systemic fungal infections, the patient has any of the following diagnoses: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis. For Cushing's syndrome: the requested drug is being prescribed for a patient who cannot tolerate surgery or where surgery has not been curative. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 6 months   |
| <b>Other Criteria</b>               | N/A  |

# KISQALI

## Products Affected

- Kisqali
- Kisqali Femara 200 Dose
- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Recurrent hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer, in combination with an aromatase inhibitor, or fulvestrant. Endometrial cancer, in combination with letrozole, for estrogen receptor positive tumors. |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# KORLYM

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## Products Affected

- Mifepristone TABS 300MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.                            |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | Prescribed by or in consultation with an endocrinologist |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# KOSELUGO

## Products Affected

- Koselugo

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | BRAF fusion or BRAF V600E activating mutation-positive recurrent or progressive circumscribed glioma, Langerhans cell histiocytosis. |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | For neurofibromatosis type 1: 2 years of age or older  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# KRAZATI

## Products Affected

- Krazati

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Recurrent KRAS G12C-positive non-small cell lung cancer (NSCLC), Central nervous system (CNS) brain metastases from KRAS G12C-positive NSCLC, KRAS G12C-positive pancreatic adenocarcinoma |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |



# KRISTALOSE

## Products Affected

- Kristalose

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For constipation: 1) The patient has experienced an inadequate treatment response to a one month trial of generic lactulose solution, OR 2) The patient has experienced an intolerance that would prohibit a one month trial of generic lactulose solution, OR 3) the patient has a contraindication to an inactive ingredient in generic lactulose solution which is not contained in the requested drug. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# LAPATINIB

## Products Affected

- Lapatinib Ditosylate

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Brain metastases from human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent HER2-positive breast cancer, recurrent epidermal growth factor receptor (EGFR)-positive chordoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer (including appendiceal adenocarcinoma).  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For breast cancer, the patient meets all the following: a) the disease is recurrent, advanced, or metastatic (including brain metastases), b) the disease is human epidermal growth factor receptor 2 (HER2)-positive, c) the requested drug will be used in combination with any of the following: 1) aromatase inhibitor, 2) capecitabine, OR 3) trastuzumab. For colorectal cancer: 1) requested drug will be used in combination with trastuzumab and 2) patient has not had previous treatment with a HER2 inhibitor. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# LAZCLUZE

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## Products Affected

- Lazcluze

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# LENVIMA

## Products Affected

- Lenvima 10 Mg Daily Dose
- Lenvima 12mg 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   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Medullary thyroid carcinoma, recurrent endometrial carcinoma, thymic carcinoma, unresectable or metastatic cutaneous melanoma.   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For differentiated thyroid cancer (follicular, papillary, or oncocytic): disease is not amenable to radioactive iodine therapy and unresectable, locally recurrent, persistent, or metastatic. For hepatocellular carcinoma (HCC): disease is unresectable or inoperable, local, metastatic or with extensive liver tumor burden. For renal cell carcinoma (RCC): the disease is advanced, relapsed, or stage IV. For endometrial carcinoma (EC), the patient meets ALL of the following: 1) The disease is advanced, recurrent, or metastatic, 2) The requested drug will be used in combination with pembrolizumab, 3) The patient experienced disease progression following prior systemic therapy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# LEUPROLIDE

## Products Affected

- Leuprolide Acetate INJ 1MG/0.2ML

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Use in combination with growth hormone for children with growth failure and advancing puberty, recurrent androgen receptor positive salivary gland tumors, central precocious puberty  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For central precocious puberty (CPP): Patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients. |
| <b>Age Restrictions</b>             | CPP: Patient must be less than 12 years old if female and less than 13 years old if male   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# LIBERVANT

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## Products Affected

- Libervant

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 2 to 5 years of age           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# LIDOCAINE PATCHES

## Products Affected

- Lidocaine PTCH 5%
- Lidocan
- Tridacaine
- Tridacaine II

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Pain associated with diabetic neuropathy, pain associated with cancer-related neuropathy (including treatment-related neuropathy [e.g., neuropathy associated with radiation treatment or chemotherapy]). |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# LINEZOLID

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## Products Affected

- Linezolid INJ

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The infection is proven or strongly suspected to be caused by susceptible bacteria based on: 1) culture and susceptibility information, OR 2) local epidemiology and susceptibility patterns. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | 28 days   |
| Other Criteria               | N/A   |



# LIVTENCITY

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## Products Affected

- Livtency

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | 12 years of age or older  |
| Prescriber Restrictions      | Prescribed by or in consultation with an infectious disease specialist, transplant specialist, hematologist, or oncologist. |
| Coverage Duration            | 3 months  |
| Other Criteria               | N/A   |

# LONSURF

## Products Affected

- Lonsurf

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Unresectable locally advanced, recurrent, or metastatic esophageal cancer. Unresectable locally advanced or recurrent gastric cancer and gastroesophageal junction cancers. Advanced or metastatic appendiceal adenocarcinoma.   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For colorectal cancer (including appendiceal adenocarcinoma): The disease is advanced or metastatic. For gastric, esophageal, or gastroesophageal junction adenocarcinoma, ALL of the following criteria must be met: 1) The disease is unresectable locally advanced, recurrent, or metastatic, and 2) The patient has been previously treated with at least two prior lines of chemotherapy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# LORBRENA

## Products Affected

- Lorbrena

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Anaplastic lymphoma kinase (ALK)-positive recurrent non-small cell lung cancer (NSCLC), proto-oncogene tyrosine-protein kinase ROS1 (ROS1) rearrangement-positive recurrent, advanced, or metastatic NSCLC, symptomatic or relapsed/refractory ALK-positive Erdheim-Chester Disease, inflammatory myofibroblastic tumor (IMT) with ALK translocation (including advanced, recurrent/metastatic, or inoperable uterine sarcoma for IMT with ALK translocation), central nervous system (CNS) brain metastases from ALK rearrangement-positive NSCLC, relapsed or refractory ALK-positive Diffuse Large B-Cell Lymphoma |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For recurrent, advanced, or metastatic non-small cell lung cancer: 1) Disease is ALK-positive AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib) OR 3) Disease is positive for ROS1 rearrangement and the requested drug is being used following disease progression on crizotinib, entrectinib, or ceritinib.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# LUMAKRAS

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## Products Affected

- Lumakras

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses               | Recurrent KRAS G12C-positive non-small cell lung cancer (NSCLC)    |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# LUPRON PED

## Products Affected

- Lupron Depot-ped (1-month)
- Lupron Depot-ped (3-month)
- Lupron Depot-ped (6-month)

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For central precocious puberty (CPP): Patients not currently receiving therapy must meet all of the following criteria: 1) Diagnosis of CPP was confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test OR a pubertal level of a third generation luteinizing hormone (LH) assay, AND 2) Assessment of bone age versus chronological age supports the diagnosis of CPP, AND 3) The onset of secondary sexual characteristics occurred prior to 8 years of age for female patients OR prior to 9 years of age for male patients. |
| Age Restrictions             | CPP: Patient must be less than 12 years old if female and less than 13 years old if male   |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# LUPRON-ENDOMETRIOSIS

## Products Affected

- Lupron Depot (1-month) INJ 3.75MG
- Lupron Depot (3-month) INJ 11.25MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Breast cancer, ovarian cancer/fallopian tube cancer/primary peritoneal cancer, androgen receptor positive recurrent salivary gland tumor  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For retreatment of endometriosis, the requested drug is used in combination with norethindrone acetate. For uterine fibroids, patient must meet one of the following: 1) diagnosis of anemia (e.g., hematocrit less than or equal to 30 percent and/or hemoglobin less than or equal to 10g/dL), OR 2) the requested medication will be used prior to surgery for uterine fibroids. For breast cancer, the requested drug is used for hormone receptor (HR)-positive disease. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Fibroids: 3 months (mo), max 6 mo total. Endometriosis: 6 mo, max 12 mo total. Others: Plan Year  |
| Other Criteria               | N/A   |

# LYNPARZA

## Products Affected

- Lynparza TABS

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Recurrent HER2-negative, BRCA 1/2-germline mutated breast cancer, recurrent or metastatic HER2-positive, BRCA 1/2-germline mutated breast cancer, uterine leiomyosarcoma.  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For recurrent or metastatic breast cancer: the disease is BRCA 1/2-germline mutated. For prostate cancer: 1) The patient has a BRCA mutation and the requested drug will be used in combination with abiraterone and an oral corticosteroid OR 2) The patient has progressed on prior treatment with an androgen receptor-directed therapy. For ovarian, fallopian tube, or primary peritoneal cancer: The requested drug is used for maintenance therapy for stage II-IV or recurrent disease who are in complete or partial response to chemotherapy. For uterine leiomyosarcoma: 1) the patient has had at least one prior therapy AND 2) the patient has BRCA-altered disease. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# LYRICA CR

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## Products Affected

- Pregabalin Er

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN): The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# LYTGOBI

## Products Affected

- Lytgobi

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Extrahepatic cholangiocarcinoma  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For cholangiocarcinoma: 1) patient has a diagnosis of unresectable, locally advanced or metastatic cholangiocarcinoma, 2) patient has received a previous treatment, AND 3) patient has a disease that has a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# MAVYRET

## Products Affected

- Mavyret

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh [CTP] class B or C).  |
| Required Medical Information | For hepatitis C virus (HCV): Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [CTP class B or C]), presence or absence of human immunodeficiency virus (HIV) coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Criteria will be applied consistent with current AASLD-IDSA guidance   |
| Other Criteria               | N/A  |

# MEKINIST

## Products Affected

- Mekinist

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with dabrafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For uveal melanoma: The requested drug will be used as a single agent. For ovarian cancer, fallopian tube cancer, and primary peritoneal cancer: The requested drug will be used to treat persistent or recurrent disease. For papillary, follicular, and oncocytic thyroid carcinoma: 1) The disease is positive for BRAF V600E mutation, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy, AND 3) The requested drug will be used in combination with dabrafenib. For solid tumors: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used in combination with dabrafenib. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# MEKTOVI

## Products Affected

- Mektovi

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Adjuvant systemic therapy for cutaneous melanoma, Langerhans Cell Histiocytosis, recurrent non-small cell lung cancer (NSCLC)  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used in combination with encorafenib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer: 1) The tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used in combination with encorafenib, AND 3) The disease is advanced, recurrent, or metastatic. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# MEMANTINE

## Products Affected

- Memantine Hcl Titration Pak
- Memantine Hydrochloride SOLN 2MG/ML
- Memantine Hydrochloride TABS
- Memantine Hydrochloride Er

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | This prior authorization only applies to patients less than 30 years of age. |

# METFORMIN ER

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## Products Affected

- Metformin Hydrochloride Er TB24 500MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The patient has experienced an intolerance that prohibited a 4-week trial of metformin immediate-release and generic Glucophage XR. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# METHYLTESTOSTERONE

## Products Affected

- Methyltestosterone CAPS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to alternative testosterone products (e.g., topical testosterone, transdermal testosterone, injectable testosterone). For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# MODAFINIL

## Products Affected

- Modafinil TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Idiopathic hypersomnia  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For excessive sleepiness associated with narcolepsy: The diagnosis has been confirmed by sleep lab evaluation. For excessive sleepiness associated with obstructive sleep apnea (OSA): The diagnosis has been confirmed by polysomnography. For idiopathic hypersomnia, initial request, the diagnosis has been confirmed by ALL of the following: 1) Patient has experienced lapses into sleep or an irrepressible need to sleep during daytime, on a daily basis, for at least 3 months, AND 2) Insufficient sleep syndrome is confirmed absent, AND 3) Cataplexy is absent, AND 4) Fewer than 2 sleep onset rapid eye movement periods (SOREMPs) or no SOREMPs, if the rapid eye movement latency on an overnight sleep study was less than or equal to 15 minutes, AND 5) Average sleep latency of less than or equal to 8 minutes on Multiple Sleep Latency Test or total 24-hour sleep time is greater than or equal to 11 hours, AND 6) Another condition (sleep disorder, medical or psychiatric disorder, or drug/medication use) does not better explain the hypersomnolence and test results. For idiopathic hypersomnia, continuation of therapy: The patient has experienced a decrease in daytime sleepiness from baseline. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# MOUNJARO

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## Products Affected

- Mounjaro

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# NAPROXEN SUSPENSION

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## Products Affected

- Naproxen SUSP

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ibuprofen oral suspension, AND<br>2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 6 months   |
| Other Criteria               | N/A  |

# NAYZILAM

## Products Affected

- Nayzilam

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 12 years of age or older      |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# NERLYNX

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## Products Affected

- Nerlynx

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer, brain metastases from HER2-positive breast cancer. |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# NEXAVAR

## Products Affected

- Nexavar

- Sorafenib Tosylate TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Acute myeloid leukemia, soft tissue sarcoma (angiosarcoma, desmoid tumors/aggressive fibromatosis, and solitary fibrous tumor subtypes), gastrointestinal stromal tumor, medullary thyroid carcinoma, osteosarcoma, recurrent chordoma, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, lymphoid and/or myeloid neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For acute myeloid leukemia: the disease is FMS-like tyrosine kinase 3-internal tandem duplication (FLT3-ITD) mutation-positive and any of the following is met :1) the requested drug will be used as maintenance therapy after hematopoietic stem cell transplant, OR 2) the requested drug is being used for low-intensity treatment induction, post-induction therapy, or consolidation therapy, OR 3) the disease is relapsed/refractory. For thyroid carcinoma: histology is follicular, papillary, oncocytic, or medullary. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture, AND 2) the disease has progressed after use of at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# NINLARO

