

Prior Authorization Criteria

Sanford

Effective: 1/1/2023

## ACTIMMUNE (S)

### Products Affected

- Actimmune

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of one of the following: 1) Chronic granulomatous disease (CGD), or 2) severe malignant osteopetrosis (SMO). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# ADBRY (S)

## Products Affected

- Adbry

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Initial: Diagnosis of moderate to severe atopic dermatitis. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least two of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. |
| <b>Age Restrictions</b>             | Initial: Patient is 18 years of age or older.  |
| <b>Prescriber Restrictions</b>      | Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist.  |
| <b>Coverage Duration</b>            | Initial: 6 months. Reauth: 12 months.  |
| <b>Other Criteria</b>               | Reauth: Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline.  |

## ADCIRCA (S)

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### Products Affected

- Alyq
- Tadalafil TABS 20MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.   |
| <b>Coverage Duration</b>            | PAH: Initial: 6 months. Reauth: 12 months.  |
| <b>Other Criteria</b>               | PAH (Reauth): Documentation of positive clinical response to therapy.   |

## ADEMPAS (S)

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### Products Affected

- Adempas

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. Chronic thromboembolic pulmonary hypertension (CTEPH) (Initial): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH, CTEPH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.  |
| <b>Coverage Duration</b>            | PAH, CTEPH: Initial: 6 months. Reauth: 12 months.   |
| <b>Other Criteria</b>               | PAH, CTEPH (Reauth): Documentation of positive clinical response to therapy.  |

# AFINITOR (S)

## Products Affected

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

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention but patient is not a candidate for curative surgical resection. Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma AND trial and failure, contraindication, or intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib). Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET that are unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC AND Patient does not require immediate surgery. Breast Cancer: Patient is a postmenopausal woman AND Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole) AND used in combination with AROMASIN (exemestane). Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, non-functional NET of GI or lung origin AND patient has unresectable, locally advanced or metastatic disease. |
| <b>Age Restrictions</b>             | SEGA associated with TSC: Patient is 1 year of age or older.  |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | All uses: 12 months   |
| <b>Other Criteria</b>               | All Indications: Approve for continuation of prior therapy.   |

# AFINITOR DISPERZ (S)

## Products Affected

- Afinitor Disperz

- Everolimus TBSO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention but patient is not a candidate for curative surgical resection. TSC-associated partial-onset seizures: Diagnosis of TSC-associated partial-onset seizures. Used as adjunctive therapy. |
| <b>Age Restrictions</b>             | SEGA associated with TSC: Patient is 1 year of age or older. TSC-associated partial-onset seizures: Patient is 2 years of age or older.  |
| <b>Prescriber Restrictions</b>      | SEGA associated with TSC: Prescribed by or in consultation with an oncologist. TSC-associated partial-onset seizures: Prescribed by or in consultation with a neurologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# AIMOVIG (S)

## Products Affected

- Aimovig

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Episodic Migraines (EM) (initial): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month.</p> <p>Chronic Migraines (CM) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months.</p> <p>All Indications (initial): Two of the following: a) History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine), OR patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine), b) History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate), c) History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol, or d) History of failure (after at least a two month trial) or intolerance to Atacand (candesartan), OR patient has a contraindication to Atacand (candesartan). Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.</p> |
| <b>Age Restrictions</b>             | EM, CM (initial): 18 years of age or older.  |
| <b>Prescriber Restrictions</b>      | EM, CM (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.  |
| <b>Coverage Duration</b>            | EM, CM (initial): 6 months. EM, CM (reauth): 12 months.  |

|                       |   |
|-----------------------|---|
| <b>Other Criteria</b> | EM, CM (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (reauth): Patient continues to be monitored for medication overuse headache. |
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# ALDURAZYME (S)

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## Products Affected

- Aldurazyme

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Mucopolysaccharidosis I: confirmed diagnosis of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I), OR confirmed diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) who have moderate to severe symptoms. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | N/A   |

## ALECENSA (S)

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### Products Affected

- Alecensa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): A) Diagnosis of metastatic NSCLC AND B) Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# ALPHA-1 PROTEINASE INHIBITOR, PROLASTIN (S)

## Products Affected

- Prolastin-c INJ 1000MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Alpha-1 antitrypsin (AAT) deficiency (initial): Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. Continued conventional treatment for emphysema (e.g., bronchodilators). One of the following: 1) PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2) other rare AAT disease genotypes associated with pre-treatment serum AAT level less than 11 $\mu$ M/L [e.g., Pi(Malton, Malton), Pi(SZ)].<br>Circulating pre-treatment serum AAT level less than 11 $\mu$ M/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry), unless the patient has a concomitant diagnosis of necrotizing panniculitis. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | AAT deficiency (initial, reauth): 12 months  |
| Other Criteria               | AAT deficiency (reauth): Documentation of positive clinical response to therapy. Continued conventional treatment for emphysema (e.g., bronchodilators).   |

# ALUNBRIG (S)

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## Products Affected

- Alunbrig

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## AMPYRA (S)

### Products Affected

- Dalfampridine Er

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Multiple Sclerosis (MS) (initial): Diagnosis of MS. Physician confirmation that patient has difficulty walking (eg, timed 25 foot walk test). One of the following: expanded disability status scale (EDSS) score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | MS (initial): Prescribed by or in consultation with a neurologist.  |
| <b>Coverage Duration</b>            | MS (Initial): 6 months. (Reauth): 12 months.  |
| <b>Other Criteria</b>               | MS (Reauth): Physician confirmation that the patient's walking improved with therapy. One of the following: EDSS score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).  |

# ANADROL-50 (S)

## Products Affected

- Anadrol-50

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Anemia (initial): Diagnosis of anemia caused by deficient red cell production AND trial and failure or intolerance to two standard therapies for anemia (i.e., erythropoiesis-stimulating agents, immunosuppressants) AND Treatment will not replace other supportive measures (e.g., transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy, corticosteroids). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Initial, reauth: 12 months  |
| <b>Other Criteria</b>               | Anemia (reauth): Documentation of a positive clinical response to therapy as evidenced by an improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions).  |

# ARCALYST (S)

## Products Affected

- Arcalyst

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Cryopyrin-Associated Periodic Syndromes (CAPS) (Initial): Diagnosis of CAPS, including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS). The medication will not be used in combination with another biologic. Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. Patient weighs at least 10 kg. Patient is currently in remission (e.g., no fever, skin rash, and bone pain/no radiological evidence of active bone lesions/C-reactive protein [CRP] less than 5 mg/L). Recurrent Pericarditis (Initial): Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart. Trial and failure, contraindication, or intolerance (TF/C/I) to at least one of the following: nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), colchicine, or corticosteroids (e.g., prednisone). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | CAPS (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist, or specialist with expertise in the management of CAPS. Recurrent Pericarditis (initial): Prescribed by or in consultation with a cardiologist.  |
| <b>Coverage Duration</b>            | CAPS, Recurrent Pericarditis (initial, reauth): 12 months. DIRA: 12 months.  |
| <b>Other Criteria</b>               | CAPS (Reauth): Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidence by one of the following: A) improvement in rash, fever, joint pain, headache, conjunctivitis, B) decreased number of disease flare days, C) normalization of inflammatory markers (CRP, ESR, SAA), D) corticosteroid dose reduction, OR E) improvement in MD global score or active joint count. Recurrent Pericarditis (Reauth): Documentation of positive clinical response to therapy.  |

# AUBAGIO (S)

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## Products Affected

- Aubagio

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| <b>Required Medical Information</b> | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | MS (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).                                      |



## AURYXIA (S)

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### Products Affected

- Auryxia

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Exclude if used for iron deficiency anemia in chronic kidney disease (CKD) not on dialysis.  |
| <b>Required Medical Information</b> | Hyperphosphatemia in chronic kidney disease: Diagnosis of hyperphosphatemia. Patient has chronic kidney disease (CKD). Patient is on dialysis. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | N/A  |

# AUSTEDO (S)

## Products Affected

- Austedo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Chorea associated with Huntington's disease (initial): Diagnosis of Chorea associated with Huntington's disease. Tardive dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following:<br>1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication<br>or 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Huntington's disease chorea (initial): Prescribed by a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist.  |
| <b>Coverage Duration</b>            | Initial: 3 months. Reauth: 12 months  |
| <b>Other Criteria</b>               | All indications (Reauth): Documentation of positive clinical response to therapy.   |

## AYVAKIT (S)

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### Products Affected

- Ayvakit

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Disease is one of the following: unresectable or metastatic. Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Advanced Systemic Mastocytosis (AdvSM): Diagnosis of AdvSM. Patient has one of the following: a) aggressive systemic mastocytosis (ASM), b) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or c) mast cell leukemia (MCL). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | GIST: Prescribed by or in consultation with an oncologist. AdvSM: Prescribed by or in consultation with an oncologist/hematologist, allergist, or immunologist.   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# BAFIERTAM (S)

## Products Affected

- Bafiertam

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| <b>Required Medical Information</b> | MS (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | MS (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).  |

# BALVERSA (S)

## Products Affected

- Balversa

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Urothelial Carcinoma: Diagnosis of urothelial carcinoma (UC). One of the following: Locally advanced or Metastatic AND Patient has fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations as detected by an U.S. Food and Drug Administration (FDA)-approved test (therascreen FGFR RGQ RT-PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: 1) Patient has progressed during or following at least one line of prior platinum-containing chemotherapy (e.g., gemcitabine with cisplatin or carboplatin, dose dense methotrexate vinblastine doxorubicin cisplatin [DDMVAC] with growth factor support, etc.) OR 2) Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., [DDMVAC] with growth factor support, gemcitabine with cisplatin, etc.). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# BENLYSTA (S)

## Products Affected

- Benlysta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Systemic lupus erythematosus (SLE) (init): Diagnosis of active SLE. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL). Currently receiving at least one standard of care treatment for active SLE (eg, antimalarials [eg, Plaquenil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine)]). Lupus Nephritis (init): Diagnosis of active lupus nephritis. Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | SLE (init): Prescribed by or in consultation with a rheumatologist. Lupus Nephritis (init): Prescribed by or in consultation with a nephrologist or rheumatologist.  |
| <b>Coverage Duration</b>            | SLE, Lupus Nephritis (init, reauth): 6 months  |
| <b>Other Criteria</b>               | SLE, Lupus Nephritis (reauth): Documentation of positive clinical response to therapy.   |

# BESREMI (S)

## Products Affected

- Besremi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of polycythemia vera as confirmed by all of the following: 1) One of the following: a) Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women, b) Hematocrit greater than 49% for men or hematocrit greater than 48% for women, or c) Increased red cell mass, AND 2) Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes, AND 3) One of the following: a) Presence of JAK2 or JAK2 exon 12 mutation or b) Subnormal serum erythropoietin level. Both of the following: 1) Trial and failure, contraindication or intolerance (TF/C/I) to hydroxyurea, AND 2) TF/C/I to one interferon therapy (e.g., Intron A, Pegasys, etc). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# BOSULIF (S)

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## Products Affected

- Bosulif

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic myelogenous/myeloid leukemia (CML): Diagnosis of Philadelphia chromosome-positive (Ph+) CML. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or hematologist                                  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |



# BRAFTOVI (S)

## Products Affected

- Braftovi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Mektovi (binimetinib). Colorectal Cancer: One of the following diagnoses: Colon Cancer or Rectal Cancer. One of the following: 1) Unresectable or advanced disease or 2) Metastatic disease. Patient has received prior therapy. Cancer is BRAF V600E mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Erbitux (cetuximab). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy  |

# BRIVIACT (S)

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## Products Affected

- Briviac SOLN
- Briviac TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                                      |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.                          |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Partial-onset seizures: Diagnosis of partial-onset seizures. |
| <b>Age Restrictions</b>             | Patient is 1 month of age or older                           |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.                   |

## BRUKINSA (S)

### Products Affected

- Brukinsa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Mantle Cell Lymphoma (MCL): Diagnosis of relapsed or refractory MCL. Trial and failure, contraindication, or intolerance to at least ONE combination treatment of rituximab and chemotherapy (e.g., BR, R-CHOP, R-CVP, R-FCM). Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. Disease is relapsed or refractory. Patient has received at least one prior anti-CD20-based regimen for MZL (e.g., rituximab, obinutuzumab). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist/hematologist.  |
| <b>Coverage Duration</b>            | 12 months.   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## CABLIVI (S)

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### Products Affected

- Cablivi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Acquired thrombotic thrombocytopenic purpura (aTTP): Diagnosis of aTTP. First dose was/will be administered by a healthcare provider as a bolus intravenous injection. Used in combination with immunosuppressive therapy (e.g. rituximab, glucocorticoids). One of the following: 1) Used in combination with plasma exchange or 2) both of the following: patient has completed plasma exchange and less than 59 days have or will have elapsed beyond the last plasma exchange. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist or oncologist.  |
| <b>Coverage Duration</b>            | 3 months   |
| <b>Other Criteria</b>               | N/A  |

# CABOMETYX (S)

## Products Affected

- Cabometyx

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Renal cell carcinoma (RCC): Diagnosis of RCC. RCC is advanced. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and failure, contraindication, or intolerance to Nexavar (sorafenib tosylate), or b) Patient has metastatic disease, or c) Patient has extensive liver tumor burden, or d) Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or e) Disease is unresectable. Differentiated Thyroid Cancer (DTC): Diagnosis of DTC. Disease is one of the following: a) locally advanced or b) metastatic. Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]). Disease or patient is refractory to radioactive iodine treatment or ineligible. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | RCC: Prescribed by or in consultation with one of the following: an oncologist or nephrologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, or gastroenterologist. DTC: Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## CALQUENCE (S)

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### Products Affected

- Calquence

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL) AND patient has received at least one prior therapy for MCL. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# CAMZYOS (S)

## Products Affected

- Camzyos

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: Diagnosis of obstructive hypertrophic cardiomyopathy (HCM). Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain). Patient has a left ventricular ejection fraction of greater than or equal to 55%. Patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation. Trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose: a) non-vasodilating beta blocker (e.g., bisoprolol, propranolol) and b) calcium channel blocker (e.g., verapamil, diltiazem). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Initial, Reauth: Prescribed by or in consultation with a cardiologist.  |
| <b>Coverage Duration</b>            | Initial: 16 weeks, Reauth: 12 months  |
| <b>Other Criteria</b>               | Reauthorization: Documentation of positive clinical response to therapy (e.g., improved symptom relief). Patient has a left ventricular ejection fraction of greater than or equal to 50%.  |

## CAPLYTA (S)

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### Products Affected

- Caplyta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Schizophrenia: Diagnosis of schizophrenia. Trial and failure, contraindication, or intolerance to two of the following oral generic formulary atypical antipsychotic agents: asenapine, aripiprazole, olanzapine, paliperidone, quetiapine (IR or ER), risperidone, ziprasidone. Bipolar disorder: Diagnosis of bipolar I or II disorder (bipolar depression). Patient has depressive episodes associated with bipolar disorder. Used as monotherapy or as adjunctive therapy with lithium or valproate. Trial and failure, contraindication, or intolerance to quetiapine (IR or ER) or olanzapine. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy  |



## CAPRELSA (S)

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### Products Affected

- Caprelsa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.                                  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Thyroid Cancer: Diagnosis of medullary thyroid cancer (MTC).         |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with oncologist or endocrinologist. |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.                           |

## CAYSTON (S)

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### Products Affected

- Cayston

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Cystic fibrosis (CF) (Initial, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs.  |
| <b>Age Restrictions</b>             | CF (Initial): 7 years of age or older   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | CF (Initial, reauth): 12 months   |
| <b>Other Criteria</b>               | CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). |

## CERDELGA (S)

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### Products Affected

- Cerdelga

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Gaucher disease: Diagnosis of Gaucher disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test. |
| <b>Age Restrictions</b>             | Gaucher disease: Patient is 18 years of age or older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Gaucher disease: 12 months  |
| <b>Other Criteria</b>               | N/A   |

# CHOLBAM (S)

## Products Affected

- Cholbam

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect based on one of the following: a) an abnormal urinary bile acid analysis by mass spectrometry OR b) molecular genetic testing consistent with the diagnosis. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of a peroxisomal disorder based on one of the following: a) an abnormal urinary bile acid analysis by mass spectrometry OR b) molecular genetic testing consistent with the diagnosis, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) will be used as an adjunctive treatment. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.   |
| <b>Coverage Duration</b>            | All uses: 4 months (initial), 12 months (reauth).  |
| <b>Other Criteria</b>               | All uses (reauth): documentation of positive clinical response to therapy as evidenced by improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT]).  |

## CIALIS (S)

### Products Affected

- Tadalafil TABS 2.5MG, 5MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Concurrent use of nitrates.   |
| <b>Required Medical Information</b> | Diagnosis of benign prostatic hyperplasia (BPH). Trial and failure, contraindication, or intolerance to an alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g., dutasteride, finasteride). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | N/A   |

# CIBINQO (S)

## Products Affected

- Cibinquo

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Initial: Diagnosis of moderate to severe atopic dermatitis. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. One of the following: 1) Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.), OR 2) Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies: Adbry (tralokinumab-ldrm) and Dupixent (dupilumab). Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine). |
| <b>Age Restrictions</b>             | (Initial): Patient is 18 years of age or older.  |
| <b>Prescriber Restrictions</b>      | Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist.  |
| <b>Coverage Duration</b>            | Initial: 6 months. Reauth: 12 months.  |
| <b>Other Criteria</b>               | Reauth: Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine).  |

# CICLOPIROX (S)

## Products Affected

- Ciclodan SOLN
- Ciclopirox Nail Lacquer

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | All of the following: 1) Patient does not have lunula (matrix) involvement, 2) one of the following: a) Diagnosis of onychomycosis of the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3) Diagnosis of onychomycosis has been confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, 4) If toenail onychomycosis, patient has mild to moderate disease involving at least 1 target toenail, AND 5) Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 48 weeks.  |
| <b>Other Criteria</b>               | N/A  |

## CIMZIA (S)

### Products Affected

- Cimzia INJ 200MG/ML

- Cimzia Starter Kit

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | <p>Rheumatoid Arthritis (RA, initial): Diagnosis (dx) of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Crohn's Disease (CD, initial): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to both Humira and Stelara (ustekinumab), OR for continuation of prior therapy. Psoriatic Arthritis (PsA, initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. One of the following: a) Either a TF/C/I to two of the following: Cosentyx (secukinumab), Enbrel, Humira, Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Rinvoq, or Xeljanz/XR, OR b) for continuation of prior therapy. Ankylosing Spondylitis (AS, initial): Dx of active AS. TF/C/I to two of the following: Enbrel, Humira, Cosentyx, Xeljanz/XR, OR for continuation of prior therapy. Plaque Psoriasis (PsO) (initial): Dx of moderate to severe PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. TF/C/I to two of the following: Humira, Enbrel, Skyrizi (risankizumab), Stelara, Cosentyx, OR for continuation of prior therapy.</p> |
| Age Restrictions             | N/A   |



|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | CD (init): Prescribed by or in consultation with a gastroenterologist. RA, AS, nr-axSpA (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.   |
| <b>Coverage Duration</b>       | RA, PsA, AS, PsO, nr-axSpA (init): 6 mos, (reauth): 12 mos. CD (init): 16 wks. (reauth): 12 mos.   |
| <b>Other Criteria</b>          | <p>Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.). Minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, meloxicam, naproxen) at maximally tolerated doses. RA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. CD (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS, nr-axSpA (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.</p> |

## CINRYZE (S)

### Products Affected

- Cinryze

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:<br>a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For prophylaxis against HAE attacks. Not used in combination with other approved treatments for prophylaxis against HAE attacks. |
| <b>Age Restrictions</b>             | HAE (prophylaxis): Patient is 6 years of age or older  |
| <b>Prescriber Restrictions</b>      | HAE (prophylaxis): Prescribed by or in consultation with an immunologist or an allergist   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | N/A  |

## COMETRIQ (S)

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### Products Affected

- Cometriq

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Medullary thyroid cancer (MTC): Diagnosis of Metastatic MTC.                              |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | MTC: Prescribed by or in consultation with an oncologist/hematologist or endocrinologist. |
| <b>Coverage Duration</b>            | All uses: 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## COPIKTRA (S)

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### Products Affected

- Copiktra

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior therapies for CLL/SLL (e.g., Leukeran [chlorambucil], Gazyva [obinutuzumab], Arzerra [ofatumumab], Bendeka [bendamustine], Imbruvica [ibrutinib], Rituxan [rituximab], etc.). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# CORLANOR (S)

## Products Affected

- Corlanor

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Chronic heart failure (CHF) (initial): Diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Patient has a left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm. Patient has a resting heart rate of greater than or equal to 70 beats per minute. One of the following: patient is on a beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate extended release) at a maximally tolerated dose, or patient has a contraindication or intolerance to beta-blocker therapy. Patient has been hospitalized for worsening HF in the previous 12 months. Trial and failure, contraindication, or intolerance to maximally tolerated doses of an ACE inhibitor (e.g., captopril, enalapril, lisinopril) or ARB (e.g., candesartan, losartan, valsartan).</p> <p>Dilated Cardiomyopathy (DCM) (initial): Diagnosis of heart failure due to DCM. Patient has NYHA Class II, III, or, IV symptoms. Patient is in sinus rhythm. Patient has an elevated heart rate. Trial and failure, contraindication or intolerance to one of the following: 1) Beta blocker (e.g., bisoprolol, metoprolol succinate extended release), 2) Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), or 3) Diuretic Agent (e.g., spironolactone, furosemide).</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | CHF, DCM (initial): Prescribed by or in consultation with a cardiologist   |
| <b>Coverage Duration</b>            | CHF, DCM (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | CHF, DCM (reauth): Documentation of positive clinical response to therapy.   |

# COSENTYX (S)

## Products Affected

- Cosentyx

- Cosentyx Sensoready Pen

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. nr-axSpA, ERA (Initial): Minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, naproxen) at maximally tolerated doses.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | <p>Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS, nr-axSpA, ERA (initial): Prescribed by or in consultation with a rheumatologist.</p>   |

|                          |  |
|--------------------------|--|
| <b>Coverage Duration</b> | All uses (initial): 6 months. All uses (reauth): 12 months   |
| <b>Other Criteria</b>    | <p>PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS, nr-axSpA (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. ERA (Reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline.</p> |