## Products Affected

- Ninlaro

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Relapsed/refractory systemic light chain amyloidosis, Waldenstrom macroglobulinemia, lymphoplasmacytic lymphoma |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# NITISINONE

## Products Affected

- Nitisinone

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For hereditary tyrosinemia type 1 (HT-1): Diagnosis of HT-1 is confirmed by one of the following: 1) biochemical testing (e.g., detection of succinylacetone in urine) OR 2) DNA testing (mutation analysis). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# NORTHERA

## Products Affected

- Droxidopa

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For neurogenic orthostatic hypotension (nOH): For initial therapy, patient has a persistent, consistent decrease in systolic blood pressure of at least 20 mmHg OR decrease in diastolic blood pressure of at least 10 mmHg within 3 minutes of standing or head-up tilt test. For continuation of therapy, patient has experienced a sustained reduction in symptoms of nOH (i.e., decrease in dizziness, lightheadedness, or feeling faint). For both initial and continuation of therapy, the requested drug will be used for patients with neurogenic orthostatic hypotension associated with one of the following diagnoses: 1) primary autonomic failure due to Parkinson's disease, multiple system atrophy, or pure autonomic failure, OR 2) dopamine beta-hydroxylase deficiency, OR 3) non-diabetic autonomic neuropathy. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | 3 months  |
| Other Criteria               | N/A   |



# NOXAFIL SUSP

## Products Affected

- Posaconazole SUSP

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | The requested drug will be used orally. For treatment of oropharyngeal candidiasis: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to fluconazole. |
| Age Restrictions             | 13 years of age or older   |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Oropharyngeal candidiasis: 1 month. All other indications: 6 months  |
| Other Criteria               | N/A  |

# NUBEQA

## Products Affected

- Nubeqa

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# NUEDEXTA

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## Products Affected

- Nuedexta

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For pseudobulbar affect (PBA) (continuation): The patient has experienced a decrease in pseudobulbar affect (PBA) episodes since starting therapy with the requested drug. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Initial: 4 months, Continuation: Plan Year   |
| Other Criteria               | N/A  |

# NUPLAZID

## Products Affected

- Nuplazid CAPS
- Nuplazid TABS 10MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For hallucinations and delusions associated with Parkinson's disease psychosis, the diagnosis of Parkinson's disease must be made prior to the onset of psychotic symptoms. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# NURTEC

## Products Affected

- Nurtec

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Acute migraine treatment: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to one triptan 5-HT <sub>1</sub> receptor agonist. Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Preventive treatment of migraine, initial: 3 months, All other indications: Plan Year   |
| Other Criteria               | N/A   |

# OCTREOTIDE

## Products Affected

- Octreotide Acetate INJ 1000MCG/ML, 100MCG/ML, 200MCG/ML, 500MCG/ML, 50MCG/ML

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Tumor control of thymomas and thymic carcinomas   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ODOMZO

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## Products Affected

- Odomzo

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# OFEV

## Products Affected

- Ofev

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For idiopathic pulmonary fibrosis (new starts only): 1) a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy reveals the usual interstitial pneumonia (UIP) pattern, OR 2) HRCT study of the chest reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported either by a lung biopsy or by a multidisciplinary discussion between at least a radiologist and pulmonologist who are experienced in idiopathic pulmonary fibrosis if a lung biopsy has not been conducted. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# OGSIVEO

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## Products Affected

- Ogsiveo

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

## OJEMDA

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### Products Affected

- Ojemda

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For relapsed or refractory pediatric low-grade glioma (LGG): the patient's tumor is positive for either a) BRAF fusion or rearrangement OR b) BRAF V600 mutation. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# OJJAARA

## Products Affected

- Ojjaara

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Accelerated or blast phase myeloproliferative neoplasms   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For myelofibrosis, patient meets ALL of the following: 1) the patient has a diagnosis of intermediate or high-risk primary myelofibrosis or secondary myelofibrosis (i.e., post-polycythemia vera or post-essential thrombocythemia), AND 2) the patient has anemia defined as hemoglobin less than 10 grams per deciliter (g/dL) or having transfusion-dependent anemia, AND 3) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Jakafi (ruxolitinib) OR has hemoglobin less than 8 g/dL. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

## OMEGA-3

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### Products Affected

- Omega-3-acid Ethyl Esters CAPS  
375MG; 465MG; 1GM

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For hypertriglyceridemia: Prior to the start of treatment with a triglyceride lowering drug, the patient has/had a pretreatment triglyceride level greater than or equal to 500 milligram per deciliter (mg/dL). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# ONCASPAR

## Products Affected

- Oncaspar

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.            |
| Off-Label Uses               | Extranodal natural killer/T-cell lymphoma, aggressive NK-cell leukemia (ANKL) |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ONUREG

## Products Affected

- Onureg

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses               | Peripheral T-cell lymphoma   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# OPSUMIT

## Products Affected

- Opsumit

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# ORACEA AET

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## Products Affected

- Doxycycline CPDR

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a formulary generic topical metronidazole. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |



## ORAL-INTRANASAL FENTANYL

### Products Affected

- Fentanyl Citrate Oral Transmucosal LPOP 1600MCG, 200MCG, 400MCG, 800MCG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For the management of breakthrough pain in cancer patients: 1) The requested drug is indicated for the treatment of breakthrough cancer-related pain only. The requested drug is being prescribed for the management of breakthrough pain in a cancer patient with underlying cancer pain AND 2) The International Classification of Diseases (ICD) diagnosis code provided supports the cancer-related diagnosis. [Note: For drug coverage approval, ICD diagnosis code provided MUST support the cancer-related diagnosis.] AND 3) The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying cancer pain AND 4) The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their current opioid use history. [Note: Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 60 mg of oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for one week or longer.]. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ORGOVYX

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## Products Affected

- Orgovyx

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# ORKAMBI

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## Products Affected

- Orkambi

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For cystic fibrosis (CF): The requested medication will not be used in combination with other medications containing ivacaftor. |
| Age Restrictions             | 1 year of age or older  |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ORSERDU

## Products Affected

- Orserdu

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Recurrent hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Breast cancer: 1) the disease is estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER2)-negative, and ESR1 mutated AND 2) the patient meets either of the following: a) the disease is advanced, recurrent, or metastatic AND the patient has disease progression following at least one line of endocrine therapy OR b) the disease had no response to preoperative systemic therapy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

## OXAZEPAM - 65

### Products Affected

- Oxazepam

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders, anxiety associated with depression, and the management of anxiety, tension, agitation and irritability in older patients: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Short-term relief anxiety-1 month, Anxiety Disorders-4 months, Alcohol Withdrawal-Plan Year   |
| <b>Other Criteria</b>               | This Prior Authorization only applies to patients 65 years of age or older.   |

# OZEMPIC

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## Products Affected

- Ozempic INJ 2MG/3ML, 4MG/3ML, 8MG/3ML

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# PANRETIN

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## Products Affected

- Panretin

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.                      |
| Off-Label Uses               | Topical treatment of cutaneous lesions in patients with non-AIDS-related Kaposi sarcoma |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# PEGASYS

## Products Affected

- Pegasys

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis), systemic mastocytosis, adult T-cell leukemia/lymphoma, mycosis fungoides/sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders, hairy cell leukemia, Erdheim-Chester disease, initial treatment during pregnancy for chronic myeloid leukemia. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For chronic hepatitis C: Hepatitis C virus (HCV) confirmed by presence of hepatitis C virus HCV RNA in serum prior to starting treatment and the planned treatment regimen.  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | HCV: 12-48wks. HBV: 48wks. Other: Plan Yr  |
| <b>Other Criteria</b>               | N/A  |



# PEMAZYRE

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## Products Affected

- Pemazyre

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# PHENYL BUTYRATE

## Products Affected

- Sodium Phenylbutyrate POWD 3GM/TSP
- Sodium Phenylbutyrate TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For urea cycle disorders (UCD): Diagnosis of UCD was confirmed by enzymatic, biochemical, or genetic testing. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# PIQRAY

## Products Affected

- Piqray 200mg Daily Dose
- Piqray 250mg Daily Dose
- Piqray 300mg Daily Dose

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated breast cancer in combination with fulvestrant. |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# POMALYST

## Products Affected

- Pomalyst

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Relapsed/refractory systemic light chain amyloidosis, primary central nervous system (CNS) lymphoma, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For multiple myeloma, patient has previously received at least two prior therapies, including an immunomodulatory agent AND a proteasome inhibitor.  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# POSACONAZOLE

## Products Affected

- Posaconazole Dr

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | The requested drug will be used orally. For prophylaxis of invasive Aspergillus and Candida infections: patient weighs greater than 40 kilograms.  |
| Age Restrictions             | Treatment of Invasive Aspergillosis: 13 years of age or older, Prophylaxis of Invasive Aspergillus and Candida Infections: 2 years of age or older |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 6 months   |
| Other Criteria               | N/A  |

# PREGABALIN

## Products Affected

- Pregabalin CAPS
- Pregabalin SOLN

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Cancer-related neuropathic pain, cancer treatment-related neuropathic pain   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For the management of postherpetic neuralgia, the management of neuropathic pain associated with diabetic peripheral neuropathy: The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to gabapentin. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# PRETOMANID AET

## Products Affected

- Pretomanid

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For tuberculosis (TB), patient meets ALL of the following: 1) the requested drug is being used for treatment of pulmonary extensively drug resistant (XDR), treatment intolerant or nonresponsive multidrug resistant (MDR) tuberculosis, AND 2) the requested drug is used in combination with bedaquiline and linezolid. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# PREVYMIS

## Products Affected

- Prevymis PACK
- Prevymis TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For prophylaxis of cytomegalovirus (CMV) infection or disease in hematopoietic stem cell transplant (HSCT): 1) the patient is CMV-seropositive, AND 2) the patient is a recipient of an allogeneic HSCT. For prophylaxis of CMV disease in kidney transplant: 1) the patient is CMV-seronegative, AND 2) the patient is a high risk recipient of kidney transplant. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | 7 months  |
| Other Criteria               | N/A   |



# PULMOZYME

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## Products Affected

- Pulmozyme SOLN 2.5MG/2.5ML

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# PYZCHIVA

## Products Affected

- Pyzchiva

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# QINLOCK

## Products Affected

- Qinlock

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Gastrointestinal stromal tumor (GIST) for residual, unresectable, tumor rupture, recurrent, or progressive disease. Metastatic or unresectable cutaneous melanoma.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For residual, unresectable, tumor rupture, advanced, recurrent/metastatic, or progressive gastrointestinal stromal tumor (GIST): 1) Patient has received prior treatment with 3 or more kinase inhibitors, including imatinib OR 2) Patient has experienced disease progression following treatment with avapritinib and dasatinib OR 3) Patient has received prior treatment with imatinib and is intolerant of second-line sunitinib. For cutaneous melanoma: 1) Disease is metastatic or unresectable AND 2) Disease is positive for KIT activating mutations AND 3) Requested drug will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# QUETIAPINE XR

## Products Affected

- Quetiapine Fumarate Er

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Maintenance monotherapy treatment in bipolar I disorder, monotherapy treatment of generalized anxiety disorder, monotherapy treatment of major depressive disorder  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | <p>For all indications: If the patient is 65 years of age or older AND is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, sertraline, clonazepam, escitalopram, alprazolam, zolpidem) with the requested drug, the prescriber determined that taking multiple central nervous system (CNS) active medications is medically necessary. [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls].</p> <p>For treatment of schizophrenia: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine immediate-release, risperidone, ziprasidone. For acute treatment of manic or mixed episodes associated with bipolar I disorder or maintenance treatment of bipolar I disorder: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine immediate-release, risperidone, ziprasidone. For acute treatment of depressive episodes associated with bipolar I disorder: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: lurasidone, olanzapine, quetiapine immediate-release. For acute treatment of depressive episodes associated with bipolar II disorder: The patient experienced an inadequate treatment response or intolerance to generic quetiapine immediate-release. For adjunctive treatment of major depressive disorder (MDD): The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, olanzapine, quetiapine immediate-release.</p> |
| <b>Age Restrictions</b>             | N/A   |

|                                |           |
|--------------------------------|-----------|
| <b>Prescriber Restrictions</b> | N/A       |
| <b>Coverage Duration</b>       | Plan Year |
| <b>Other Criteria</b>          | N/A       |

# QUININE SULFATE

## Products Affected

- Quinine Sulfate CAPS 324MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.          |
| Off-Label Uses               | Babesiosis, uncomplicated Plasmodium vivax malaria.                         |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For babesiosis: the requested drug is used in combination with clindamycin. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | 1 month   |
| Other Criteria               | N/A   |

# QULIPTA

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## Products Affected

- Qulipta

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Preventive treatment of migraine, continuation: The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Initial: 3 months, Continuation: Plan Year  |
| Other Criteria               | N/A   |

# RALDESY

## Products Affected

- Raldesy

| PA Criteria                  | Criteria Details                                    |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.                       |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | The patient is unable to swallow trazodone tablets. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# REGRANEX

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## Products Affected

- Regranex

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | 20 weeks                      |
| Other Criteria               | N/A                           |

# REPATHA

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## Products Affected

- Repatha
- Repatha Pushtronex System
- Repatha Sureclick

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# RETEVMO

## Products Affected

- Retevmo

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Recurrent rearranged during transfection (RET)-rearrangement positive non-small cell lung cancer (NSCLC), brain metastases from RET fusion-positive NSCLC, Langerhans Cell Histiocytosis with a RET gene fusion, symptomatic or relapsed/refractory Erdheim-Chester Disease with a RET gene fusion, symptomatic or relapsed/refractory Rosai-Dorfman Disease with a RET gene fusion, occult primary cancer with RET gene fusion, solid tumors with RET-gene fusion for recurrent disease  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For non-small cell lung cancer (NSCLC), patient must meet all of the following: 1) The disease is recurrent, advanced or metastatic, AND 2) The tumor is rearranged during transfection (RET) fusion-positive or RET rearrangement positive. For solid tumors, patient must meet all of the following: 1) The disease is recurrent, persistent, progressive, unresectable, locally advanced, or metastatic, 2) The patient has progressed on or following prior systemic treatment or has no satisfactory alternative treatment options, AND 3) The tumor is RET fusion-positive. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# REVLIMID

## Products Affected

- Lenalidomide

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Systemic light chain amyloidosis, classical Hodgkin lymphoma, myelodysplastic syndrome without the 5q deletion cytogenetic abnormality, myelofibrosis-associated anemia, POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome, myeloproliferative neoplasms, Kaposi Sarcoma, Langerhans cell histiocytosis, Rosai-Dorfman disease, peripheral T-Cell lymphomas not otherwise specified, angioimmunoblastic T-cell lymphoma (AITL), enteropathy-associated T-cell lymphoma, monomorphic epitheliotropic intestinal T-cell lymphoma, nodal peripheral T-cell lymphoma, adult T-cell leukemia/lymphoma, hepatosplenic T-cell lymphoma, primary central nervous system (CNS) lymphoma, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), human immunodeficiency virus (HIV)-related B-cell lymphomas, monomorphic post-transplant lymphoproliferative disorder, diffuse large B-cell lymphoma, multicentric Castlemans disease, high-grade B-cell lymphomas, histologic transformation of indolent lymphoma to diffuse large B-cell lymphoma |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For myelodysplastic syndrome (MDS): patient has lower risk MDS with symptomatic anemia per the Revised International Prognostic Scoring System (IPSS-R), International Prognostic Scoring System (IPSS), or World Health organization (WHO) classification-based Prognostic Scoring System (WPSS).   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# REVUFORJ

## Products Affected

- Revuforj

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# REZLIDHIA

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## Products Affected

- Rezlidhia

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# REZUROCK

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## Products Affected

- Rezurock

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 12 years of age or older      |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# RINVOQ

## Products Affected

- Rinvoq

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | <p>For moderately to severely active rheumatoid arthritis (new starts only): Patient has experienced an inadequate treatment response, intolerance or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For active psoriatic arthritis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]).</p> <p>For moderately to severely active ulcerative colitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Humira [adalimumab], Idacio [adalimumab-aacf]). For moderately to severely active Crohn's disease (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Humira [adalimumab], Idacio [adalimumab-aacf]). For atopic dermatitis (new starts only): 1) Patient has refractory, moderate to severe disease, AND 2) Patient has had an inadequate response to treatment with at least one other systemic drug product, including biologics, or use of these therapies are inadvisable. For atopic dermatitis (continuation of therapy): Patient achieved or maintained positive clinical response. For active ankylosing spondylitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For non-radiographic axial spondyloarthritis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor.</p> |
| Age Restrictions             | Atopic dermatitis: 12 years of age or older  |



|                                |   |
|--------------------------------|---|
| <b>Prescriber Restrictions</b> | N/A   |
| <b>Coverage Duration</b>       | Atopic dermatitis (initial): 4 months, All others: Plan Year  |
| <b>Other Criteria</b>          | For active polyarticular juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). |

# RINVOQ LQ

## Products Affected

- Rinvoq Lq

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | <p>For moderately to severely active rheumatoid arthritis (new starts only): Patient has experienced an inadequate treatment response, intolerance or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For active psoriatic arthritis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]).</p> <p>For moderately to severely active ulcerative colitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Humira [adalimumab], Idacio [adalimumab-aacf]). For moderately to severely active Crohn's disease (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Humira [adalimumab], Idacio [adalimumab-aacf]). For atopic dermatitis (new starts only): 1) Patient has refractory, moderate to severe disease, AND 2) Patient has had an inadequate response to treatment with at least one other systemic drug product, including biologics, or use of these therapies are inadvisable. For atopic dermatitis (continuation of therapy): Patient achieved or maintained positive clinical response. For active ankylosing spondylitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For non-radiographic axial spondyloarthritis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor.</p> |
| Age Restrictions             | Atopic dermatitis: 12 years of age or older  |

|                                |   |
|--------------------------------|---|
| <b>Prescriber Restrictions</b> | N/A   |
| <b>Coverage Duration</b>       | Atopic dermatitis (initial): 4 months, All others: Plan Year  |
| <b>Other Criteria</b>          | For active polyarticular juvenile idiopathic arthritis (new starts only): patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). |

# ROMVIMZA

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## Products Affected

- Romvimza

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# ROZLYTREK

## Products Affected

- Rozlytrek

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Recurrent ROS1-positive non-small cell lung cancer (NSCLC), Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors, ROS1-gene fusion-positive cutaneous melanoma |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors: the disease is without a known acquired resistance mutation. For ROS1-positive non-small cell lung cancer: the patient has recurrent, advanced, or metastatic disease.          |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# RUBRACA

## Products Affected

- Rubraca

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Uterine leiomyosarcoma, pancreatic adenocarcinoma, advanced (stage II-IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For metastatic castration-resistant prostate cancer with a deleterious breast cancer susceptibility gene (BRCA) mutation (germline and/or somatic): 1) patient has been treated with androgen receptor-directed therapy, AND 2) patient has been treated with a taxane-based chemotherapy or the patient is not fit for chemotherapy, AND 3) the requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. For maintenance treatment of BRCA mutated ovarian, fallopian tube, primary peritoneal cancer: 1) the patient has advanced (stage II-IV) disease and is in complete or partial response to primary therapy, OR 2) the patient has recurrent disease and is in complete or partial response to platinum-based chemotherapy. For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy, AND 2) the patient has BRCA-altered disease. For pancreatic adenocarcinoma: 1) the patient has metastatic disease, AND 2) the patient has somatic or germline BRCA or PALB-2 mutations. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# RYBELSUS

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## Products Affected

- Rybelsus TABS 14MG, 3MG, 7MG

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# RYDAPT

## Products Affected

- Rydapt

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Relapsed or refractory acute myeloid leukemia (AML), myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FGFR1 or FLT3 rearrangements, post-induction therapy for AML, re-induction in residual disease for AML  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For acute myeloid leukemia (AML): AML is FMS-like tyrosine kinase 3 (FLT3) mutation-positive. For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and Fibroblast growth factor receptor type 1 (FGFR1) or FLT3 rearrangements: the disease is in chronic or blast phase. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |



# SAPROPTERIN

## Products Affected

- Javygtor

- Sapropterin Dihydrochloride

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For phenylketonuria (PKU): For patients who have not yet received a therapeutic trial of the requested drug, the patient's pretreatment (including before dietary management) phenylalanine level is greater than 6 mg/dL (360 micromol/L). For patients who completed a therapeutic trial of the requested drug, the patient must have experienced improvement (e.g., reduction in blood phenylalanine levels, improvement in neuropsychiatric symptoms). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Initial: 2 months, All others: Plan Year   |
| Other Criteria               | N/A  |

# SCSEMBLIX

## Products Affected

- Scemblix

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic phase or blast phase.   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For chronic myeloid leukemia (CML) in the chronic phase: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) Patient meets one of the following: A) Patient has newly diagnosed CML and has resistance or intolerance to imatinib, dasatinib, or nilotinib OR B) Patient has previously treated CML AND at least one of the prior treatments was imatinib, dasatinib, or nilotinib OR C) Patient is positive for the T315I mutation, AND 3) Patient is negative for the following mutations: A337T, P465S. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# SIGNIFOR

## Products Affected

- Signifor

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.                            |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | Prescribed by or in consultation with an endocrinologist |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# SIKLOS

## Products Affected

- Siklos

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# SILDENAFIL

## Products Affected

- Sildenafil Citrate TABS 20MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) If the request is for an adult, pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# SILDENAFIL INJ

## Products Affected

- Sildenafil INJ

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) If the request is for an adult, pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 1 month  |
| Other Criteria               | Patient was previously receiving oral Revatio or sildenafil but is now temporarily unable to take oral medications.  |

# SIRTURO

## Products Affected

- Sirturo

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | Prescribed by or in consultation with an infectious disease specialist |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# SKYRIZI

## Products Affected

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML, 600MG/10ML
- Skyrizi Pen

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |



# SOMATULINE DEPOT

## Products Affected

- Somatuline Depot

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Tumor control of neuroendocrine tumors (NETs) (including tumors of the lung, thymus, well-differentiated grade 3 NETs not of gastroenteropancreatic origin with favorable biology, and pheochromocytoma/paraganglioma)   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# SOMAVERT

## Products Affected

- Somavert

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For acromegaly, initial: 1) Patient has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range, AND 2) Patient had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy. For acromegaly, continuation of therapy: Patient's IGF-1 level has decreased or normalized since initiation of therapy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# SOTYKTU

## Products Affected

- Sotyktu

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# SPRYCEL

## Products Affected

- Dasatinib

- Sprycel

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Gastrointestinal stromal tumor (GIST), metastatic and/or widespread chondrosarcoma, recurrent chordoma, T-cell acute lymphoblastic leukemia (ALL), and Philadelphia (Ph)-like B-ALL, myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase, cutaneous melanoma   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For chronic myeloid leukemia (CML), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia (Ph) chromosome or BCR-ABL gene AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L. For acute lymphoblastic leukemia (ALL), the patient has a diagnosis of one of the following: 1) Philadelphia chromosome positive ALL, including patients who have received a hematopoietic stem cell transplant: Diagnosis that has been confirmed by detection of the Ph chromosome or BCR-ABL gene AND if patient experienced resistance to an alternative tyrosine kinase inhibitor, patient is negative for all of the following mutations: T315I/A, F317L/V/I/C, and V299L OR 2) Ph-like B-ALL with ABL-class kinase fusion OR 3) Relapsed or refractory T-cell ALL with ABL-class translocation. For gastrointestinal stromal tumor (GIST): 1) Patient meets all of the following: A) Disease is residual, unresectable, recurrent/progressive, or metastatic/tumor rupture, B) Patient has received prior therapy with avapritinib AND C) Patient is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutations. For cutaneous melanoma: 1) Disease is metastatic or unresectable, 2) Disease is positive for c-KIT activating mutations AND 3) Requested drug will be used as subsequent therapy AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy. |
| <b>Age Restrictions</b>             | N/A   |

|                                |           |
|--------------------------------|-----------|
| <b>Prescriber Restrictions</b> | N/A       |
| <b>Coverage Duration</b>       | Plan Year |
| <b>Other Criteria</b>          | N/A       |

# STELARA

## Products Affected

- Stelara

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# STIVARGA

## Products Affected

- Stivarga

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Osteosarcoma, glioblastoma, angiosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma, rhabdomyosarcoma, soft tissue sarcomas of the extremities, body wall, head and neck, appendiceal adenocarcinoma    |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For colorectal cancer: 1) The disease is advanced or metastatic, AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to Lonsurf (trifluridine/tipiracil). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# SUTENT

## Products Affected

- Sunitinib Malate

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Thyroid carcinoma (follicular, medullary, papillary, and oncocytic), soft tissue sarcoma (angiosarcoma, solitary fibrous tumor, and alveolar soft part sarcoma subtypes), recurrent chordoma, thymic carcinoma, lymphoid and/or myeloid neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase, pheochromocytoma, paraganglioma, well differentiated grade 3 neuroendocrine tumors |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For renal cell carcinoma (RCC): 1) The disease is relapsed, advanced, or stage IV OR 2) the requested drug is being used as adjuvant treatment for patients that are at high risk of recurrent RCC following nephrectomy.  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |



# SYMLIN

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## Products Affected

- Symlinpen 120
- Symlinpen 60

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# SYMPAZAN

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## Products Affected

- Sympazan

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.              |
| Off-Label Uses               | Seizures associated with Dravet syndrome  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | Seizures associated with Lennox-Gastaut syndrome (LGS): 2 years of age or older |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# TABRECTA

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## Products Affected

- Tabrecta

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Recurrent non-small cell lung cancer (NSCLC), NSCLC with high-level mesenchymal-epithelial transition (MET) amplification, central nervous system (CNS) brain metastases from MET exon-14 mutated NSCLC |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC): Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation.                                     |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

## TADALAFIL (BPH)

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### Products Affected

- Cialis TABS 5MG
- Tadalafil TABS 5MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | Erectile Dysfunction.  |
| Required Medical Information | For benign prostatic hyperplasia (BPH): the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to both of the following: 1) alpha blocker, 2) 5-alpha reductase inhibitor (5-ARI). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 26 weeks   |
| Other Criteria               | N/A  |

## TADALAFIL (PAH)

### Products Affected

- Tadalafil TABS 20MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For PAH new starts only: 1) Pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) Pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) Pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# TAFINLAR