## COTELLIC (S)

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### Products Affected

- Cotellic

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Melanoma: Diagnosis of unresectable or metastatic melanoma. Patient has a BRAF V600E or V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



## CUVPOSA (S)

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### Products Affected

- Glycopyrrolate ORAL SOLN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Initial: Diagnosis of chronic severe drooling (sialorrhea). Diagnosis of a neurologic condition (e.g., cerebral palsy) associated with chronic severe drooling (sialorrhea). |
| <b>Age Restrictions</b>             | Initial: Patient is between 3 and 16 years of age.   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Initial, Reauth: 12 months.  |
| <b>Other Criteria</b>               | Reauth: Documentation of a positive clinical response to therapy (e.g., reduction in drooling severity compared to baseline).  |

# CYSTARAN (S)

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## Products Affected

- Cystaran

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Cystinosis: Diagnosis of cystinosis, confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | N/A   |

## DALIRESP (S)

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### Products Affected

- Daliresp

- Roflumilast

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic Obstructive Pulmonary Disease (COPD) (initial): Diagnosis of COPD. History of COPD exacerbations which required the use of systemic corticosteroids, antibiotics, or hospital admission. Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g., Combivent, Spiriva). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | COPD (init, reauth): 12 months   |
| <b>Other Criteria</b>               | COPD (reauth): Documentation of positive clinical response to therapy.   |

## DANYELZA (S)

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### Products Affected

- Danyelza

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Neuroblastoma: Diagnosis of high-risk neuroblastoma in bone or bone marrow. Disease is relapsed or refractory. Used in combination with granulocyte-macrophage colony-stimulating factor [e.g., Leukine (sargramostim)]. Patient has had prior therapy with one of the following responses: partial response, minor response, or stable disease. |
| <b>Age Restrictions</b>             | Neuroblastoma: Patient is 1 year of age or older.  |
| <b>Prescriber Restrictions</b>      | Neuroblastoma: Prescribed by or in consultation with an oncologist or hematologist.  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# DARAPRIM (S)

## Products Affected

- Pyrimethamine TABS

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Toxoplasmosis: 1) Patient is using pyrimethamine for the treatment of toxoplasmic encephalitis, secondary prophylaxis of toxoplasmic encephalitis, or treatment of congenital toxoplasmosis OR 2) Patient is using pyrimethamine for the primary prophylaxis of toxoplasmic encephalitis, patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX), and one of the following: patient has been re-challenged with TMP-SMX using a desensitization protocol and is still unable to tolerate, or evidence of life-threatening reaction to TMP-SMX in the past (eg, toxic epidermal necrolysis, Stevens-Johnson syndrome). Malaria: Patient is using pyrimethamine for the treatment of acute malaria or chemoprophylaxis of malaria. Patient does not have megaloblastic anemia due to folate deficiency. The provider acknowledges that pyrimethamine is not recommended by the Centers for Disease Control and Prevention (CDC) for the treatment and/or prophylaxis of malaria. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an infectious disease specialist  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Toxoplasmosis only: Approve for continuation of prior therapy.  |

# DARZALEX FASPRO (S)

## Products Affected

- Darzalex Faspro

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | <p>Relapsed/Refractory Multiple Myeloma (MM): Diagnosis of MM. One of the following: A) Both of the following: Used as monotherapy and One of the following: i) Patient has received at least three prior treatment regimens which included both a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis]) and an immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid]) or ii) patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent. OR B) Both of the following: used in combination with one of the following treatment regimens: lenalidomide and dexamethasone, bortezomib and dexamethasone, or carfilzomib and dexamethasone, AND patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid]). OR C) Both of the following: used in combination with both pomalidomide and dexamethasone, AND patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis]). Newly Diagnosed MM: Newly diagnosed MM. One of the following: A) Both of the following: patient is ineligible for autologous stem cell transplant AND one of the following: 1) used in combination with all of the following: bortezomib, melphalan, and prednisone or 2) used in combination with both of the following: lenalidomide and dexamethasone. OR B) Both of the following: patient is eligible for autologous stem cell transplant AND used in combination with all of the following: bortezomib, thalidomide, and dexamethasone. Light Chain (AL) Amyloidosis: Newly diagnosed light chain (AL) amyloidosis. Used in combination with all of the following: bortezomib, cyclophosphamide, and dexamethasone. All of the following: patient does not have New York Association (NYHA) Class IIIB disease, patient does not have NYHA class IV disease, and patient does not have Mayo Stage IIIB disease.</p> |
| Age Restrictions             | N/A  |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | MM: Prescribed by or in consultation with an oncologist/hematologist.<br>Light Chain (AL) Amyloidosis: Prescribed by or in consultation with a hematologist. |
| <b>Coverage Duration</b>       | 12 months  |
| <b>Other Criteria</b>          | Approve for continuation of prior therapy  |

## DAURISMO (S)

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### Products Affected

- Daurismo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Acute myeloid leukemia (AML): Diagnosis of newly-diagnosed acute myeloid leukemia (AML) AND Used in combination with low-dose cytarabine AND One of the following: 1) Patient is greater than or equal to 75 years old, or 2) Patient has comorbidities that preclude the use of intensive induction chemotherapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |



# DEFERASIROX (S)

## Products Affected

- Deferasirox

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L. |
| <b>Age Restrictions</b>             | Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 mo. NTDT (initial, reauth): 6mo.   |
| <b>Other Criteria</b>               | Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC.  |

## **DEMSER (S)**

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### **Products Affected**

- Metyrosine

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Preoperative preparation: Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: a) plasma free metanephrines OR b) urinary fractionated metanephrines. Medication is being used for preoperative preparation. Trial and failure, contraindication, or intolerance to both of the following: a) alpha-adrenergic blocker (e.g., phenoxybenzamine, doxazosin, terazosin) AND b) beta-adrenergic blocker (e.g., propranolol, metoprolol). Treatment of pheochromocytoma (initial): Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: a) plasma free metanephrines OR b) urinary fractionated metanephrines. Patient with hormonally active (catecholamine excess) pheochromocytoma. One of the following: a) patient is not a candidate for surgery OR b) chronic treatment due to malignant pheochromocytoma. Patient has not reached normotension after treatment with a selective alpha-1-adrenergic blocker (e.g., doxazosin, terazosin) and beta-adrenergic blocker (e.g., propranolol, metoprolol). Medication will not be used to control essential hypertension. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Preop prep: Prescribed by or in consultation with an endocrinologist OR Endocrine surgeon. Pheochromocytoma (initial): Prescribed by or in consultation with endocrinologist OR provider who specializes in the management of pheochromocytoma.   |
| <b>Coverage Duration</b>            | Preop prep: 4 wks. Treatment of pheo (initial): 6 months, (reauth): 12 months.  |
| <b>Other Criteria</b>               | Treatment of pheochromocytoma (reauth): Documentation of positive clinical response to therapy (e.g., decreased frequency and severity of hypertensive attacks).  |

## DIACOMIT (S)

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### Products Affected

- Diacomit

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with clobazam. Patient weighs 7kg or more. |
| <b>Age Restrictions</b>             | Patient is 6 months of age or older.   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## DUPIXENT (S)

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### Products Affected

- Dupixent

| <b>PA Criteria</b>                  | <b>Criteria Details</b> |
|-------------------------------------|-------------------------|
| <b>Indications</b>                  | Pending CMS Review      |
| <b>Off-Label Uses</b>               | Pending CMS Review      |
| <b>Exclusion Criteria</b>           | Pending CMS Review      |
| <b>Required Medical Information</b> | Pending CMS Review      |
| <b>Age Restrictions</b>             | Pending CMS Review      |
| <b>Prescriber Restrictions</b>      | Pending CMS Review      |
| <b>Coverage Duration</b>            | Pending CMS Review      |
| <b>Other Criteria</b>               | Pending CMS Review      |

## ELAPRASE (S)

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### Products Affected

- Elaprase

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.                              |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of Hunter Syndrome (Mucopolysaccharidosis II (MPS II)) |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | N/A  |

# EMGALITY (S)

## Products Affected

- Emgality

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | <p>Episodic Migraines (EM) (120 mg/mL strength only) (initial): Diagnosis of EM. Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month. Chronic Migraines (CM) (120 mg strength/mL only) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months. Episodic Cluster Headache (ECH) (100 mg/mL strength only) (initial): Diagnosis of episodic cluster headache. Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months. Medication will not be used in combination with another injectable CGRP inhibitor. EM, CM (120 mg/mL strength only) (initial): Two of the following: a) History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine), OR patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine), b) History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate), c) History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol, OR patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol, or d) History of failure (after at least a two month trial) or intolerance to Atacand (candesartan), OR patient has a contraindication to Atacand (candesartan). Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.</p> |
| Age Restrictions             | EM, CM, ECH (initial): 18 years of age or older.  |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | EM, CM, ECH (initial, reauth): Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.   |
| <b>Coverage Duration</b>       | EM, CM (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (reauth): 12 months.  |
| <b>Other Criteria</b>          | EM, CM (120 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (120 mg/mL strength only) (reauth): Patient continues to be monitored for medication overuse headache. ECH (100 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Medication will not be used in combination with another injectable CGRP inhibitor. |



## EMPAVELI (S)

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### Products Affected

- Empaveli

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Paroxysmal Nocturnal Hemoglobinuria (PNH) (initial): Diagnosis of PNH. Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab).   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | PNH (initial, reauth): 12 months   |
| <b>Other Criteria</b>               | PNH (reauth): Documentation of positive clinical response to therapy (e.g., improvement in hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions). |

## ENBREL (S)

### Products Affected

- Enbrel
- Enbrel Mini
- Enbrel Sureclick

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | RA (initial), PJIA (initial), AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist.  |

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| <b>Coverage Duration</b> | All uses (initial): 6 months. All uses (reauth): 12 months  |
| <b>Other Criteria</b>    | <p>RA, PJIJA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count.</p> |

# ENJAYMO (S)

## Products Affected

- Enjaymo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Initial: Diagnosis of cold agglutinin disease (CAD) based on ALL of the following: a) Presence of chronic hemolysis (e.g., bilirubin level above the normal reference range, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count), b) Positive polyspecific direct antiglobulin test (DAT), c) Monospecific DAT strongly positive for C3d, d) Cold agglutinin titer greater than or equal to 64 measured at 4 degree celsius, e) Direct antiglobulin test (DAT) result for Immunoglobulin G (IgG) of 1+ or less. Patient does not have cold agglutinin syndrome secondary to other factors (e.g., overt hematologic malignancy, primary immunodeficiency, infection, rheumatologic disease, systemic lupus erythematosus or other autoimmune disorders). Baseline hemoglobin level less than or equal to 10.0 gram per deciliter (g/dL). One of the following: a) Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg OR b) Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Initial, Reauth: Prescribed by or in consultation with a hematologist.   |
| <b>Coverage Duration</b>            | Initial: 6 months. Reauth: 12 months   |

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| <b>Other Criteria</b> | Reauth: Documentation of a positive clinical response to therapy as evidenced by ALL of the following: a) The patient has not required any blood transfusions after the first 5 weeks of therapy with Enjaymo AND b) Hemoglobin level greater than or equal to 12 gram per deciliter (g/dL) or increased greater than or equal to 2 g/dL from baseline. One of the following: a) Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg OR b) Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater. |
|-----------------------|--|