## Products Affected

- Tafinlar

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Langerhans cell histiocytosis, Erdheim-Chester disease.   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For melanoma: 1) The tumor is positive for a BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) The requested drug will be used as a single agent or in combination with trametinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, b) adjuvant systemic therapy. For non-small cell lung cancer: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used as a single agent or in combination with trametinib. For papillary, follicular, and oncocytic thyroid carcinoma: 1) The tumor is BRAF V600E-positive, AND 2) The disease is not amenable to radioactive iodine (RAI) therapy, AND 3) the requested drug will be used in combination with trametinib. For Langerhans Cell Histiocytosis and Erdheim-Chester Disease: The disease is positive for a BRAF V600E mutation. For solid tumors: 1) The tumor is positive for a BRAF V600E mutation, AND 2) The requested drug will be used in combination with trametinib. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# TAGRISO

## Products Affected

- Tagrisso

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Sensitizing epidermal growth factor receptor (EGFR) mutation-positive recurrent non-small cell lung cancer (NSCLC), brain metastases from sensitizing EGFR mutation-positive NSCLC, leptomeningeal metastases from EGFR mutation-positive NSCLC  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For non-small cell lung cancer (NSCLC), the requested drug is used in any of the following settings: 1) The patient meets both of the following: a) patient has unresectable, metastatic, advanced, or recurrent NSCLC (including brain and/or leptomeningeal metastases from NSCLC) and b) patient has a sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease, OR 2) The patient meets both of the following: a) request is for adjuvant treatment of NSCLC following tumor resection and b) patient has EGFR mutation-positive disease. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# TALZENNA

## Products Affected

- Talzenna

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.                |
| Off-Label Uses               | Recurrent germline breast cancer susceptibility gene (BRCA)-mutated breast cancer |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# TARGRETIN TOPICAL

## Products Affected

- Bexarotene GEL

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Mycosis fungoides (MF)/Sezary syndrome (SS), chronic or smoldering adult T-cell leukemia/lymphoma (ATLL), primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# TASIGNA

## Products Affected

- Tasigna

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), gastrointestinal stromal tumor (GIST), myeloid and/or lymphoid neoplasms with eosinophilia and ABL1 rearrangement in the chronic phase or blast phase, pigmented villonodular synovitis/tenosynovial giant cell tumor, cutaneous melanoma.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For chronic myeloid leukemia (CML), including patients newly diagnosed with CML and patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If patient experienced resistance to an alternative tyrosine kinase inhibitor for CML, patient is negative for T315I, Y253H, E255K/V, and F359V/C/I mutations. For acute lymphoblastic leukemia (ALL), including patients who have received a hematopoietic stem cell transplant: 1) Diagnosis was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene, AND 2) If the patient has experienced resistance to an alternative tyrosine kinase inhibitor for ALL, patient is negative for T315I, Y253H, E255K/V, F359V/C/I and G250E mutations. For gastrointestinal stromal tumor (GIST): 1) Disease is residual, unresectable, recurrent/progressive, or metastatic/tumor rupture, AND 2) Disease has progressed on at least 2 Food and Drug Administration (FDA)-approved therapies (e.g. imatinib, sunitinib, regorafenib, ripretinib). For cutaneous melanoma: 1) Disease is metastatic or unresectable, AND 2) Disease is positive for c-KIT activating mutations, AND 3) Requested drug will be used as subsequent therapy, AND 4) Patient has had disease progression, intolerance, or risk of progression with BRAF-targeted therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |

|                       |     |
|-----------------------|-----|
| <b>Other Criteria</b> | N/A |
|-----------------------|-----|

# TAVNEOS

## Products Affected

- Tavneos

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For continuation of treatment for severe anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: the patient has experienced benefit from therapy. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# TAZAROTENE

## Products Affected

- Tazarotene CREA
- Tazarotene GEL
- Tazorac CREA 0.05%

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For plaque psoriasis, the patient meets the following criteria: 1) the patient has less than or equal to 20 percent of affected body surface area (BSA), AND 2) the patient experienced an inadequate treatment response or intolerance to at least one topical corticosteroid OR has a contraindication that would prohibit a trial of topical corticosteroids. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# TAZVERIK

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## Products Affected

- Tazverik

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | Epithelioid sarcoma: 16 years of age or older, Follicular lymphoma: 18 years of age or older |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# TECVAYLI

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## Products Affected

- Tecvayli

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# TEMAZEPAM 30MG - 65

## Products Affected

- Temazepam CAPS 30MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For short-term treatment of insomnia: 1) The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The use of this medication is potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | This Prior Authorization only applies to patients 65 years of age or older.  |



# TEPMETKO

## Products Affected

- Tepmetko

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Recurrent non-small cell lung cancer (NSCLC), NSCLC with high level mesenchymal-epithelial transition (MET) amplification, central nervous system (CNS) cancer including brain metastases and leptomeningeal metastases from MET exon-14 mutated NSCLC |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC): Tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutation.  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# TESTOSTERONE ENANTHATE INJ

## Products Affected

- Testosterone Enanthate INJ

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Gender Dysphoria  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For primary hypogonadism or hypogonadotropic hypogonadism, initial therapy: The patient has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For primary hypogonadism or hypogonadotropic hypogonadism, continuation of therapy: The patient had a confirmed low morning serum total testosterone concentration based on the reference laboratory range or current practice guidelines before starting testosterone therapy [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]. For gender dysphoria: The patient is able to make an informed decision to engage in hormone therapy. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# TETRABENAZINE

## Products Affected

- Tetrabenazine

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Tic disorders, tardive dyskinesia, hemiballismus, chorea not associated with Huntington's disease.   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For treatment of tardive dyskinesia and treatment of chorea associated with Huntington's disease: The patient has experienced an inadequate treatment response or intolerable adverse event to deutetrabenazine. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# THALOMID

## Products Affected

- Thalomid

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Myelofibrosis-associated anemia, acquired immunodeficiency syndrome (AIDS)-related aphthous stomatitis, Kaposi sarcoma, multicentric Castleman's disease, Rosai-Dorfman disease, Langerhans cell histiocytosis |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# TIBSOVO

## Products Affected

- Tibsovo

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Conventional (grades 1-3) or dedifferentiated chondrosarcoma, central nervous system (CNS) cancers (astrocytoma, oligodendroglioma)  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient has disease with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation. For acute myeloid leukemia (AML): 1) patient has newly-diagnosed AML and meets one of the following: a) 75 years of age or older, b) patient has comorbidities that preclude use of intensive induction chemotherapy, OR 2) the requested drug will be used as post-induction therapy following response to induction therapy with the requested drug, OR 3) patient has relapsed or refractory AML. For locally advanced, unresectable, resected gross residual, or metastatic cholangiocarcinoma: the requested drug will be used as subsequent treatment for progression on or after systemic treatment. For CNS cancers: 1) disease is recurrent or progressive, AND 2) patient has oligodendroglioma or astrocytoma. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# TOBI INHALER

## Products Affected

- Tobi Podhaler

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Non-cystic fibrosis bronchiectasis   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For cystic fibrosis and non-cystic fibrosis bronchiectasis: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of Pseudomonas aeruginosa infection or colonization in the airways. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# TOBRAMYCIN

## Products Affected

- Tobramycin NEBU 300MG/5ML

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Non-cystic fibrosis bronchiectasis   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For cystic fibrosis and non-cystic fibrosis bronchiectasis: 1) Pseudomonas aeruginosa is present in the patient's airway cultures, OR 2) The patient has a history of Pseudomonas aeruginosa infection or colonization in the airways. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.   |

# TOPICAL DOXEPIN

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## Products Affected

- Doxepin Hydrochloride CREA

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a topical corticosteroid or a topical calcineurin inhibitor. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 1 month  |
| Other Criteria               | N/A  |



# TOPICAL LIDOCAINE

## Products Affected

- Lidocaine OINT 5%
- Lidocaine Hydrochloride EXTERNAL SOLN

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | 1) The requested drug is being used for topical anesthesia, AND 2) If the requested drug will be used as part of a compounded product, then all the active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | 3 months  |
| Other Criteria               | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.  |

# TOPICAL TRETINOIN

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## Products Affected

- Tretinoin CREA
- Tretinoin GEL

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# TOREMIFENE

## Products Affected

- Toremifene Citrate

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | Congenital/acquired QT prolongation (long QT syndrome), uncorrected hypokalemia, or uncorrected hypomagnesemia. |
| Required Medical Information | N/A   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# TREMFYA

## Products Affected

- Tremfya

- Tremfya Induction Pack For Crohns Disease

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For moderate to severe plaque psoriasis (new starts): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# TREPROSTINIL INJ

## Products Affected

- Treprostinil

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For pulmonary arterial hypertension (World Health Organization [WHO] Group 1): PAH was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.   |

# TRIENTINE

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## Products Affected

- Trientine Hydrochloride

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# TRIKAFTA

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## Products Affected

- Trikafta

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For cystic fibrosis: The requested medication will not be used in combination with other medications containing ivacaftor. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# TRINTELLIX

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## Products Affected

- Trintellix

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For major depressive disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to ONE of the following generic products: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |



# TRULICITY

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## Products Affected

- Trulicity

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | For glycemic control in type 2 diabetes mellitus:10 years of age or older |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# TRUQAP

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## Products Affected

- Truqap

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# TRUXIMA

## Products Affected

- Truxima

| PA Criteria        | Criteria Details   |
|--------------------|--|
| Indications        | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses     | Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, extranodal marginal zone lymphoma), Burkitt lymphoma, high-grade B-cell lymphoma, histological transformation from indolent lymphomas to diffuse large B-cell lymphoma, histological transformation chronic lymphocytic leukemia (CLL)/SLL to diffuse large B-cell lymphoma, primary cutaneous B-cell lymphoma, Castleman disease, human immunodeficiency virus (HIV)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD), B-cell lymphoblastic lymphoma], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, immune checkpoint inhibitor-related toxicities, Rosai-Dorfman disease, pemphigus vulgaris, pediatric aggressive mature B-cell lymphomas (including Burkitt-like lymphoma, primary mediastinal large B-cell lymphoma), and pediatric mature B-cell acute leukemia |
| Exclusion Criteria | N/A  |

|                                     |  |
|-------------------------------------|--|
| <b>Required Medical Information</b> | <p>For moderately to severely active rheumatoid arthritis (new starts only):</p> <p>1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD.</p> <p>Hematologic malignancies must be CD20-positive. For multiple sclerosis:</p> <p>1) patient has a diagnosis of relapsing remitting multiple sclerosis, AND 2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year   |
| <b>Other Criteria</b>               | N/A  |

# TUKYSA

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## Products Affected

- Tukysa

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Recurrent human epidermal growth factor receptor 2 (HER2)-positive breast cancer   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For colorectal cancer (including appendiceal adenocarcinoma): 1) the patient has advanced, unresectable, or metastatic disease, AND 2) the patient has human epidermal growth factor receptor 2 (HER2)-positive disease, AND 3) the patient has RAS wild-type disease, AND 4) the requested drug will be used in combination with trastuzumab, AND 5) the patient has not previously been treated with a HER2 inhibitor. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# TURALIO

## Products Affected

- Turalio CAPS 125MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Langerhans cell histiocytosis, Erdheim-Chester disease, Rosai-Dorfman disease   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For Langerhans cell histiocytosis: 1) disease has colony stimulating factor 1 receptor (CSF1R) mutation. For Erdheim-Chester disease and Rosai-Dorfman disease: 1) disease has CSF1R mutation AND patient has any of the following: a) symptomatic disease OR b) relapsed/refractory disease. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# TYENNE

## Products Affected

- Tyenne

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Castleman's disease, systemic sclerosis-associated interstitial lung disease  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For moderately to severely active rheumatoid arthritis (new starts only):<br>1) Patient has experienced an inadequate treatment response, intolerance or contraindication to methotrexate (MTX) OR 2) Patient has experienced an inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# UBRELVY

## Products Affected

- Ubrelvy

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For acute treatment of migraine: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to at least one triptan 5-HT1 receptor agonist. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# VALCHLOR

## Products Affected

- Valchlor

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Chronic or smoldering adult T-cell leukemia/lymphoma (ATLL), Stage 2 or higher mycosis fungoides (MF)/Sezary syndrome (SS), primary cutaneous marginal zone lymphoma, primary cutaneous follicle center lymphoma, CD30-positive lymphomatoid papulosis (LyP), unifocal Langerhans cell histiocytosis (LCH) with isolated skin disease |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# VALTOCO

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## Products Affected

- Valtoco 10 Mg Dose
- Valtoco 15 Mg Dose
- Valtoco 20 Mg Dose
- Valtoco 5 Mg Dose

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 6 years of age or older       |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

## VANFLYTA

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### Products Affected

- Vanflyta

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Relapsed or refractory acute myeloid leukemia  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For acute myeloid leukemia (AML): AML is FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (ITD)-positive. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# VELSIPITY

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## Products Affected

- Velsipity

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# VENCLEXTA

## Products Affected

- Venclexta

- Venclexta Starting Pack

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Mantle cell lymphoma, blastic plasmacytoid dendritic cell neoplasm (BPDCN), multiple myeloma, relapsed or refractory acute myeloid leukemia (AML), Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, relapsed or refractory systemic light chain amyloidosis with translocation t(11:14), accelerated or blast phase myeloproliferative neoplasms, B-cell acute lymphoblastic leukemia/T-cell acute lymphoblastic leukemia (B-ALL/T-ALL), hairy cell leukemia   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For acute myeloid leukemia (AML): 1) patient has newly-diagnosed AML and meets one of the following: a) 75 years of age or older, b) patient has comorbidities that preclude use of intensive induction chemotherapy, OR 2) patient has poor/adverse risk disease and is a candidate for intensive induction therapy, OR 3) patient has relapsed or refractory AML. For blastic plasmacytoid dendritic cell neoplasm (BPDCN): 1) patient has systemic disease being treated with palliative intent, OR 2) patient has relapsed or refractory disease. For multiple myeloma: 1) the disease is relapsed or progressive, AND 2) the requested drug will be used in combination with dexamethasone, AND 3) patient has t(11:14) translocation. For Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma: 1) patient has previously treated disease that did not respond to primary therapy, OR 2) patient has progressive or relapsed disease. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Plan Year   |
| <b>Other Criteria</b>               | N/A   |

# VEOZAH

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## Products Affected

- Veozah

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# VERQUVO

## Products Affected

- Verquvo

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For symptomatic chronic heart failure: the patient has a left ventricular ejection fraction (LVEF) less than 45 percent. For initial therapy, the patient meets ANY of the following: 1) hospitalization for heart failure within the past 6 months OR 2) use of outpatient intravenous diuretics for heart failure within the past 3 months. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# VERSACLOZ

## Products Affected

- Versacloz

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For the treatment of a severely ill patient with schizophrenia who failed to respond adequately to standard antipsychotic treatment (i.e., treatment-resistant schizophrenia): 1) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# VERZENIO

## Products Affected

- Verzenio

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | <p>Recurrent hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer in combination with fulvestrant or an aromatase inhibitor, or as a single agent if progression on prior endocrine therapy and prior chemotherapy in the metastatic setting.</p> <p>Endometrial cancer, in combination with letrozole for estrogen receptor positive tumor.</p> |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# VIGABATRIN

## Products Affected

- Vigabatrin
- Vigadrone
- Vigpoder

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For complex partial seizures (i.e., focal impaired awareness seizures): patient has experienced an inadequate treatment response to at least two antiepileptic drugs for complex partial seizures (i.e., focal impaired awareness seizures). |
| Age Restrictions             | Infantile Spasms: 1 month to 2 years of age. Complex partial seizures (i.e., focal impaired awareness seizures): 2 years of age or older   |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# VIGAFYDE

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## Products Affected

- Vigafyde

| PA Criteria                  | Criteria Details                            |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.               |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | N/A   |
| Age Restrictions             | Infantile Spasms: 1 month to 2 years of age |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year                                   |
| Other Criteria               | N/A   |

# VITRAKVI

## Products Affected

- Vitrakvi

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Non-metastatic neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, first-line treatment of NTRK gene fusion-positive solid tumors. |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For all neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive solid tumors, the disease is without a known acquired resistance mutation.           |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# VIZIMPRO

## Products Affected

- Vizimpro

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Recurrent non-small cell lung cancer (NSCLC)  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For non-small cell lung cancer (NSCLC): 1) the disease is recurrent, advanced, or metastatic, and 2) the patient has sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# VONJO

## Products Affected

- Vonjo

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses               | Accelerated or blast phase myeloproliferative neoplasms            |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# VORANIGO

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## Products Affected

- Voranigo

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# VORICONAZOLE

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## Products Affected

- Voriconazole INJ
- Voriconazole SUSR

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.                                    |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | The patient will use the requested drug orally or intravenously. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 6 months   |
| Other Criteria               | N/A  |



# VOSEVI

## Products Affected

- Vosevi

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | Decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C)  |
| Required Medical Information | For hepatitis C: Infection confirmed by presence of HCV RNA in the serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated substitutions where applicable, transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) treatment guidelines. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Criteria will be applied consistent with current AASLD-IDSA guidance.   |
| Other Criteria               | N/A   |

# VOTRIENT

## Products Affected

- Pazopanib Hydrochloride

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Thyroid carcinoma (follicular, papillary, oncocytic, or medullary), uterine sarcoma, chondrosarcoma, gastrointestinal stromal tumor  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For renal cell carcinoma: 1) the disease is advanced, relapsed, or stage IV, OR 2) the requested drug will be used for von Hippel-Lindau (VHL)-associated renal cell carcinoma. For gastrointestinal stromal tumor (GIST): 1) the disease is residual, unresectable, recurrent, or metastatic/tumor rupture AND 2) the patient meets one of the following: a) the disease has progressed after at least two FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib, ripretinib), b) the disease is succinate dehydrogenase (SDH)-deficient GIST. For soft tissue sarcoma (STS): the patient does not have an adipocytic soft tissue sarcoma. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# VOWST

## Products Affected

- Vowst

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For the prevention of recurrence of Clostridioides difficile infection (CDI): 1) The diagnosis of CDI has been confirmed by a positive stool test for C. difficile toxin, AND 2) The requested drug will be administered at least 48 hours after the last dose of antibiotics used for the treatment of recurrent CDI. |
| Age Restrictions             | 18 years of age or older   |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 1 month  |
| Other Criteria               | N/A  |

# WELIREG

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## Products Affected

- Welireg

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# XALKORI

## Products Affected

- Xalkori

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Recurrent non-small cell lung cancer (NSCLC), NSCLC with high-level MET amplification or MET exon 14 skipping mutation, symptomatic or relapsed/refractory anaplastic lymphoma kinase (ALK)-fusion positive Erdheim-Chester Disease, symptomatic or relapsed/refractory (ALK)-fusion positive Rosai-Dorfman Disease, (ALK)-fusion positive Langerhans Cell Histiocytosis, metastatic or unresectable ROS1 gene fusion positive cutaneous melanoma.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For non-small cell lung cancer (NSCLC), the requested drug is used in any of the following settings: 1) the patient has recurrent, advanced or metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib), OR 3) the patient has recurrent, advanced or metastatic ROS-1 positive NSCLC, OR 4) the patient has NSCLC with high-level MET amplification or MET exon 14 skipping mutation. For inflammatory myofibroblastic tumor (IMT), the disease is ALK-positive. For anaplastic large cell lymphoma (ALCL): 1) the disease is relapsed or refractory, AND 2) the disease is ALK-positive. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# XDEMVI

## Products Affected

- Xdemvy

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# XELJANZ

## Products Affected

- Xeljanz

- Xeljanz Xr

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For moderately to severely active rheumatoid arthritis (new starts only): Patient has experienced an inadequate treatment response, intolerance or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For active psoriatic arthritis (new starts only): 1) Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one TNF inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]) AND 2) the requested drug is used in combination with a nonbiologic DMARD. For active ankylosing spondylitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). For moderately to severely active ulcerative colitis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Humira [adalimumab], Idacio [adalimumab-aacf]). For active polyarticular course juvenile idiopathic arthritis (new starts only): Patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab-aacf, Enbrel [etanercept], Humira [adalimumab], Idacio [adalimumab-aacf]). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |

|                       |     |
|-----------------------|-----|
| <b>Other Criteria</b> | N/A |
|-----------------------|-----|



# XERMELO

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## Products Affected

- Xermelo

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | N/A                           |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# XGEVA

## Products Affected

- Xgeva

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For hypercalcemia of malignancy: condition is refractory to intravenous (IV) bisphosphonate therapy or there is a clinical reason to avoid IV bisphosphonate therapy.  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual. |

# XHANCE

## Products Affected

- Xhance

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 18 years of age or older      |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

# XIFAXAN

## Products Affected

- Xifaxan TABS 550MG

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Small intestinal bacterial overgrowth syndrome (SIBO)  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For irritable bowel syndrome with diarrhea (IBS-D): 1) The patient has not previously received treatment with the requested drug, OR 2) The patient has previously received treatment with the requested drug, AND a) the patient is experiencing a recurrence of symptoms, AND b) the patient has not already received an initial 14-day course of treatment and two additional 14-day courses of treatment with the requested drug. For small intestinal bacterial overgrowth (SIBO): 1) the patient is experiencing a recurrence after completing a successful course of treatment with the requested drug OR 2) diagnosis has been confirmed by one of the following: a) quantitative culture of upper gut aspirate, b) breath testing (e.g., lactulose hydrogen or glucose hydrogen breath test). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Reduction in risk of overt HE recurrence: 6 months, IBS-D and SIBO: 14 days  |
| <b>Other Criteria</b>               | N/A  |

# XOLAIR

## Products Affected

- Xolair

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For moderate to severe persistent asthma, initial therapy (tx): 1) Patient (pt) has a positive skin test (or blood test) to at least one perennial aeroallergen, 2) Pt has baseline immunoglobulin E (IgE) level greater than or equal to 30 international units per milliliter (IU/mL), AND 3) Pt has inadequate asthma control despite current tx with both of the following medications: a) Medium-to-high-dose inhaled corticosteroid, AND b) Additional controller (i.e., long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless pt has an intolerance or contraindication to such therapies. For moderate to severe persistent asthma, continuation of tx (COT): Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms (sx) and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For chronic spontaneous urticaria (CSU), initial tx: 1) Pt has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1 (IL-1)-associated urticarial syndromes (e.g., auto-inflammatory disorders, urticarial vasculitis), 2) Pt has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks, AND 3) Pt remains symptomatic despite H1 antihistamine treatment. For CSU, COT: Pt has experienced a benefit (e.g., improved sx) since initiation of tx. For chronic rhinosinusitis with nasal polyps (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) Pt has experienced inadequate treatment response to Xhance (fluticasone). For IgE-mediated food allergy, initial tx: Pt has baseline IgE level greater than or equal to 30 IU/mL. For IgE-mediated food allergy, COT: Pt has experienced a benefit as evidenced by a decrease in hypersensitivity (e.g., moderate to severe skin, respiratory or gastrointestinal sx) to food allergen. |
| Age Restrictions             | CSU: 12 years of age or older. Asthma: 6 years of age or older. CRSwNP: 18 years of age or older. IgE-mediated food allergy: 1 year of age or older  |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | N/A  |
| <b>Coverage Duration</b>       | CSU initial: 6 months, All others: Plan Year |
| <b>Other Criteria</b>          | N/A  |

# XOSPATA

## Products Affected

- Xospata

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| Off-Label Uses               | Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement   |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FMS-like tyrosine kinase 3 (FLT3) rearrangement: the disease is in chronic or blast phase. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# XPOVIO

## Products Affected

- Xpovio
- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Twice Weekly

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma, Human Immunodeficiency Virus (HIV)-related B-cell lymphoma, high-grade B-cell lymphoma, post-transplant lymphoproliferative disorders |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For multiple myeloma: Patient must have been treated with at least one prior therapy. For B-cell lymphomas: Patient must have been treated with at least two lines of systemic therapy.                                 |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |



# XTANDI

## Products Affected

- Xtandi

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For the treatment of castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer: The requested drug will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or after bilateral orchiectomy. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# XYREM

## Products Affected

- Sodium Oxybate

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For the treatment of excessive daytime sleepiness in a patient with narcolepsy, initial request: 1) The diagnosis has been confirmed by sleep lab evaluation, AND 2) The patient meets one of the following criteria: a) if the patient is 17 years of age or younger, the patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate), OR has a contraindication that would prohibit a trial of central nervous system (CNS) stimulant drugs (e.g., amphetamine, dextroamphetamine, methylphenidate), b) If the patient is 18 years of age or older, the patient has experienced an inadequate treatment response or intolerance to at least one central nervous system (CNS) wakefulness promoting drug (e.g., armodafinil, modafinil), OR has a contraindication that would prohibit a trial of central nervous system (CNS) wakefulness promoting drugs (e.g., armodafinil, modafinil). For the treatment of cataplexy in a patient with narcolepsy, initial request: The diagnosis has been confirmed by sleep lab evaluation. If the request is for a continuation of therapy, then the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy. |
| Age Restrictions             | 7 years of age or older   |
| Prescriber Restrictions      | Prescribed by or in consultation with a sleep disorder specialist or neurologist  |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# YESINTEK

## Products Affected

- Yesintek

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) patient meets any of the following: a) patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the body surface area or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |

# ZARXIO

## Products Affected

- Zarxio

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| <b>Off-Label Uses</b>               | Neutropenia in myelodysplastic syndromes (MDS), agranulocytosis, neutropenia in aplastic anemia, human immunodeficiency virus (HIV)-related neutropenia   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | If receiving chemotherapy, the requested drug will be administered at least 24 hours after chemotherapy. For prophylaxis or treatment of myelosuppressive chemotherapy-induced febrile neutropenia (FN) patient must meet both of the following: 1) Patient has a solid tumor or non-myeloid cancer, AND 2) Patient has received, is currently receiving, or will be receiving treatment with myelosuppressive anti-cancer therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 6 months  |
| <b>Other Criteria</b>               | N/A   |

## ZEJULA

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### Products Affected

- Zejula TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Uterine leiomyosarcoma  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For uterine leiomyosarcoma: 1) the requested drug is used as second-line therapy AND 2) the patient has BRCA-altered disease. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ZELBORAF