# ENTYVIO (S)

## Products Affected

- Entyvio

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Ulcerative Colitis (UC) (init): Diagnosis (Dx) of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Humira (adalimumab), Stelara (ustekinumab), Rinvoq (upadacitinib), or Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy. Crohn's Disease (CD) (init): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to both Humira and Stelara, OR for continuation of prior therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | UC, CD (init): Prescribed by or in consultation with a gastroenterologist  |
| <b>Coverage Duration</b>            | UC, CD (init): 14 weeks. UC, CD (reauth): 12 months.   |
| <b>Other Criteria</b>               | UC, CD (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state.   |

## EPCLUSA PREFERRED (S)

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### Products Affected

- Sofosbuvir/velpatasvir

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C. Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.           |
| <b>Coverage Duration</b>            | 12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.  |
| <b>Other Criteria</b>               | N/A   |

# EPIDIOLEX (S)

## Products Affected

- Epidiolex

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Lennox-Gastaut syndrome (LGS): Diagnosis of seizures associated with LGS. Trial of, contraindication, or intolerance to two formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate). Dravet syndrome (DS): Diagnosis of seizures associated with DS. Tuberous sclerosis complex (TSC): Diagnosis of seizures associated with TSC. |
| <b>Age Restrictions</b>             | LGS, DS, TSC: Patient is 1 year of age or older.   |
| <b>Prescriber Restrictions</b>      | LGS, DS, TSC: Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |



# EPOETIN ALFA (S)

## Products Affected

- Procrit

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial): Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is receiving chemo.</p> <p>Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% or Hgb less than 12 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa.</p> <p>Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |

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|--------------------------|---|
| <b>Coverage Duration</b> | CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo.  |
| <b>Other Criteria</b>    | <p>Subject to ESRD review. CKD, Chemo, MDS (init): History of use or unavailability of both Aranesp and Retacrit. HIV, Preop, HCV (init): History of use or unavailability of Retacrit. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Documentation of a positive clinical response to therapy from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Documentation of a positive clinical response to therapy from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Documentation of a positive clinical response to therapy from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Documentation of a positive clinical response to therapy from pre-treatment level. Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.</p> |

# EPOPROSTENOL (S)

## Products Affected

- Epoprostenol Sodium

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.   |
| <b>Coverage Duration</b>            | PAH (Initial): 6 months. (Reauth): 12 months  |
| <b>Other Criteria</b>               | Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.  |

## ERIVEDGE (S)

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### Products Affected

- Erivedge

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Basal cell carcinoma: One of the following: A) Diagnosis of metastatic basal cell carcinoma OR B) Both of the following: 1) Diagnosis of locally advanced basal cell carcinoma AND 2) One of the following: a) Disease recurred following surgery or b) Patient is not a candidate for surgery and radiation. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or dermatologist  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## ERLEADA (S)

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### Products Affected

- Erleada

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-metastatic castration-resistant or castration-recurrent prostate cancer (NM-CRPC): Diagnosis of non-metastatic, castration-resistant (chemical or surgical) or recurrent prostate cancer. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic, castration-sensitive prostate cancer. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | NM-CRPC, M-CSPC: Prescribed by or in consultation with an oncologist or urologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# ESBRIET (S)

## Products Affected

- Esbriet CAPS

- Pirfenidone

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | IPF (initial): Prescribed by or in consultation with a pulmonologist  |
| <b>Coverage Duration</b>            | initial, reauth: 12 months  |
| <b>Other Criteria</b>               | IPF (reauth): Documentation of positive clinical response to therapy.   |

## EUCRISA (S)

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### Products Affected

- Eucrisa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Atopic dermatitis (initial): Diagnosis of mild to moderate atopic dermatitis. Trial and failure, contraindication, or intolerance to one prescription strength topical corticosteroid (e.g., triamcinolone acetonide, fluocinolone acetonide), unless the affected area is sensitive (i.e., face, axillae, groin). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Reauth: Documentation of a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity).   |

# EVRYSDI (S)

## Products Affected

- Evrysdi

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Spinal muscular atrophy (SMA) (initial): Diagnosis of spinal muscular atrophy (SMA) type I, II, or III. Both of the following: a) The mutation or deletion of genes in chromosome 5q resulting in one of the following: 1) Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13) or 2) Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]) AND b) Patient has at least 2 copies of SMN2. Patient is not dependent on both of the following: 1) Invasive ventilation or tracheostomy and 2) Use of non-invasive ventilation beyond use for naps and nighttime sleep. At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability: Hammersmith Infant Neurological Exam (HINE) (infant to early childhood), Hammersmith Functional Motor Scale Expanded (HFMSSE), Upper Limb Module (ULM) Test (Non ambulatory), or Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), or Motor Function Measure 32 (MFM-32) Scale. Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).</p> |
| <b>Age Restrictions</b>             | Initial: Patient is at least 2 months of age or older  |
| <b>Prescriber Restrictions</b>      | SMA (Initial, Reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA  |
| <b>Coverage Duration</b>            | Initial, Reauth: 12 months   |



|                       |   |
|-----------------------|---|
| <b>Other Criteria</b> | SMA (Reauth): Documentation of positive clinical response to therapy. Patient (Pt) continues to not be dependent on both of the following: 1) Invasive ventilation or tracheostomy AND 2) use of non-invasive ventilation beyond use for naps and nighttime sleep. Pt is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) pt has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) pt has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months). |
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## EXKIVITY (S)

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### Products Affected

- Exkivity

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) locally advanced or b) metastatic. Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin, cisplatin). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# FABRAZYME (S)

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## Products Affected

- Fabrazyme

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Fabry Disease: Diagnosis of Fabry disease. Fabrazyme will not be used in combination with Galafold (migalastat). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Fabry Disease: 12 months   |
| <b>Other Criteria</b>               | N/A  |

## FARYDAK (S)

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### Products Affected

- Farydak

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Multiple Myeloma (MM): Diagnosis of MM. Used in combination with both of the following: Velcade (bortezomib) and dexamethasone. Patient has received at least two prior treatment regimens which included both of the following: Velcade (bortezomib) and an immunomodulatory agent [eg, Revlimid (lenalidomide), Thalomid (thalidomide)]. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist/hematologist   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## FASENRA (S)

### Products Affected

- Fasenra

- Fasenra Pen

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR 2) Prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and ii) additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. |
| <b>Age Restrictions</b>             | Asthma (Initial): Patient is 12 years of age or older  |
| <b>Prescriber Restrictions</b>      | Asthma (Initial/Reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist   |
| <b>Coverage Duration</b>            | Asthma (init): 6 months. Asthma (reauth): 12 months  |

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| <b>Other Criteria</b> | Asthma (Reauth): Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. |
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# FENSOLVI (S)

## Products Affected

- Fensolvi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range. Trial and failure or intolerance to Lupron Depot-Ped. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.  |
| <b>Coverage Duration</b>            | CPP (Initial, reauth): 12 months   |
| <b>Other Criteria</b>               | CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.  |

# FENTANYL (S)

## Products Affected

- Fentanyl Citrate Oral Transmucosal

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.   |
| Coverage Duration            | 12 months  |
| Other Criteria               | N/A  |



# FERRIPROX (S)

## Products Affected

- Deferiprone

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Transfusional iron overload (Initial): Diagnosis of transfusional iron overload due to one of the following: thalassemia syndromes, sickle cell disease, or other transfusion-dependent anemias. Patient has Absolute Neutrophil Count (ANC) greater than $1.5 \times 10^9/L$ . One of the following:<br>A) Trial and failure to one chelation therapy (e.g., generic deferasirox)<br>OR B) History of contraindication or intolerance to one chelation therapy (e.g., generic deferasirox). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | All uses (reauth): Documentation of positive clinical response to therapy. ANC greater than $1.5 \times 10^9/L$ .  |

## FINTEPLA (S)

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### Products Affected

- Fintepla

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Dravet Syndrome: Diagnosis of seizures associated with Dravet syndrome. Lennox-Gastaut Syndrome: Diagnosis of seizures associated with Lennox-Gastaut syndrome. |
| <b>Age Restrictions</b>             | Lennox-Gastaut Syndrome: Patient is 2 years of age or older.  |
| <b>Prescriber Restrictions</b>      | All Indications: Prescribed by or in consultation with a neurologist.   |
| <b>Coverage Duration</b>            | All Indications: 12 months  |
| <b>Other Criteria</b>               | All Indications: Approve for continuation of prior therapy.   |

## FIRAZYR (S)

### Products Affected

- Icatibant Acetate
- Sajazir

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:<br>a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks. |
| <b>Age Restrictions</b>             | Patient is 18 years of age or older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an immunologist or an allergist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | N/A   |

## FIRMAGON (S)

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### Products Affected

- Firmagon INJ 120MG/VIAL, 80MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                              |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.                  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of advanced or metastatic prostate cancer. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.           |

## FOTIVDA (S)

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### Products Affected

- Fotivda

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of renal cell carcinoma. Disease is one of the following: relapsed or refractory. Patient has received two or more prior systemic therapies (e.g., cabozantinib + nivolumab, lenvatinib + pembrolizumab, etc.). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or urologist.   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## FYARRO (S)

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### Products Affected

- Fyarro

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Perivascular Epithelioid Cell Tumor (PEComa): Diagnosis of malignant PEComa. Disease is one of the following: a) unresectable locally advanced or b) metastatic. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## GAMASTAN S/D (S)

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### Products Affected

- Gamastan

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).   |
| <b>Required Medical Information</b> | Immune globulin is being used intramuscularly. The immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Patient requires immunization for hepatitis A, measles, rubella, or varicella. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 months (Approve one dose only)   |
| <b>Other Criteria</b>               | Subject to Part B vs D review.   |

## GATTEX (S)

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### Products Affected

- Gattex

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Short Bowel Syndrome (SBS) (Initial): Diagnosis of SBS. Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 months. |
| <b>Age Restrictions</b>             | SBS (initial): Patient is 1 year of age or older.  |
| <b>Prescriber Restrictions</b>      | SBS (Init, reauth): Prescribed by or in consultation with a gastroenterologist.  |
| <b>Coverage Duration</b>            | SBS (Init): 6 months. SBS (Reauth): 12 months.   |
| <b>Other Criteria</b>               | SBS (Reauth): Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on therapy.                     |



# GAVRETO (S)

## Products Affected

- Gavreto

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene mutation tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | NSCLC, MTC: Prescribed by or in consultation with an oncologist. Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy  |

## GILENYA (S)

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### Products Affected

- Fingolimod

- Gilenya

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| <b>Required Medical Information</b> | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | MS (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).                                      |

# GILOTRIF (S)

## Products Affected

- Gilotrif

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): A) Diagnosis of advanced or metastatic (stage IIIB or IV) NSCLC AND B) One of the following: 1) Both of the following: a) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND b) GILOTRIF will be used as first-line treatment, OR 2) All of the following: a) disease progressed after platinum-based chemotherapy (e.g., cisplatin, carboplatin) and b) squamous NSCLC. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# GLATIRAMER ACETATE (S)

## Products Affected

- Glatiramer Acetate

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| <b>Required Medical Information</b> | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | MS (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).                                      |