## Products Affected

- Zelboraf

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Non-small cell lung cancer, hairy cell leukemia, central nervous system cancer (i.e., glioma, glioblastoma, pediatric diffuse high-grade glioma), adjuvant systemic therapy for cutaneous melanoma, Langerhans cell histiocytosis.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For central nervous system (CNS) cancer (i.e., glioma, astrocytoma, glioblastoma, pediatric diffuse high-grade glioma): 1) The tumor is positive for BRAF V600E mutation, AND 2) The requested drug will be used in combination with cobimetinib OR the requested drug is being used for the treatment of pediatric diffuse high-grade glioma. For melanoma: 1) The tumor is positive for BRAF V600 activating mutation (e.g., V600E or V600K), AND 2) the requested drug will be used as a single agent, or in combination with cobimetinib, AND 3) The requested drug will be used for either of the following: a) unresectable, limited resectable, or metastatic disease, or b) adjuvant systemic therapy. For Erdheim-Chester Disease and Langerhans Cell Histiocytosis: Tumor is positive for BRAF V600 mutation. For non-small cell lung cancer: 1) The tumor is positive for the BRAF V600E mutation, AND 2) The patient has recurrent, advanced, or metastatic disease. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# ZIRABEV

## Products Affected

- Zirabev

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Ampullary adenocarcinoma, appendiceal adenocarcinoma, breast cancer, central nervous system (CNS) cancers (including pediatric diffuse high-grade gliomas), pleural mesothelioma, peritoneal mesothelioma, pericardial mesothelioma, tunica vaginalis testis mesothelioma, soft tissue sarcomas, uterine neoplasms, endometrial carcinoma, vulvar cancers, small bowel adenocarcinoma, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.   |

# ZOLINZA

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## Products Affected

- Zolinza

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications. |
| Off-Label Uses               | Mycosis fungoides (MF)/Sezary syndrome (SS)                        |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Plan Year  |
| Other Criteria               | N/A  |



# ZONISADE

## Products Affected

- Zonisade

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For adjunctive treatment of partial-onset seizures (i.e., focal-onset seizures): 1) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to a generic anticonvulsant AND the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to any of the following: Aptiom, Xcopri, Spritam OR 2) The patient has difficulty swallowing solid oral dosage forms (e.g., tablets, capsules). |
| Age Restrictions             | 16 years of age or older  |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

## ZTALMY

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### Products Affected

- Ztalmy

| PA Criteria                  | Criteria Details              |
|------------------------------|-------------------------------|
| Indications                  | All FDA-approved Indications. |
| Off-Label Uses               | N/A                           |
| Exclusion Criteria           | N/A                           |
| Required Medical Information | N/A                           |
| Age Restrictions             | 2 years of age or older       |
| Prescriber Restrictions      | N/A                           |
| Coverage Duration            | Plan Year                     |
| Other Criteria               | N/A                           |

## ZURZUVAE

### Products Affected

- Zurzuvae

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For the treatment of postpartum depression (PPD): diagnosis was confirmed using standardized rating scales that reliably measure depressive symptoms (e.g., Hamilton Depression Rating Scale [HDRS], Edinburgh Postnatal Depression Scale [EPDS], Patient Health Questionnaire 9 [PHQ9], Montgomery-Asberg Depression Rating Scale [MADRS], Beck's Depression Inventory [BDI], etc.). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | 1 month   |
| Other Criteria               | N/A   |

## ZYDELIG

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### Products Affected

- Zydelig

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications, Some Medically accepted Indications.  |
| Off-Label Uses               | Small lymphocytic lymphoma (SLL)  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | For chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL): the requested drug is used as second-line or subsequent therapy. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

# ZYKADIA

## Products Affected

- Zykadia TABS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All FDA-approved Indications, Some Medically accepted Indications.   |
| <b>Off-Label Uses</b>               | Recurrent anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), recurrent, advanced, or metastatic ROS1-positive NSCLC, Erdheim-Chester Disease (ECD) with ALK-fusion, inflammatory myofibroblastic tumor (IMT), brain metastases from NSCLC, relapsed or refractory ALK-positive anaplastic large cell lymphoma (ALCL)  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For non-small cell lung cancer (NSCLC): 1) the patient has recurrent, advanced, or metastatic anaplastic lymphoma kinase (ALK)-positive AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following products: Alecensa (alectinib) or Alunbrig (brigatinib) OR 3) ROS1-positive disease. For inflammatory myofibroblastic tumor: the disease is ALK-positive. For brain metastases from NSCLC: the patient has ALK-positive NSCLC. For anaplastic large cell lymphoma (ALCL): the patient has relapsed or refractory ALK-positive disease. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Plan Year  |
| <b>Other Criteria</b>               | N/A  |

# ZYPREXA RELPREVV

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## Products Affected

- Zyprexa Relprevv

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All FDA-approved Indications.                           |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Tolerability with oral olanzapine has been established. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | Plan Year   |
| Other Criteria               | N/A   |

## PART B VERSUS PART D

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### Products Affected

- Abelcet
- Acetylcysteine INHALATION SOLN
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Aprepitant CAPS
- Astagraf XL
- Azathioprine INJ
- Azathioprine TABS 50MG
- Budesonide SUSP
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix 6/5
- Clinimix 8/10
- Clinimix 8/14
- Clinisol Sf 15%
- Clinolipid
- Cromolyn Sodium NEBU
- Cyclosporine CAPS
- Cyclosporine INJ
- Cyclosporine Modified
- Dextrose 50%
- Dextrose 70%
- Emend SUSR
- Engerix-b
- Epoprostenol Sodium
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Fiasp Pumpcart
- Gamastan
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Granisetron Hydrochloride TABS
- Heplisav-b
- Humulin R U-500 (concentrated)
- Hydromorphone Hydrochloride INJ 0.25MG/0.5ML
- Imovax Rabies (h.d.c.v.)
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Isolyte-s INJ 27MEQ/L; 98MEQ/L; 23MEQ/L; 3MEQ/L; 5MEQ/L; 140MEQ/L
- Isolyte-s Ph 7.4
- Jynneos
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- Levalbuterol Hydrochloride NEBU 0.63MG/3ML
- Methylprednisolone TABS
- Methylprednisolone Acetate INJ 40MG/ML, 80MG/ML
- Methylprednisolone Sodium Succinate
- Methylprednisolone Sodiumsuccinate INJ 40MG
- Morphine Sulfate INJ 0.5MG/ML, 10MG/ML, 1MG/ML, 2MG/ML, 4MG/ML, 50MG/ML, 5MG/ML, 8MG/ML
- Morphine Sulfate/sodium Chloride INJ 1MG/ML
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil INJ
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nulojix
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hcl TABS 24MG
- Ondansetron Hydrochloride TABS
- Ondansetron Odt TBP 4MG, 8MG
- Pentamidine Isethionate INHALATION SOLR

- Plenamine INJ 147.4MEQ/L;  
2.17GM/100ML; 1.47GM/100ML;  
434MG/100ML; 749MG/100ML;  
1.04GM/100ML; 894MG/100ML;  
749MG/100ML; 1.04GM/100ML;  
1.18GM/100ML; 749MG/100ML;  
1.04GM/100ML; 894MG/100ML;  
592MG/100ML; 749MG/100ML;  
250MG/100ML; 39MG/100ML;  
960MG/100ML
- Prednisolone SOLN
- Prednisolone Sodium Phosphate ORAL  
SOLN 10MG/5ML, 15MG/5ML,  
20MG/5ML, 25MG/5ML, 5MG/5ML
- Prednisone SOLN
- Prednisone TABS 10MG, 1MG,  
2.5MG, 20MG, 50MG, 5MG
- Prednisone Intensol
- Premasol INJ 52MEQ/L;  
1760MG/100ML; 880MG/100ML;  
34MEQ/L; 1760MG/100ML;  
372MG/100ML; 406MG/100ML;  
526MG/100ML; 492MG/100ML;  
492MG/100ML; 526MG/100ML;  
356MG/100ML; 356MG/100ML;  
390MG/100ML; 34MG/100ML;  
152MG/100ML
- Prograf PACK
- Prosol
- Rabavert
- Recombivax Hb
- Sandimmune SOLN
- Sirolimus SOLN
- Sirolimus TABS
- Tacrolimus CAPS
- Tpn Electrolytes INJ 29.5MEQ/20ML;  
4.5MEQ/20ML; 35MEQ/20ML;  
5MEQ/20ML; 20MEQ/20ML;  
35MEQ/20ML
- Travasol INJ 52MEQ/L;  
1760MG/100ML; 880MG/100ML;  
34MEQ/L; 1760MG/100ML;  
372MG/100ML; 406MG/100ML;  
526MG/100ML; 492MG/100ML;  
492MG/100ML; 526MG/100ML;  
356MG/100ML; 500MG/100ML;  
356MG/100ML; 390MG/100ML;  
34MG/100ML; 152MG/100ML
- Trophamine INJ 0.54GM/100ML;  
1.2GM/100ML; 0.32GM/100ML; 0; 0;  
0.5GM/100ML; 0.36GM/100ML;  
0.48GM/100ML; 0.82GM/100ML;  
1.4GM/100ML; 1.2GM/100ML;  
0.34GM/100ML; 0.48GM/100ML;  
0.68GM/100ML; 0.38GM/100ML;  
5MEQ/L; 0.025GM/100ML;  
0.42GM/100ML; 0.2GM/100ML;  
0.24GM/100ML; 0.78GM/100ML

## Details

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.



# INDEX

## A

|   |     |
|---|-----|
| Abelcet .....   | 359 |
| Abiraterone.....  | 1   |
| Abiraterone Acetate.....  | 1   |
| Abirtega.....   | 1   |
| Accutane.....   | 154 |
| Acetylcysteine .....  | 359 |
| Acitretin.....  | 2   |
| Actimmune .....   | 3   |
| Acyclovir Sodium .....  | 359 |
| Adalimumab-aacf (2 Pen) .....                                   | 138 |
| Adalimumab-aacf (2 Syringe).....                                | 138 |
| Adalimumab-aacf Starter Pack/cd/uc/hs (6 Pen)<br>.....          | 138 |
| Adalimumab-aacf Starter Pack/psoriasis/uveitis (4<br>Pen) ..... | 138 |
| Aimovig.....  | 4   |
| Akeega.....   | 5   |
| Albuterol Sulfate .....   | 359 |
| Alcohol Prep Pads .....   | 151 |
| Alecensa .....  | 6   |
| Alosetron .....   | 7   |
| Alosetron Hydrochloride.....                                    | 7   |
| Alpha1-proteinase Inhibitor .....                               | 8   |
| Alunbrig .....  | 9   |
| Alvaiz .....  | 10  |
| Ambrisentan .....   | 12  |
| Amitriptyline Hcl .....   | 127 |
| Amitriptyline Hydrochloride.....                                | 127 |
| Amnesteem.....  | 154 |
| Amphotericin B.....   | 359 |
| Amphotericin B Liposome .....                                   | 359 |
| Aprepitant.....   | 359 |
| Arcalyst .....  | 13  |
| Arikayce .....  | 14  |
| Armodafinil .....   | 15  |
| Asparlas.....   | 16  |

|                                       |     |
|---------------------------------------|-----|
| Astagraf XL .....                     | 359 |
| Aubagio.....                          | 17  |
| Augtyro .....                         | 18  |
| Austedo .....                         | 19  |
| Austedo Xr.....                       | 19  |
| Austedo Xr Patient Titration Kit..... | 19  |
| Auvelity.....                         | 20  |
| Ayvakit.....                          | 21  |
| Azathioprine.....                     | 359 |

## B

|  |         |
|--|---------|
| Bafiertam.....   | 22      |
| Balversa.....  | 23      |
| Banzel .....   | 24      |
| Bd Insulin Syringe Safetyglide/1ml/29g X 1/2..             | 151     |
| B-d Insulin Syringe Ultrafine Ii/0.3ml/31g X 5/16<br>..... | 151     |
| Bd Insulin Syringe Ultra-fine/0.5ml/30g X<br>12.7mm .....  | 151     |
| Bd Insulin Syringe Ultra-fine/1ml/31g X 8mm .              | 151     |
| Bd Pen Needle/original/ultra-fine/29g X 12.7mm<br>.....    | 151     |
| Bd Veo Insulin Syringe Ultra-fine/0.3ml/31g X<br>6mm ..... | 151     |
| Benlysta.....  | 25      |
| Benzotropine Mesylate .....                                | 121     |
| Berinert .....   | 26      |
| Besremi .....  | 27      |
| Betaseron.....   | 28      |
| Bexarotene .....   | 29, 281 |
| Bosentan.....  | 30      |
| Bosulif.....   | 31      |
| Braftovi .....   | 32      |
| Briviact.....  | 33, 34  |
| Briviact Inj .....   | 34      |
| Bronchitol .....   | 35      |
| Brukina .....  | 36      |
| Budesonide.....  | 359     |

|                           |        |
|---------------------------|--------|
| Buprenorphine .....       | 37, 38 |
| Buprenorphine Hcl .....   | 37     |
| Buprenorphine Patch ..... | 38     |