# GLEEVEC (S)

## Products Affected

- Imatinib Mesylate

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | One of the following: A) Diagnosis of Philadelphia chromosome positive (Ph+)/BCR ABL-positive chronic myelogenous leukemia (CML) OR B) Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) AND one of the following: 1) Patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST, OR 2) Patient had resection of c-KIT (CD117) positive GIST and imatinib will be used as adjuvant therapy OR D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic OR E) Hypereosinophilic syndrome or chronic eosinophilic leukemia OR F) Myelodysplastic syndrome (MDS) or myeloproliferative disease associated with platelet-derived growth factor receptor gene rearrangements OR G) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Hypereosinophilic syndrome or chronic eosinophilic leukemia, Aggressive systemic mastocytosis: Prescribed by or in consultation with an oncologist, hematologist, allergist, or immunologist. All other uses: Prescribed by or in consultation with an oncologist or hematologist.   |
| <b>Coverage Duration</b>            | All uses: 12 months  |
| <b>Other Criteria</b>               | All uses: Approve for continuation of prior therapy.   |

# GLYCOPYRROLATE TABLET (S)

## Products Affected

- Glycopyrrolate TABS 1MG, 2MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: Diagnosis of peptic ulcer. One of the following: 1) Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole), OR 2) Both of the following: a) Patient has a contraindication or intolerance to PPIs, and b) Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine).  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Initial, Reauth: Prescribed by or in consultation with a gastroenterologist.  |
| <b>Coverage Duration</b>            | Initial, Reauth: 3 months.  |
| <b>Other Criteria</b>               | Reauth: One of the following: 1) Patient's peptic ulcer has not healed, OR 2) Patient has a new peptic ulcer. One of the following: 1) Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole), OR 2) Both of the following: a) Patient has a contraindication or intolerance to PPIs, and b) Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine). Patient experienced a reduction in peptic ulcer symptoms while on therapy. |

## GROWTH HORMONE, PREFERRED (S)

### Products Affected

- Genotropin

- Genotropin Miniquick

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | <p>PGHD(initial):less than 4mo w/suspected GD based on clinical presentation (eg, persistent neonatal hypoglycemia, persistent/prolonged neonatal jaundice/elev bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive),OR hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)]. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender assoc with growth rates unlikely to permit attainment of adult height in the normal range. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.</p> |
| Age Restrictions             | N/A  |

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 Last Updated: October 2022

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist   |
| <b>Coverage Duration</b>       | All uses (initial, reauth): 12 months  |
| <b>Other Criteria</b>          | <p>AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT],glucagon,macimorelin) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IGF-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab.</p> <p>AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones: ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,glucagon,macimorelin) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [glucagon at or below 3mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, glucagon, macimorelin) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [glucagon at or below 3mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3). IGHDA(initial):doc GHD after 2 GH stim tests(ITT,glucagon,macimorelin), w/ 2 corresponding peak GH values [ITT at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin less than 2.8 ng/mL 30,45,60,90 mins after admin].</p> |



# HRM - MEGESTROL SUSPENSION

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## Products Affected

- Megestrol Acetate SUSP 40MG/ML, 625MG/5ML

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication. |
| <b>Age Restrictions</b>             | PA applies to patients 65 years or older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | N/A   |

# HRM - MEGESTROL TABLET

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## Products Affected

- Megestrol Acetate TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication. |
| <b>Age Restrictions</b>             | PA applies to patients 65 years or older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Applies to New Starts only.   |

# HUMIRA (S)

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## Products Affected

- Humira
- Humira Pediatric Crohns Disease Starter Pack
- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter

| <b>PA Criteria</b>        | <b>Criteria Details</b>             |
|---------------------------|-------------------------------------|
| <b>Indications</b>        | All Medically-accepted Indications. |
| <b>Off-Label Uses</b>     | N/A                                 |
| <b>Exclusion Criteria</b> | N/A                                 |

|                                     |  |
|-------------------------------------|--|
| <b>Required Medical Information</b> | <p>Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PsO (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week TF/C/I to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | <p>RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.</p>  |
| <b>Coverage Duration</b>            | <p>UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo.</p>   |

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**Other Criteria**

Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to therapy. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.

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## IBRANCE (S)

### Products Affected

- Ibrance

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Breast Cancer: Diagnosis of advanced or metastatic breast cancer. Disease is a) hormone receptor (HR)-positive, and b) human epidermal growth factor receptor 2 (HER2)-negative. One of the following: 1) used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) and one of the following: a) patient is a male, or b) patient is a postmenopausal woman, OR 2) both of the following: used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# ICLUSIG (S)

## Products Affected

- Iclusig

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Chronic myelogenous leukemia: Diagnosis of chronic myelogenous leukemia AND One of the following: A) Trial and failure, contraindication, or intolerance to at least TWO other tyrosine kinase inhibitors (e.g., Gleevec [imatinib], Sprycel, Tassigna, and Bosulif) or B) Patient has the T315I mutation. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) AND One of the following: A) Trial and failure, resistance relapse, contraindication, or intolerance to at least TWO other FDA-approved tyrosine kinase inhibitors (e.g., Gleevec [imatinib], Sprycel), or B) Patient has the T315I mutation. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with an oncologist or hematologist   |
| <b>Coverage Duration</b>            | All uses: 12 months   |
| <b>Other Criteria</b>               | All uses: Approve for continuation of prior therapy.  |

## IDHIFA (S)

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### Products Affected

- Idhifa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Patient has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH2 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



# ILARIS (S)

## Products Affected

- Ilaris INJ 150MG/ML

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Periodic Fever Syndromes (Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF)). (Initial) Diagnosis of one of the autoinflammatory Periodic Fever Syndromes: CAPS (including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS)), TRAPS, HIDS/MKD, or FMF, AND The medication will not be used in combination with another biologic agent. Systemic juvenile idiopathic arthritis (sJIA) (Initial): Diagnosis of active sJIA. Still's Disease (Initial): Diagnosis of Still's Disease, including Adult-Onset Still's Disease (AOSD). SJIA, Still's Disease (initial): Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: minimum duration of a one month trial of a non-steroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen), minimum duration of a 3-month trial of methotrexate, or minimum duration of a 2-week trial of a systemic corticosteroid (e.g., prednisone). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Periodic Fever Syndromes (CAPS, TRAPS, HIDS/MKD, FMF) (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist. SJIA, Still's Disease (initial): Prescribed by or in consultation with a rheumatologist.   |
| <b>Coverage Duration</b>            | All uses (initial): 6 months, (reauth): 12 months   |

|                       |   |
|-----------------------|---|
| <b>Other Criteria</b> | Periodic Fever Syndrome (CAPS, TRAPS, HIDS/MKD, FMF), Still's Disease (Reauth): Documentation of positive clinical response to therapy.<br>SJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in clinical features or symptoms (eg, pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline. |
|-----------------------|---|

## ILUMYA (S)

### Products Affected

- Ilumya

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Plaque Psoriasis (initial): Diagnosis of moderate-to-severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. One of the following: a) Trial and failure, contraindication, or intolerance to two of the following: Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), Stelara (ustekinumab), OR b) for continuation of prior therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist  |
| <b>Coverage Duration</b>            | Plaque Psoriasis (initial): 6 months. Plaque Psoriasis (reauth): 12 months.  |
| <b>Other Criteria</b>               | Plaque Psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.   |

# IMBRUVICA (S)

## Products Affected

- Imbruvica CAPS
- Imbruvica TABS

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Mantle cell lymphoma (MCL): Diagnosis of MCL AND patient has relapsed or is refractory to at least one prior therapy for the treatment of MCL. Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Waldenstrom's macroglobulinemia: Diagnosis of Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Marginal zone lymphoma (MZL): Diagnosis of MZL AND patient has received at least one prior anti-CD20-based therapy for MZL [e.g., Rituxan (rituximab), Zevalin (ibritumomab), Gazyva (obinutuzumab, etc.)]. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD AND trial and failure of one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | All uses (except chronic graft versus host disease): Prescribed by or in consultation with an oncologist or hematologist. Chronic graft versus host disease: Prescribed by or in consultation with a hematologist, oncologist, or physician experienced in the management of transplant patients.   |
| <b>Coverage Duration</b>            | All Uses: 12 months   |
| <b>Other Criteria</b>               | All Uses: Approve for continuation of prior therapy.  |

## INBRIJA (S)

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### Products Affected

- Inbrija

| <b>PA Criteria</b>                  | <b>Criteria Details</b> |
|-------------------------------------|-------------------------|
| <b>Indications</b>                  | Pending CMS Review      |
| <b>Off-Label Uses</b>               | Pending CMS Review      |
| <b>Exclusion Criteria</b>           | Pending CMS Review      |
| <b>Required Medical Information</b> | Pending CMS Review      |
| <b>Age Restrictions</b>             | Pending CMS Review      |
| <b>Prescriber Restrictions</b>      | Pending CMS Review      |
| <b>Coverage Duration</b>            | Pending CMS Review      |
| <b>Other Criteria</b>               | Pending CMS Review      |

# INCRELEX (S)

## Products Affected

- Increlex

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). GH gene deletion (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Initial: Prescribed by or in consultation with an endocrinologist   |
| <b>Coverage Duration</b>            | Initial, reauth: 12 months  |
| <b>Other Criteria</b>               | (Reauth): Documentation of positive clinical response to therapy.   |

# INFLECTRA (S)

## Products Affected

- Inflectra

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | <p>Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Diagnosis (Dx) of moderately to severely active CD or FCD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (eg, prednisone), methotrexate. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, 6-mercaptopurine. Rheumatoid arthritis (RA) (initial): Dx of moderately to severely active RA. Used in combination with methotrexate. Psoriatic arthritis (PsA) (initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar.</p> |
| Age Restrictions             | N/A   |

|                                |   |
|--------------------------------|---|
| <b>Prescriber Restrictions</b> | RA, AS: Prescribed or recommended by a rheumatologist. PsA: Prescribed or recommended by rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed or recommended by a gastroenterologist. Plaque Psoriasis: Prescribed or recommended by a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.   |
| <b>Coverage Duration</b>       | All uses (initial): 6 months, (reauth): 12 months   |
| <b>Other Criteria</b>          | Ankylosing spondylitis (AS) (initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Sarcoidosis (initial): Dx of sarcoidosis. TF/C/I to one of the following: corticosteroid (eg, prednisone) OR immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine). All indications (initial): Trial and failure or intolerance to Remicade or Infliximab. Plaque psoriasis (reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (reauth): Documentation of positive clinical response to therapy. |



# INGREZZA (S)

## Products Affected

- Ingrezza CAPS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Tardive Dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: a) patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication OR b) patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Initial: Prescribed by or in consultation with a neurologist or psychiatrist.  |
| <b>Coverage Duration</b>            | Initial: 3 months. Reauth: 12 months   |
| <b>Other Criteria</b>               | Tardive Dyskinesia (reauth): Documentation of positive clinical response to therapy.   |

## INLYTA (S)

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### Products Affected

- Inlyta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: (1) disease has relapsed or (2) diagnosis of stage IV disease. One of the following: (1) used as first-line treatment in combination with avelumab or pembrolizumab or (2) used after failure of one prior systemic therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# INQOVI (S)

## Products Affected

- Inqovi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome. Patient has ONE of the following French- American-British subtypes: a) refractory anemia, b) refractory anemia with ringed sideroblasts, c) refractory anemia with excess blasts, or d) chronic myelomonocytic leukemia (CMML). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## INREBIC (S)