## C

|  |     |
|--|-----|
| Cabometyx .....                                | 39  |
| Calcipotriene .....                            | 40  |
| Calcipotriene/betamethasone Dipropionate ..... | 40  |
| Calcitrene .....                               | 40  |
| Calcitriol.....                                | 40  |
| Calquence .....                                | 41  |
| Caprelsa .....                                 | 42  |
| Carac.....                                     | 43  |
| Carbaglu .....                                 | 44  |
| Carbinoxamine Maleate .....                    | 128 |
| Carglumic Acid .....                           | 44  |
| Cayston.....                                   | 45  |
| Cerdelga .....                                 | 46  |
| Chantix Aet .....                              | 47  |
| Chlordiazepoxide - 65 .....                    | 48  |
| Chlordiazepoxide Hcl.....                      | 48  |
| Chlordiazepoxide Hydrochloride .....           | 48  |
| Chlordiazepoxide/amitriptyline.....            | 117 |
| Chlorzoxazone.....                             | 131 |
| Cialis .....                                   | 276 |
| Claravis.....                                  | 154 |
| Clemastine Fumarate.....                       | 129 |
| Clemasz .....                                  | 129 |
| Clinimix 4.25%/dextrose 10% .....              | 359 |
| Clinimix 4.25%/dextrose 5% .....               | 359 |
| Clinimix 5%/dextrose 15% .....                 | 359 |
| Clinimix 5%/dextrose 20% .....                 | 359 |
| Clinimix 6/5 .....                             | 359 |
| Clinimix 8/10 .....                            | 359 |
| Clinimix 8/14 .....                            | 359 |
| Clinisol Sf 15% .....                          | 359 |
| Clinolipid.....                                | 359 |
| Clobazam.....                                  | 49  |
| Clomipramine.....                              | 50  |
| Clomipramine Hydrochloride .....               | 50  |
| Clorazepate.....                               | 51  |
| Clorazepate Dipotassium.....                   | 51  |
| Clozapine Odt.....                             | 52  |
| Cobenfy .....                                  | 53  |
| Cobenfy Starter Pack.....                      | 53  |

|                                     |     |
|-------------------------------------|-----|
| Colistimethate Sodium.....          | 54  |
| Coly-mycin .....                    | 54  |
| Cometriq .....                      | 55  |
| Copiktra.....                       | 56  |
| Cosentyx .....                      | 57  |
| Cosentyx Sensoready Pen .....       | 57  |
| Cosentyx Unoready.....              | 57  |
| Cotellic.....                       | 59  |
| Cromolyn Sodium.....                | 359 |
| Curity Gauze Pads 2.....            | 151 |
| Cyclobenzaprine Hydrochloride ..... | 131 |
| Cyclophosphamide.....               | 60  |
| Cyclophosphamide Oral.....          | 60  |
| Cyclosporine .....                  | 359 |
| Cyclosporine Modified .....         | 359 |
| Cyproheptadine Hcl .....            | 122 |
| Cyproheptadine Hydrochloride.....   | 122 |
| Cystagon .....                      | 61  |
| Cystaran .....                      | 62  |

## D

|                                 |         |
|---------------------------------|---------|
| Dalfampridine .....             | 63      |
| Dalfampridine Er .....          | 63      |
| Danziten .....                  | 64      |
| Daraprim .....                  | 65      |
| Dasatinib .....                 | 268     |
| Daurismo.....                   | 66      |
| Deferasirox.....                | 67      |
| Demser .....                    | 68      |
| Desipramine Hydrochloride.....  | 127     |
| Dextrose 50%.....               | 359     |
| Dextrose 70%.....               | 359     |
| Dhe Nasal.....                  | 69      |
| Diacomit.....                   | 70      |
| Diazepam .....                  | 71      |
| Diazepam Aet.....               | 71      |
| Diazepam Intensol .....         | 71      |
| Dicyclomine Hcl .....           | 117     |
| Dicyclomine Hydrochloride.....  | 117     |
| Dihydroergotamine Mesylate..... | 69, 117 |
| Dipyridamole .....              | 117     |
| Disopyramide Phosphate .....    | 117     |
| Doptelet.....                   | 72      |
| Doptelet Aet.....               | 72      |
| Doxepin Hcl .....               | 123     |

|                            |          |
|----------------------------|----------|
| Doxepin Hydrochloride..... | 123, 296 |
| Doxycycline .....          | 216      |
| Drizalma .....             | 73       |
| Drizalma Sprinkle .....    | 73       |
| Dronabinol.....            | 74       |
| Droxidopa.....             | 200      |
| Dupixent.....              | 75       |

## **E**

|                                  |         |
|----------------------------------|---------|
| Eligard .....                    | 77      |
| Emend.....                       | 359     |
| Emsam .....                      | 78      |
| Enbrel .....                     | 89      |
| Enbrel Mini .....                | 89      |
| Enbrel Sureclick .....           | 89      |
| Endari .....                     | 79      |
| Engerix-b .....                  | 359     |
| Enstilar .....                   | 40      |
| Epclusa .....                    | 80      |
| Epidiolex .....                  | 81      |
| Epo .....                        | 82      |
| Epoprostenol Sodium .....        | 359     |
| Eprontia .....                   | 83      |
| Ergotamine .....                 | 84      |
| Ergotamine Tartrate/cafeine..... | 84      |
| Erivedge .....                   | 85      |
| Erleada.....                     | 86      |
| Erlotinib.....                   | 87      |
| Erlotinib Hydrochloride .....    | 87      |
| Esbriet.....                     | 88      |
| Eszopiclone .....                | 119     |
| Etanercept.....                  | 89      |
| Everolimus .....                 | 91, 359 |
| Exkivity .....                   | 93      |

## **F**

|  |     |
|--|-----|
| Fanapt.....                              | 94  |
| Fanapt Titration Pack .....              | 94  |
| Fasenra .....                            | 95  |
| Fasenra Pen .....                        | 95  |
| Fentanyl.....                            | 96  |
| Fentanyl Citrate Oral Transmucosal ..... | 217 |
| Fentanyl Patch .....                     | 96  |
| Fetzima.....                             | 97  |
| Fetzima Titration Pack .....             | 97  |

|                               |     |
|-------------------------------|-----|
| Fiasp Pumpcart.....           | 359 |
| Fingolimod Hydrochloride..... | 108 |
| Fintepla .....                | 98  |
| Firmagon .....                | 99  |
| Flucytosine.....              | 100 |
| Fluorouracil.....             | 43  |
| Forteo .....                  | 101 |
| Fotivda .....                 | 103 |
| Fruzaqla.....                 | 104 |
| Fycompa.....                  | 105 |

## **G**

|                                   |     |
|-----------------------------------|-----|
| Gamastan.....                     | 359 |
| Gammaked .....                    | 158 |
| Gamunex-c .....                   | 158 |
| Ganciclovir.....                  | 359 |
| Gattex .....                      | 106 |
| Gavreto.....                      | 107 |
| Gefitinib .....                   | 153 |
| Gengraf .....                     | 359 |
| Genotropin .....                  | 112 |
| Genotropin Miniquick.....         | 112 |
| Gilenya.....                      | 108 |
| Gilotrif.....                     | 109 |
| Glatiramer .....                  | 110 |
| Glatiramer Acetate .....          | 110 |
| Glatopa.....                      | 110 |
| Gomekli.....                      | 111 |
| Granisetron Hydrochloride .....   | 359 |
| Growth Hormone .....              | 112 |
| Guanfacine Hydrochloride.....     | 117 |
| Guanfacine Hydrochloride Er ..... | 117 |

## **H**

|                                 |     |
|---------------------------------|-----|
| Haegarda .....                  | 114 |
| Harvoni .....                   | 115 |
| Heplisav-b .....                | 359 |
| Hetlioz.....                    | 116 |
| High Risk Medication - 65.....  | 117 |
| Hrm - Anticonvulsants - 65..... | 118 |
| Hrm - Hypnotics - 65 .....      | 119 |
| Hrm - Scopolamine - 65.....     | 120 |
| Hrm-antiparkinson - 65.....     | 121 |
| Hrm-cyproheptadine - 65.....    | 122 |
| Hrm-doxepin - 65.....           | 123 |

|  |          |
|--|----------|
| Hrm-hydroxyzine - 65 .....                 | 124      |
| Hrm-hydroxyzine Inj - 65 .....             | 125      |
| Hrm-promethazine - 65 .....                | 126      |
| Hrms - Antidepressants .....               | 127      |
| Hrms - Carbinoxamine .....                 | 128      |
| Hrms - Clemastine- 65 .....                | 129      |
| Hrms - Tcas .....                          | 130      |
| Hrm-skeletal Muscle Relaxants - 65 .....   | 131      |
| Humira.....                                | 132      |
| Humira Pen.....                            | 132      |
| Humira Pen-cd/uc/hs Starter .....          | 132      |
| Humira Pen-pediatric Uc Starter Pack ..... | 132      |
| Humira Pen-ps/uv Starter .....             | 132      |
| Humulin R U-500 (concentrated).....        | 359      |
| Hydrocodone Bitartrate Er .....            | 152      |
| Hydromorphone Hydrochloride .....          | 359      |
| Hydroxyzine Hcl .....                      | 124, 125 |
| Hydroxyzine Hydrochloride.....             | 124, 125 |
| Hydroxyzine Pamoate .....                  | 124      |
| Hypnotic-benzodiazepines - 65 .....        | 134      |

## **I**

|   |     |
|---|-----|
| Ibrance.....                                      | 135 |
| Icatibant.....                                    | 136 |
| Icatibant Acetate.....                            | 136 |
| Iclusig.....                                      | 137 |
| Idacio.....                                       | 138 |
| Idacio (2 Pen) .....                              | 138 |
| Idacio (2 Syringe).....                           | 138 |
| Idacio Starter Package For Crohns Disease .....   | 138 |
| Idacio Starter Package For Plaque Psoriasis ..... | 138 |
| Idhifa .....                                      | 140 |
| Imatinib .....                                    | 141 |
| Imatinib Mesylate.....                            | 141 |
| Imbruvica .....                                   | 142 |
| Imipramine Hcl .....                              | 127 |
| Imipramine Hydrochloride.....                     | 127 |
| Imipramine Pamoate .....                          | 127 |
| Imkeldi .....                                     | 144 |
| Imovax Rabies (h.d.c.v.) .....                    | 359 |
| Impavido.....                                     | 145 |
| Inbrija .....                                     | 146 |
| Increlex.....                                     | 147 |
| Inlyta.....                                       | 148 |
| Inqovi .....                                      | 149 |

|  |     |
|--|-----|
| Inrebic .....                              | 150 |
| Insulin Supplies.....                      | 151 |
| Ipratropium Bromide .....                  | 359 |
| Ipratropium Bromide/albuterol Sulfate..... | 359 |
| Ir Before Er .....                         | 152 |
| Iressa .....                               | 153 |
| Isolyte-s.....                             | 359 |
| Isolyte-s Ph 7.4.....                      | 359 |
| Isotretinoin .....                         | 154 |
| Itovebi .....                              | 155 |
| Itraconazole.....                          | 156 |
| Ivermectin .....                           | 157 |
| Ivermectin Tab .....                       | 157 |
| Ivig.....                                  | 158 |
| Iwilfin.....                               | 159 |

## **J**

|                |     |
|----------------|-----|
| Jakafi.....    | 160 |
| Javygtor.....  | 257 |
| Jaypirca ..... | 161 |
| Jynneos.....   | 359 |

## **K**

|                              |     |
|------------------------------|-----|
| Kalydeco .....               | 162 |
| Kesimpta .....               | 163 |
| Ketoconazole.....            | 164 |
| Ketorolac Tromethamine ..... | 117 |
| Kisqali.....                 | 165 |
| Kisqali Femara 200 Dose..... | 165 |
| Kisqali Femara 400 Dose..... | 165 |
| Kisqali Femara 600 Dose..... | 165 |
| Korlym .....                 | 166 |
| Koselugo .....               | 167 |
| Krazati.....                 | 168 |
| Kristalose .....             | 169 |

## **L**

|                               |     |
|-------------------------------|-----|
| Lapatinib .....               | 170 |
| Lapatinib Ditosylate.....     | 170 |
| Lazcluze .....                | 171 |
| Lenalidomide .....            | 244 |
| Lenvima .....                 | 172 |
| Lenvima 10 Mg Daily Dose..... | 172 |
| Lenvima 12mg Daily Dose ..... | 172 |
| Lenvima 14 Mg Daily Dose..... | 172 |

|                                  |          |
|----------------------------------|----------|
| Lenvima 18 Mg Daily Dose .....   | 172      |
| Lenvima 20 Mg Daily Dose .....   | 172      |
| Lenvima 24 Mg Daily Dose .....   | 172      |
| Lenvima 4 Mg Daily Dose .....    | 172      |
| Lenvima 8 Mg Daily Dose .....    | 172      |
| Leuprolide .....                 | 173      |
| Leuprolide Acetate .....         | 173      |
| Levalbuterol .....               | 359      |
| Levalbuterol Hcl.....            | 359      |
| Levalbuterol Hydrochloride ..... | 359      |
| L-glutamine .....                | 79       |
| Libervant .....                  | 174      |
| Lidocaine .....                  | 175, 297 |
| Lidocaine Hydrochloride.....     | 297      |
| Lidocaine Patches.....           | 175      |
| Lidocan.....                     | 175      |
| Linezolid.....                   | 176      |
| Livtencity .....                 | 177      |
| Lonsurf .....                    | 178      |
| Lorbrena .....                   | 179      |
| Lumakras .....                   | 180      |
| Lupron Depot (1-month) .....     | 182      |
| Lupron Depot (3-month) .....     | 182      |
| Lupron Depot-ped (1-month) ..... | 181      |
| Lupron Depot-ped (3-month) ..... | 181      |
| Lupron Depot-ped (6-month) ..... | 181      |
| Lupron Ped .....                 | 181      |
| Lupron-endometriosis .....       | 182      |
| Lynparza.....                    | 183      |
| Lyrica Cr .....                  | 184      |
| Lytgobi .....                    | 185      |