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### Products Affected

- Inrebic

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Myelofibrosis: Diagnosis of one of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# INTRON A (S)

## Products Affected

- Intron A

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Diagnosis of chronic hepatitis C, patient without decompensated liver disease, patient has not previously been treated with interferon, and one of the following - 1) used in combination with ribavirin or 2) contraindication or intolerance to ribavirin. Metastatic renal cell carcinoma (RCC): diagnosis of metastatic RCC, used in combination with Avastin (bevacizumab). Other: diagnosis of condylomata acuminata (genital or perianal), diagnosis of hairy cell leukemia, diagnosis of AIDS-related Kaposi's sarcoma, diagnosis of malignant melanoma, diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | RCC: Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | HepB, HepC: 48 wks. Condylomata acuminata (genital or perianal): 6 wks. Other: 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## IRESSA (S)

### Products Affected

- Iressa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# ISOTRETINOIN (S)

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## Products Affected

- Accutane
- Amnesteem
- Claravis
- Isotretinoin CAPS 10MG, 20MG, 30MG, 40MG
- Myorisan
- Zenatane

| <b>PA Criteria</b>                  | <b>Criteria Details</b> |
|-------------------------------------|-------------------------|
| <b>Indications</b>                  | Pending CMS Review      |
| <b>Off-Label Uses</b>               | Pending CMS Review      |
| <b>Exclusion Criteria</b>           | Pending CMS Review      |
| <b>Required Medical Information</b> | Pending CMS Review      |
| <b>Age Restrictions</b>             | Pending CMS Review      |
| <b>Prescriber Restrictions</b>      | Pending CMS Review      |
| <b>Coverage Duration</b>            | Pending CMS Review      |
| <b>Other Criteria</b>               | Pending CMS Review      |

## ISTODAX (S)

### Products Affected

- Romidepsin INJ 27.5MG/5.5ML

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least one systemic therapy for the treatment of CTCL [e.g., Trexall (methotrexate), Targretin (bexarotene), cyclophosphamide]. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist/hematologist  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



# ITRACONAZOLE CAPSULE (S)

## Products Affected

- Itraconazole CAPS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Systemic Fungal Infection (SFI): Diagnosis of a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis). Fingernail Onychomycosis: Diagnosis of fingernail onychomycosis as confirmed by one of the following: i) positive potassium hydroxide (KOH) preparation, ii) fungal culture, OR iii) nail biopsy. Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine. Toenail Onychomycosis: Diagnosis of toenail onychomycosis as confirmed by one of the following: i) positive potassium hydroxide (KOH) preparation, ii) fungal culture, OR iii) nail biopsy. Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | SFI:6mo.Fingernail Onychomycosis:5wks.Toenail Onychomycosis:3mo.   |
| <b>Other Criteria</b>               | N/A  |

# IVERMECTIN (S)

## Products Affected

- Ivermectin TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Strongyloidiasis: Diagnosis of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis.<br>Onchocerciasis: Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Strongyloidiasis: 3 weeks. Onchocerciasis: 6 months.  |
| <b>Other Criteria</b>               | N/A   |

## IVIG (S)

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### Products Affected

- Asceniv
- Bivigam INJ 10%, 5GM/50ML
- Carimune Nanofiltered INJ 12GM, 6GM
- Gammaked INJ 10GM/100ML, 1GM/10ML, 20GM/200ML, 5GM/50ML
- Gamunex-c
- Octagam
- Panzyga
- Privigen

| <b>PA Criteria</b>        | <b>Criteria Details</b>   |
|---------------------------|---|
| <b>Indications</b>        | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>     | N/A   |
| <b>Exclusion Criteria</b> | All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. |

|                                     |   |
|-------------------------------------|---|
| <b>Required Medical Information</b> | Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG – Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient’s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 10 <sup>9</sup> /L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm <sup>3</sup> . Continued in Other Criteria Section. |
| <b>Age Restrictions</b>             | HIV (initial): patient is less than or equal to 12 years of age.  |
| <b>Prescriber Restrictions</b>      | All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist).  |
| <b>Coverage Duration</b>            | 4 months: Solid organ transplant. 12 months: all other diagnoses.   |

**Other Criteria**

[D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barré syndrome. 3) Inflammatory myopathies (dermatomyositis or polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants).

[E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

## JAKAFI (S)

### Products Affected

- Jakafi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Myelofibrosis: Diagnosis of primary myelofibrosis, OR post-polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND trial and failure, contraindication, or intolerance to hydroxyurea. Acute graft versus host disease (aGVHD): Diagnosis of aGVHD. Disease is steroid-refractory. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD. Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Myelofibrosis, Polycythemia vera: Prescribed by or in consultation with a hematologist/oncologist. aGVHD, cGVHD: Prescribed by or in consultation with one of the following: hematologist, oncologist, physician experienced in the management of transplant patients.   |
| <b>Coverage Duration</b>            | 12 months.   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# JEMPERLI (S)

## Products Affected

- Jemperli

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Endometrial Cancer: Diagnosis of endometrial cancer. Disease is one of the following: a) advanced or b) recurrent. Disease is mismatch repair deficient (dMMR) as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin, cisplatin). Solid Tumors: Diagnosis of solid tumor. Disease is one of the following: a) advanced or b) recurrent. Disease is mismatch repair deficient (dMMR) as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has progressed on or following prior treatment. Patient does not have satisfactory alternative treatment options. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## JUXTAPID (S)

### Products Affected

- Juxtapid

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient is receiving other lipid-lowering therapy. Trial and failure, contraindication, or intolerance to Repatha therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.   |
| <b>Coverage Duration</b>            | HoFH (initial): 6 months. (reauth): 12 months   |
| <b>Other Criteria</b>               | HoFH (reauthorization): Patient continues to receive other lipid-lowering therapy. Submission of medical records (eg, chart notes, laboratory values) documenting LDL-C reduction while on therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.   |



# KALYDECO (S)

## Products Affected

- Kalydeco

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | CF (Initial): 4 months of age or older   |
| <b>Prescriber Restrictions</b>      | CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist   |
| <b>Coverage Duration</b>            | CF (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | CF (Reauth): Documentation of positive clinical response (i.e. improvement in lung function [percent predicted forced expiratory volume in one second (PPFEV1)], decreased number of pulmonary exacerbations) while on therapy.  |

# KANJINTI (S)

## Products Affected

- Kanjinti

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-overexpressing breast cancer. One of the following treatment regimens: a) As adjuvant treatment, b) metastatic disease and one of the following: 1) used in combination with a taxane (eg, docetaxel, paclitaxel), or 2) used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease, or c) used in combination with Perjeta (pertuzumab). Gastric Cancer: Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic). Used in combination with one of the following treatment regimens: a) Platinol (cisplatin) and Adrucil (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## KANUMA (S)

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### Products Affected

- Kanuma

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Lysosomal acid lipase deficiency: Diagnosis of lysosomal acid lipase deficiency (LAL-D). Diagnosis was confirmed by an enzymatic blood (e.g., dried blood spot test) or genetic test. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, gastroenterologist, or lipidologist                                   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | N/A   |

# KERENDIA (S)

## Products Affected

- Kerendia

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Initial: Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) defined by one of the following: 1) All of the following: a) urinary albumin-to-creatinine ratio (UACR) of 30 to 300 mg/g, b) estimated glomerular filtration rate (eGFR) 25 to 60 mL/min/1.73 m <sup>2</sup> , and c) diabetic retinopathy, OR 2) Both of the following: a) UACR of greater than or equal to 300 mg/g and b) eGFR of 25 to 75 mL/min/1.73 m <sup>2</sup> . One of the following: 1) Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following: a) generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril), or b) generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Initial, Reauth: 12 months   |
| <b>Other Criteria</b>               | Reauth: Documentation of positive clinical response to therapy. One of the following: 1) Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB, OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs.  |

# KESIMPTA (S)

## Products Affected

- Kesimpta

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Multiple Sclerosis (MS) (Initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following: A) Aubagio (teriflunomide), B) Mavenclad (cladribine), C) Plegridy (peginterferon beta-1a), D) Any one of the interferon beta-1a injections (eg, Avonex), E) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), F) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), G) Any one of the glatiramer acetates (eg, Copaxone, Glatopa, generic glatiramer acetate), H) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya [fingolimod], Mayzent [siponimod], Zeposia [ozanimod]), OR 2) For continuation of prior therapy. Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS (Initial, Reauth): Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | MS (Initial, Reauth): 12 months  |
| <b>Other Criteria</b>               | MS (Reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapse, or disease progression). Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]).  |

# KIMMTRAK (S)

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## Products Affected

- Kimmtrak

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of uveal melanoma. Disease is unresectable or metastatic. Patient is HLA-A*02:01 genotype positive as determined by a high-resolution genotyping test. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# KISQALI (S)

## Products Affected

- Kisqali

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Breast cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: A) Used in combination with an aromatase inhibitor [e.g., Femara (letrozole)] OR B) Used in combination with Faslodex (fulvestrant). One of the following: A) Patient is a postmenopausal woman OR B) Both of the following: a) Patient is a pre/perimenopausal woman or male AND b) Treated with a Luteinizing Hormone-Releasing Hormone (LHRH) agonist (e.g., leuprolide). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy  |

## KISQALI-FEMARA PACK (S)

### Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Breast cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: A) Patient is a postmenopausal woman OR B) Both of the following: a) Patient is a pre/perimenopausal woman or male AND b) Treated with a Luteinizing Hormone-Releasing Hormone (LHRH) agonist (e.g., leuprolide). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



## KORLYM (S)

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### Products Affected

- Korlym

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Cushing's syndrome (Initial): Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus or diagnosis of glucose intolerance. Patient has either failed surgery or patient is not a candidate for surgery. Patient is not pregnant. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Initial: Prescribed by or in consultation with an endocrinologist.  |
| <b>Coverage Duration</b>            | Initial, reauth: 6 months   |
| <b>Other Criteria</b>               | Reauth: Documentation of one of the following: patient has improved glucose tolerance while on therapy or patient has stable glucose tolerance while on therapy.  |

# KORSUVA (S)

## Products Affected

- Korsuva

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic kidney disease (CKD) (init): Diagnosis of CKD. Patient is currently undergoing hemodialysis (HD). Patient is experiencing moderate to severe pruritus associated with CKD (CKD-aP). Exclusion of other causes of pruritus (e.g., eczema, infections, drug-induced skin dryness). Trial and failure of at least two standard of care treatments for CKD-aP (e.g., topical corticosteroids [e.g., hydrocortisone, triamcinolone], oral antihistamines [e.g., diphenhydramine, hydroxyzine], gabapentin, pregabalin). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | CKD (init): Prescribed by or in consultation with a nephrologist or dermatologist.   |
| <b>Coverage Duration</b>            | CKD (init): 3 months. CKD (reauth): 12 months.   |
| <b>Other Criteria</b>               | CKD (reauth): Patient is currently undergoing HD. Documentation of positive clinical response to therapy (e.g., improved worst itching intensity numerical rating score from baseline).  |

# KOSELUGO (S)

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## Products Affected

- Koselugo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has plexiform neurofibromas that are both of the following: inoperable and causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment). Patient is able to swallow a capsule whole. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with one of the following: oncologist or neurologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## KUVAN (S)

### Products Affected

- Sapropterin Dihydrochloride

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient will have blood Phe levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | PKU (Init): 2 months (Reauth): 12 months  |
| <b>Other Criteria</b>               | PKU (reauth): Documentation of a positive clinical response to therapy. Patient will continue to have blood Phe levels measured periodically during therapy.  |

## KYNMOBI (S)

### Products Affected

- Kynmobi

- Kynmobi Titration Kit

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Parkinson's disease (PD) (Initial): Not used with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)  |
| <b>Required Medical Information</b> | Parkinson's disease (PD) (Initial): Diagnosis of PD. Patient is experiencing acute intermittent hypomobility (defined as “off” episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). Used in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, etc.). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PD (Initial): Prescribed by or in consultation with a neurologist.  |
| <b>Coverage Duration</b>            | PD (Initial, reauth): 12 months   |
| <b>Other Criteria</b>               | PD (Reauth): Documentation of positive clinical response to therapy.  |

# LANREOTIDE (S)

## Products Affected

- Lanreotide Acetate

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Acromegaly: Diagnosis of acromegaly. One of the following: A) Inadequate response to one of the following: surgery or radiotherapy, OR B) Not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (120mg/0.5mL strength only): Diagnosis of GEP-NETs. Disease is one of the following: (a) unresectable, locally advanced or (b) metastatic. Carcinoid syndrome (120mg/0.5mL strength only): Diagnosis of carcinoid syndrome. Used to reduce the frequency of short-acting somatostatin analog rescue therapy. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | Acromegaly (initial): Prescribed by or in consultation with an endocrinologist. GEP-NETs (initial): Prescribed by or in consultation with an oncologist. Carcinoid syndrome (initial): Prescribed by or in consultation with an endocrinologist or oncologist.  |
| Coverage Duration            | All uses: 12 months   |
| Other Criteria               | All Indications: Approve for continuation of prior therapy.   |

# LEMTRADA (S)

## Products Affected

- Lemtrada

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Patient has not been previously treated with alemtuzumab, and failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Mavenclad (cladribine), C) Plegridy (peginterferon beta-1a), D) Tysabri (natalizumab), E) Any one of the interferon beta-1a injections (eg, Avonex), F) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), G) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), H) Any one of the glatiramer acetate injections (eg, Copaxone, Glatopa, generic glatiramer acetate), I) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya [fingolimod], Mayzent [siponimod], Zeposia [ozanimod]), J) Any one of the B-cell targeted therapies (eg, Ocrevus [ocrelizumab], Kesimpta [ofatumumab]), or 2) Patient has previously received treatment with alemtuzumab, and at least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab. Not used in combination with another disease-modifying therapy for MS. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS: Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | MS: 12 months.   |
| <b>Other Criteria</b>               | N/A  |

# LENVIMA (S)

## 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  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | <p>Differentiated thyroid cancer (DTC): Diagnosis of DTC. Disease is locally recurrent or metastatic. Patient has symptomatic or progressive disease. Disease is refractory to radioactive iodine treatment. Renal Cell Carcinoma (RCC): Diagnosis of advanced RCC. One of the following: 1) Both of the following: a) Used as first-line treatment and b) Used in combination with Keytruda (pembrolizumab), or 2) Both of the following: a) Treatment follows one prior anti-angiogenic therapy and b) Used in combination with everolimus. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Endometrial Carcinoma (EC): Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). Patient has disease progression following systemic therapy. Used in combination with Keytruda (pembrolizumab) therapy. Patient is not a candidate for curative surgery or radiation.</p> |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | DTC/RCC/EC: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with one of the following: oncologist, hepatologist, or gastroenterologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



# LETAIRIS (S)

## Products Affected

- Ambrisentan

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.   |
| <b>Coverage Duration</b>            | PAH (Initial): 6 months. PAH (Reauth): 12 months  |
| <b>Other Criteria</b>               | PAH (Reauth): Documentation of positive clinical response to therapy.   |

## LIDOCAINE TOPICAL (S)

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### Products Affected

- Glydo
- Lidocaine OINT 5%
- Lidocaine Hcl PRSY
- Lidocaine Hcl Jelly PRSY
- Lidocaine/prilocaine CREA
- Lidocaine-prilocaine-cream Base CREA 2.5%; 2.5%
- Premium Lidocaine

| <b>PA Criteria</b>                  | <b>Criteria Details</b>             |
|-------------------------------------|-------------------------------------|
| <b>Indications</b>                  | All Medically-accepted Indications. |
| <b>Off-Label Uses</b>               | N/A                                 |
| <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>            | 3 months                            |
| <b>Other Criteria</b>               | N/A                                 |

# LIDODERM (S)

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## Products Affected

- Lidocaine PTCH 5%

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.                            |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Post-herpetic neuralgia: Diagnosis of post-herpetic neuralgia. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | N/A  |

# LIVMARLI (S)

## Products Affected

- Livmarli

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Alagille syndrome (ALGS) (initial): Both of the following: a) Diagnosis of ALGS, and b) Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene. Documentation of ONE of the following: a) Total serum bile acid greater than 3 times the upper limit of normal (ULN), b) Conjugated bilirubin greater than 1 mg/dL, c) Fat soluble vitamin deficiency otherwise unexplainable, or d) Gammaglutamyl transpeptidase (GGT) greater than 3 times the ULN. Patient is experiencing moderate to severe cholestatic pruritus. Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: a) Ursodeoxycholic acid (e.g., Ursodiol), b) Antihistamines (e.g., diphenhydramine, hydroxyzine), c) Rifampin, or d) Bile acid sequestrants (e.g., Questran, Colestid, Welchol). |
| <b>Age Restrictions</b>             | ALGS (initial): Patient is 1 year of age or older.   |
| <b>Prescriber Restrictions</b>      | ALGS (initial): Prescribed by or in consultation with a hepatologist.  |
| <b>Coverage Duration</b>            | ALGS (initial, reauth): 12 months.   |
| <b>Other Criteria</b>               | ALGS (reauth): Documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score).   |

# LONSURF (S)

## Products Affected

- Lonsurf

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | <p>Colorectal Cancer: Diagnosis of metastatic colorectal cancer AND trial and failure, contraindication, or intolerance to at least one component in the following: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND trial and failure, contraindication, or intolerance to at least one anti-VEGF therapy (e.g., bevacizumab)) AND One of the following: A) patient has KRAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR Patient has KRAS mutant tumors. Gastric/Gastroesophageal Junction</p> <p>Adenocarcinoma: Diagnosis of metastatic gastric cancer or diagnosis of metastatic gastroesophageal junction adenocarcinoma. Trial and failure, contraindication or intolerance to at least two of the following: fluopyrimidine-based chemotherapy (e.g. fluorouracil), Platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin), Taxane (e.g., docetaxel, paclitaxel) or irinotecan-based chemotherapy, HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression).</p> |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## LORBRENA (S)

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### Products Affected

- Lorbrena

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# LOTRONEX (S)

## Products Affected

- Alosetron Hydrochloride

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women (initial): All of the following: 1) diagnosis of severe diarrhea-predominant IBS, 2) symptoms for at least 6 months, 3) female patient, AND 4) trial and failure, contraindication, or intolerance to an antidiarrheal agent [eg, loperamide]. |
| <b>Age Restrictions</b>             | Initial: 18 years of age or older  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | IBS (initial): 12 weeks. IBS (reauth): 6 mo.   |
| <b>Other Criteria</b>               | IBS (reauth): Symptoms of IBS continue to persist. Documentation of positive clinical response to therapy (e.g., relief of IBS abdominal pain and discomfort, improvement in stool consistency and frequency, improvement as measured by the Global Improvement Scale).  |

# LUMAKRAS (S)

## Products Affected

- Lumakras

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: a) locally advanced or b) metastatic. Tumor is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., cisplatin/pemetrexed, atezolizumab, nivolumab, capmatinib). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



# LUMIZYME (S)

## Products Affected

- Lumizyme

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | <p>Infantile Onset Pompe Disease (IOPD) (initial): Diagnosis of IOPD (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: 1) Absence or deficiency (less than 1% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay, OR 2) Molecular genetic testing confirms mutations in the GAA gene. Presence of clinical signs and symptoms of the disease (e.g., cardiomegaly, hypotonia, etc.). Late Onset Pompe Disease (LOPD) (initial): Diagnosis of LOPD (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: 1) Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay, OR 2) Molecular genetic testing confirms mutations in the GAA gene. Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.).</p> |
| <b>Age Restrictions</b>             | IOPD (initial): Patient is less than or equal to 12 months of age. LOPD (initial): Patient is 1 year of age or older.   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | IOPD, LOPD (initial, reauth): 12 months   |
| <b>Other Criteria</b>               | IOPD, LOPD (reauth): Documentation of positive clinical response to therapy.  |

# LUPRON (S)

## Products Affected

- Leuprolide Acetate INJ 1MG/0.2ML

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.                                   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Prostate CA: 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.                            |

# LUPRON DEPOT (S)

## Products Affected

- Lupron Depot (1-month)
- Lupron Depot (3-month)
- Lupron Depot (4-month)
- Lupron Depot (6-month)

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Diagnosis of advanced or metastatic prostate cancer. Endometriosis (3.75 mg, 11.25 mg) (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl estradiol, estradiol and norethindrone). Uterine Leiomyomata (UL) (3.75 mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all of the following: treatment of anemia, anemia is caused by uterine leiomyomata (fibroids), and for use prior to surgery. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Prostate CA: 12 mo. Endomet (init, reauth):6mo. UL (anemia):3 mo (fibroids):4 mo  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# LUPRON DEPOT PED (S)

## Products Affected

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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.  |
| <b>Coverage Duration</b>            | CPP (init, reauth): 12 months  |
| <b>Other Criteria</b>               | CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.  |

# LYNPARZA TABLET (S)

## Products Affected

- Lynparza TABS

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | <p>Ovarian cancer, advanced disease with known or suspected BRCA mutation with 3 or more prior lines of chemotherapy: Diagnosis of advanced ovarian cancer. Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Trial and failure, contraindication, or intolerance to three or more prior lines of chemotherapy (e.g., paclitaxel with cisplatin). Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). High risk early breast cancer: Diagnosis of high risk early breast cancer. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by CLIA. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Patient has been previously treated with neoadjuvant and adjuvant chemotherapy (e.g., anthracycline, taxane). Metastatic breast cancer: Diagnosis of metastatic breast cancer. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by CLIA. Disease is HER2-negative. Patient has been previously treated with chemotherapy (e.g., anthracycline, taxane) in the neoadjuvant, adjuvant, or metastatic setting. One of the following: a) Disease is hormone receptor (HR)-negative, or b) Disease is HR-positive and one of the following: i) patient has been treated with prior endocrine therapy or ii) patient is considered an inappropriate candidate for endocrine therapy.</p> |
| Age Restrictions             | N/A   |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | All uses (except prostate cancer): Prescribed by or in consultation with an oncologist. Prostate cancer: Prescribed by or in consultation with an oncologist or urologist.   |
| <b>Coverage Duration</b>       | 12 months  |
| <b>Other Criteria</b>          | <p>First-line maintenance treatment of BRCA-mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Presence of deleterious or suspected deleterious BRCA-mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin). Will be used as first-line maintenance treatment. Pancreatic adenocarcinoma: Diagnosis of metastatic pancreatic adenocarcinoma. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has not progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen (e.g., FOLFIRINOX, FOLFOX, etc.). First-line maintenance treatment of HRD-positive advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with bevacizumab: Diagnosis of advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Cancer is associated with homologous recombination deficiency (HRD)-positive status (defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has had a complete or partial response to first-line platinum-based chemotherapy (e.g., carboplatin, cisplatin). Used in combination with bevacizumab (e.g., Avastin, Mvasi). Will be used as first-line maintenance treatment. Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer. Presence of deleterious or suspected deleterious homologous recombination repair (HRR) gene mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed following prior treatment with one of the following: a) enzalutamide (Xtandi) or b) abiraterone (e.g., Zytiga, Yonsa). All indications: Approve for continuation of prior therapy.</p> |