## **M**

|                                  |     |
|----------------------------------|-----|
| Mavyret .....                    | 186 |
| Mekinist.....                    | 187 |
| Mektovi .....                    | 188 |
| Memantine.....                   | 189 |
| Memantine Hcl Titration Pak..... | 189 |
| Memantine Hydrochloride .....    | 189 |
| Memantine Hydrochloride Er ..... | 189 |
| Meprobamate.....                 | 117 |
| Metformin Er.....                | 190 |
| Metformin Hydrochloride Er ..... | 190 |
| Methadone Hcl .....              | 152 |
| Methadone Hydrochloride .....    | 152 |

|   |     |
|---|-----|
| Methscopolamine Bromide .....             | 117 |
| Methylprednisolone .....                  | 359 |
| Methylprednisolone Acetate .....          | 359 |
| Methylprednisolone Sodium Succinate ..... | 359 |
| Methylprednisolone Sodiumsuccinate .....  | 359 |
| Methyltestosterone.....                   | 191 |
| Metyrosine .....                          | 68  |
| Mifepristone.....                         | 166 |
| Modafinil.....                            | 192 |
| Morphine Sulfate .....                    | 359 |
| Morphine Sulfate Er.....                  | 152 |
| Morphine Sulfate/sodium Chloride.....     | 359 |
| Mounjaro.....                             | 193 |
| Mycophenolate Mofetil.....                | 359 |
| Mycophenolic Acid Dr .....                | 359 |

## **N**

|                          |     |
|--------------------------|-----|
| Naproxen.....            | 194 |
| Naproxen Suspension..... | 194 |
| Nayzilam .....           | 195 |
| Nerlynx .....            | 196 |
| Nexavar .....            | 197 |
| Ninlaro .....            | 198 |
| Nitisinone.....          | 199 |
| Northera .....           | 200 |
| Noxafil Susp.....        | 201 |
| Nubeqa .....             | 202 |
| Nuedexta .....           | 203 |
| Nulojix .....            | 359 |
| Nuplazid.....            | 204 |
| Nurtec.....              | 205 |
| Nutrilipid.....          | 359 |

## **O**

|                                 |     |
|---------------------------------|-----|
| Octagam .....                   | 158 |
| Octreotide.....                 | 206 |
| Octreotide Acetate .....        | 206 |
| Odomzo .....                    | 207 |
| Ofev.....                       | 208 |
| Ogsiveo .....                   | 209 |
| Ojemda.....                     | 210 |
| Ojjaara.....                    | 211 |
| Omega-3.....                    | 212 |
| Omega-3-acid Ethyl Esters ..... | 212 |
| Oncaspar .....                  | 213 |

|                                 |     |
|---------------------------------|-----|
| Ondansetron Hcl.....            | 359 |
| Ondansetron Hydrochloride ..... | 359 |
| Ondansetron Odt .....           | 359 |
| Onureg.....                     | 214 |
| Opsumit.....                    | 215 |
| Oracea Aet.....                 | 216 |
| Oral-intranasal Fentanyl.....   | 217 |
| Orgovyx.....                    | 218 |
| Orkambi.....                    | 219 |
| Orserdu.....                    | 220 |
| Oxazepam.....                   | 221 |
| Oxazepam - 65 .....             | 221 |
| Ozempic .....                   | 222 |

## **P**

|                                     |          |
|-------------------------------------|----------|
| Panretin.....                       | 223      |
| Part B Versus Part D .....          | 359      |
| Pazopanib Hydrochloride.....        | 330      |
| Pegasys.....                        | 224      |
| Pemazyre .....                      | 225      |
| Pentamidine Isethionate .....       | 359      |
| Perphenazine/amitriptyline.....     | 117      |
| Phenobarbital.....                  | 118      |
| Phenobarbital Sodium .....          | 118      |
| Phenylbutyrate.....                 | 226      |
| Piqray .....                        | 227      |
| Piqray 200mg Daily Dose .....       | 227      |
| Piqray 250mg Daily Dose .....       | 227      |
| Piqray 300mg Daily Dose .....       | 227      |
| Pirfenidone .....                   | 88       |
| Plenamine.....                      | 360      |
| Pomalyst.....                       | 228      |
| Posaconazole .....                  | 201, 229 |
| Posaconazole Dr.....                | 229      |
| Prednisolone.....                   | 360      |
| Prednisolone Sodium Phosphate ..... | 360      |
| Prednisone .....                    | 360      |
| Prednisone Intensol .....           | 360      |
| Pregabalin.....                     | 230      |
| Pregabalin Er .....                 | 184      |
| Premasol .....                      | 360      |
| Pretomanid .....                    | 231      |
| Pretomanid Aet.....                 | 231      |
| Prevymis.....                       | 232      |
| Privigen .....                      | 158      |

|  |     |
|--|-----|
| Procrit.....                           | 82  |
| Prograf.....                           | 360 |
| Prolastin-c .....                      | 8   |
| Promethazine Hcl.....                  | 126 |
| Promethazine Hydrochloride .....       | 126 |
| Promethazine Hydrochloride Plain ..... | 126 |
| Promethegan .....                      | 126 |
| Prosol .....                           | 360 |
| Protriptyline Hcl.....                 | 130 |
| Pulmozyme .....                        | 233 |
| Pyrimethamine .....                    | 65  |
| Pyzchiva.....                          | 234 |

## **Q**

|                              |     |
|------------------------------|-----|
| Qinlock.....                 | 235 |
| Quetiapine Fumarate Er ..... | 236 |
| Quetiapine Xr.....           | 236 |
| Quinine Sulfate .....        | 238 |
| Qulipta.....                 | 239 |

## **R**

|                                |     |
|--------------------------------|-----|
| Rabavert .....                 | 360 |
| Raldesy.....                   | 240 |
| Recombivax Hb .....            | 360 |
| Regranex .....                 | 241 |
| Repatha .....                  | 242 |
| Repatha Pushtronex System..... | 242 |
| Repatha Sureclick .....        | 242 |
| Retevmo .....                  | 243 |
| Revlimid.....                  | 244 |
| Revuforj .....                 | 245 |
| Rezlidhia .....                | 246 |
| Rezurock .....                 | 247 |
| Rinvoq.....                    | 248 |
| Rinvoq Lq .....                | 250 |
| Romvimza.....                  | 252 |
| Rozlytrek.....                 | 253 |
| Rubraca .....                  | 254 |
| Rufinamide.....                | 24  |
| Rybelsus.....                  | 255 |
| Rydapt.....                    | 256 |

## **S**

|                  |     |
|------------------|-----|
| Sajazir .....    | 136 |
| Sandimmune ..... | 360 |

|                                   |          |
|-----------------------------------|----------|
| Sapropterin .....                 | 257      |
| Sapropterin Dihydrochloride ..... | 257      |
| Scemblix .....                    | 258      |
| Scopolamine .....                 | 120      |
| Signifor .....                    | 259      |
| Siklos .....                      | 260      |
| Sildenafil .....                  | 261, 262 |
| Sildenafil Citrate .....          | 261      |
| Sildenafil Inj .....              | 262      |
| Sirolimus .....                   | 360      |
| Sirturo .....                     | 263      |
| Skyrizi .....                     | 264      |
| Skyrizi Pen .....                 | 264      |
| Sodium Oxybate .....              | 346      |
| Sodium Phenylbutyrate .....       | 226      |
| Somatuline Depot .....            | 265      |
| Somavert .....                    | 266      |
| Sorafenib Tosylate .....          | 197      |
| Sotyktu .....                     | 267      |
| Sprycel .....                     | 268      |
| Stelara .....                     | 270      |
| Stivarga .....                    | 271      |
| Sunitinib Malate .....            | 272      |
| Sutent .....                      | 272      |
| Symlin .....                      | 273      |
| Symlinpen 120 .....               | 273      |
| Symlinpen 60 .....                | 273      |
| Sympazan .....                    | 274      |

## **T**

|   |          |
|---|----------|
| Tabrecta .....                                | 275      |
| Tacrolimus .....                              | 360      |
| Tadalafil .....                               | 276, 277 |
| Tadalafil (bph) .....                         | 276      |
| Tadalafil (pah) .....                         | 277      |
| Tafinlar .....                                | 278      |
| Tagrisso .....                                | 279      |
| Talzenna .....                                | 280      |
| Targretin Topical .....                       | 281      |
| Tasigna .....                                 | 282      |
| Tasimelteon .....                             | 116      |
| Tavneos .....                                 | 284      |
| Tazarotene .....                              | 285      |
| Tazorac .....                                 | 285      |
| Tazverik .....                                | 286      |
| Tecvayli .....                                | 287      |
| Temazepam .....                               | 134, 288 |
| Temazepam 30mg - 65 .....                     | 288      |
| Tepmetko .....                                | 289      |
| Teriflunomide .....                           | 17       |
| Teriparatide .....                            | 101      |
| Testosterone Enanthate .....                  | 290      |
| Testosterone Enanthate Inj .....              | 290      |
| Tetrabenazine .....                           | 291      |
| Thalomid .....                                | 292      |
| Thioridazine Hydrochloride .....              | 117      |
| Tibsovo .....                                 | 293      |
| Tobi Inhaler .....                            | 294      |
| Tobi Podhaler .....                           | 294      |
| Tobramycin .....                              | 295      |
| Topical Doxepin .....                         | 296      |
| Topical Lidocaine .....                       | 297      |
| Topical Tretinoin .....                       | 298      |
| Toremifene .....                              | 299      |
| Toremifene Citrate .....                      | 299      |
| Torpenz .....                                 | 91       |
| Tpn Electrolytes .....                        | 360      |
| Travasol .....                                | 360      |
| Tremfya .....                                 | 300      |
| Tremfya Induction Pack For Crohns Disease ... | 300      |
| Treprostinil .....                            | 301      |
| Treprostinil Inj .....                        | 301      |
| Tretinoin .....                               | 298      |
| Triazolam .....                               | 134      |
| Tridacaine .....                              | 175      |
| Tridacaine II .....                           | 175      |
| Trientine .....                               | 302      |
| Trientine Hydrochloride .....                 | 302      |
| Trihexyphenidyl Hcl .....                     | 121      |
| Trihexyphenidyl Hydrochloride .....           | 121      |
| Trikafta .....                                | 303      |
| Trimethobenzamide Hydrochloride .....         | 117      |
| Trimipramine Maleate .....                    | 130      |
| Trintellix .....                              | 304      |
| Trophamine .....                              | 360      |
| Trulicity .....                               | 305      |
| Truqap .....                                  | 306      |
| Truxima .....                                 | 307      |
| Tukysa .....                                  | 309      |

|                                  |     |
|----------------------------------|-----|
| Turalio .....                    | 310 |
| Tyenne .....                     | 311 |
| <b>U</b>                         |     |
| Ubrelvy .....                    | 312 |
| <b>V</b>                         |     |
| Valchlor .....                   | 313 |
| Valtoco .....                    | 314 |
| Valtoco 10 Mg Dose .....         | 314 |
| Valtoco 15 Mg Dose .....         | 314 |
| Valtoco 20 Mg Dose .....         | 314 |
| Valtoco 5 Mg Dose .....          | 314 |
| Vanflyta .....                   | 315 |
| Varenicline Starting Month ..... | 47  |
| Varenicline Tartrate .....       | 47  |
| Velsipity .....                  | 316 |
| Venclexta .....                  | 317 |
| Venclexta Starting Pack .....    | 317 |
| Veozah .....                     | 318 |
| Verquvo .....                    | 319 |
| Versacloz .....                  | 320 |
| Verzenio .....                   | 321 |
| Vigabatrin .....                 | 322 |
| Vigadrone .....                  | 322 |
| Vigafyde .....                   | 323 |
| Vigpoder .....                   | 322 |
| Vitrakvi .....                   | 324 |
| Vizimpro .....                   | 325 |
| Vonjo .....                      | 326 |
| Voranigo .....                   | 327 |
| Voriconazole .....               | 328 |
| Vosevi .....                     | 329 |
| Votrient .....                   | 330 |
| Vowst .....                      | 331 |
| <b>W</b>                         |     |
| Welireg .....                    | 332 |

|                                 |     |
|---------------------------------|-----|
| <b>X</b>                        |     |
| Xalkori .....                   | 333 |
| Xdemvy .....                    | 334 |
| Xeljanz .....                   | 335 |
| Xeljanz Xr .....                | 335 |
| Xermelo .....                   | 337 |
| Xgeva .....                     | 338 |
| Xhance .....                    | 339 |
| Xifaxan .....                   | 340 |
| Xolair .....                    | 341 |
| Xospata .....                   | 343 |
| Xpovio .....                    | 344 |
| Xpovio 60 Mg Twice Weekly ..... | 344 |
| Xpovio 80 Mg Twice Weekly ..... | 344 |
| Xtandi .....                    | 345 |
| Xyrem .....                     | 346 |
| <b>Y</b>                        |     |
| Yesintek .....                  | 347 |
| <b>Z</b>                        |     |
| Zaleplon .....                  | 119 |
| Zarxio .....                    | 348 |
| Zejula .....                    | 349 |
| Zelboraf .....                  | 350 |
| Zenatane .....                  | 154 |
| Zirabev .....                   | 351 |
| Zolinza .....                   | 352 |
| Zolpidem Tartrate .....         | 119 |
| Zonisade .....                  | 353 |
| Ztalmy .....                    | 354 |
| Zurzuva .....                   | 355 |
| Zydelig .....                   | 356 |
| Zykadia .....                   | 357 |
| Zyprexa Relprevv .....          | 358 |