# MAKENA (S)

## Products Affected

- Makena INJ 275MG/1.1ML

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Preterm birth prophylaxis: Patient had a previous singleton (single offspring) spontaneous preterm birth. Patient is having a singleton pregnancy. Therapy will be started between 16 weeks, 0 days and 20 weeks, 6 days of gestation. Therapy will be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Preterm birth prophylaxis: Prescribed by or in consultation with a specialist in obstetrics and gynecology  |
| <b>Coverage Duration</b>            | Preterm birth prophylaxis: 21 weeks   |
| <b>Other Criteria</b>               | N/A   |

# MARINOL (S)

## Products Affected

- Dronabinol

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance to one 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). Trial and failure, contraindication, or intolerance to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS. Patient is on antiretroviral therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | CINV: 6 months. AIDS anorexia: 3 months.  |
| <b>Other Criteria</b>               | Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving cancer chemotherapy.  |



# MAVYRET (S)

## Products Affected

- Mavyret

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier]. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.   |
| <b>Coverage Duration</b>            | 8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.   |
| <b>Other Criteria</b>               | N/A   |

# MAYZENT (S)

## Products Affected

- Mayzent

- Mayzent Starter Pack

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| <b>Required Medical Information</b> | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | MS (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).                                      |

# MEKINIST (S)

## Products Affected

- Mekinist

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Melanoma: Diagnosis of unresectable or metastatic melanoma AND cancer is BRAF V600E or V600K mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Tafenlar (dabrafenib). Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Tafenlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic ATC. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Tafenlar (dabrafenib). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# MEKTOVI (S)

## Products Affected

- Mektovi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Braftovi (encorafenib). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy   |

# MIGRANAL (S)

## Products Affected

- Dihydroergotamine Mesylate SOLN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Initial: Diagnosis of migraine headaches with or without aura. Will be used for the acute treatment of migraine. One of the following: Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or contraindication to all triptans. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.   |
| <b>Coverage Duration</b>            | Initial: 3 months. Reauth: 12 months.  |
| <b>Other Criteria</b>               | Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea).  |

# MONJUVI (S)

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## Products Affected

- Monjuvi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diffuse Large B-cell Lymphoma (DLBCL): Diagnosis of DLBCL. Disease is one of the following: relapsed or refractory. Used in combination with lenalidomide. Patient is not eligible for autologous stem cell transplant (ASCT). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | DLBCL: Prescribed by or in consultation with an oncologist or hematologist   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## MS INTERFERONS (NON-PREFERRED) (S)

### Products Affected

- Rebif
- Rebif Rebidose
- Rebif Rebidose Titration Pack
- Rebif Titration Pack

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.   |
| <b>Required Medical Information</b> | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Extavia (interferon beta-1b), Plegridy (peginterferon beta-1a), or 2) for continuation of prior therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | MS (initial, reauth): Prescribed by or in consultation with a neurologist   |
| <b>Coverage Duration</b>            | MS (initial, reauth): 12 months   |
| <b>Other Criteria</b>               | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).   |

## MS INTERFERONS (PREFERRED) (S)

### Products Affected

- Avonex
- Avonex Pen
- Betaseron
- Plegridy
- Plegridy Starter Pack

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| <b>Required Medical Information</b> | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | MS (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).                                      |



# MVASI (S)

## Products Affected

- Mvasi

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Non-Small Cell Lung Cancer: Excluded if squamous cell histology.  |
| <b>Required Medical Information</b> | <p>Colorectal Cancer: Diagnosis of metastatic colorectal cancer. One of the following: 1) Both of the following: a) used as first- or second-line treatment and b) used in combination with an intravenous 5-fluorouracil-based chemotherapy, OR 2) All of the following: a) used as second-line treatment, b) used in combination with fluoropyrimidine-irinotecan-based chemotherapy or fluoropyrimidine-oxaliplatin-based chemotherapy, and c) patient has progressed on a first-line bevacizumab-containing regimen.</p> <p>Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is unresectable, locally advanced, recurrent, or metastatic. Used as first-line treatment. Used in combination with paclitaxel and carboplatin.</p> <p>Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with interferon-alpha.</p> <p>Cervical Cancer: Diagnosis of carcinoma of the cervix. Disease is persistent, recurrent, or metastatic. Used in combination with one of the following: a) paclitaxel and cisplatin or b) paclitaxel and topotecan.</p> <p>Glioblastoma: Diagnosis of recurrent glioblastoma.</p> <p>Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) All of the following: a) disease is stage 3 or 4, b) patient has been treated with bevacizumab as a single agent, c) treatment is following surgical resection, and d) used in combination with carboplatin and paclitaxel, OR 2) All of the following: a) disease is platinum-resistant recurrent, b) patient has received no more than 2 prior chemotherapy regimens, and c) used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, OR 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, and c) used in combination with one of the following: i) carboplatin and paclitaxel or ii) carboplatin and gemcitabine.</p> |
| <b>Age Restrictions</b>             | N/A   |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>       | 12 months  |
| <b>Other Criteria</b>          | Hepatocellular Carcinoma (HCC): Diagnosis of hepatocellular carcinoma. Disease is unresectable or metastatic. Used in combination with Tecentriq (atezolizumab). Patient has not received prior systemic therapy. Approve for continuation of prior therapy. |

# MYFEMBREE (S)

## Products Affected

- Myfembree

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | <p>Uterine Leiomyomas (Fibroids) (initial): Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids). Patient is premenopausal. One of the following: 1) History of inadequate control of bleeding following a trial of 30 days, or history of intolerance or contraindication to one of the following: combination (estrogen/progestin) contraceptive, progestins, or tranexamic acid or 2) Patient has had a previous interventional therapy to reduce bleeding. Treatment duration of therapy has not exceeded a total of 24 months. Pain Associated with Endometriosis (initial): Diagnosis of moderate to severe pain associated with endometriosis. Patient is premenopausal. One of the following: 1) History of inadequate pain control response following a trial of 30 days, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progestin) contraceptive, or progestins or 2) Patient has had surgical ablation to prevent recurrence. Treatment duration of Myfembree has not exceeded a total of 24 months.</p> |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | All Indications (initial, reauth): 12 months.   |
| <b>Other Criteria</b>               | <p>Uterine Leiomyomas (Fibroids) (reauth): Patient has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.). Treatment duration of therapy has not exceeded a total of 24 months. Pain Associated with Endometriosis (reauth): Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain). Treatment duration of Myfembree has not exceeded a total of 24 months.</p>  |

## NAGLAZYME (S)

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### Products Affected

- Naglazyme

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Mucopolysaccharidosis (MPS VI): Diagnosis of MPS VI (Maroteaux-Lamy Syndrome). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | MPS VI: 12 months  |
| <b>Other Criteria</b>               | N/A  |

# NATPARA (S)

## Products Affected

- Natpara

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Hypocalcemia (Initial): Diagnosis of hypocalcemia due to chronic hypoparathyroidism. Not used in the setting of acute post-surgical hypoparathyroidism. Patient does not have a known calcium-sensing receptor mutation. Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months. Patient has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy (or if on therapy, the dose had to have been stable for greater than or equal to 3 months). Patient has normal magnesium and serum 25-hydroxyvitamin D concentrations. Will be used as an adjunct treatment. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Hypocalcemia (initial): Prescribed by or in consultation with an endocrinologist.  |
| <b>Coverage Duration</b>            | Initial: 6 months. Reauth: 12 months   |
| <b>Other Criteria</b>               | Hypocalcemia (Reauth): Documentation of positive clinical response to therapy.   |

## NERLYNX (S)

### Products Affected

- Nerlynx

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Early Stage Breast cancer: Diagnosis (dx) of early stage breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received adjuvant trastuzumab-based therapy. Advanced or Metastatic Breast Cancer: Dx of advanced or metastatic breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received two or more prior anti-HER2 based regimens (e.g., trastuzumab + pertuzumab + docetaxel, ado-trastuzumab emtansine, etc.). Used in combination with capecitabine. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# NEULASTA (S)

## Products Affected

- Neulasta

- Neulasta Onpro Kit

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute’s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). Treatment of FN: Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with a hematologist/oncologist  |
| <b>Coverage Duration</b>            | ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.  |
| <b>Other Criteria</b>               | N/A  |

# NEXAVAR (S)

## Products Affected

- Sorafenib

- Sorafenib Tosylate TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease, metastatic disease, or unresectable disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC. One of the following: 1) Disease is progressive or 2) Disease is symptomatic with distant metastases. Trial and failure, contraindication, or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | DTC, MTC: Prescribed by or in consultation with an oncologist. RCC: Prescribed by or in consultation with an oncologist or nephrologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



# NEXLETOL (S)

## Products Affected

- Nexletol

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: One of the following diagnoses: A) Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age), AND b) One of the following: i) Family history (hx) of myocardial infarction in 1st-degree relative less than 60 years of age, ii) Family hx of myocardial infarction in 2nd-degree relative less than 50 years of age, iii) Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, iv) Family hx of FH in 1st- or 2nd-degree relative, or v) Family hx of tendinous xanthomas and/or arcus cornealis in 1st- or 2nd-degree relative, or (2) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age), AND b) One of the following: i) Functional mutation in the LDL receptor, ApoB, or PCSK9 gene, ii) Tendinous xanthomata, or iii) Arcus cornealis before age 45 OR B) Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, hx of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization (eg, percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG] surgery), stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin, or clinically significant coronary heart disease diagnosed by invasive or noninvasive testing (e.g., coronary angiography, stress test using treadmill, stress echocardiography or nuclear imaging). One of the following LDL-C values while on max tolerated statin tx within the last 120 days: (1) LDL-C greater than or equal to 70 mg/dL with ASCVD or (2) LDL-C greater than or equal to 100 mg/dL without ASCVD. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |

|                          |   |
|--------------------------|---|
| <b>Coverage Duration</b> | Initial: 6 months. Reauth: 12 months  |
| <b>Other Criteria</b>    | <p>Initial, cont: One of the following: (1) Pt has been receiving at least 12 weeks of one high-intensity statin (HIS) therapy (tx) [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIS at max tolerated dose, OR (2) Both of the following: a) Pt is unable to tolerate HIS as evidenced by one of the following intolerable and persistent (ie, more than 2 wks) symptoms: myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN) AND b) Pt has been receiving at least 12 weeks of one moderate-intensity statin (MIS) [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] or one low-intensity statin (LIS) [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] tx and will continue to receive a MIS or LIS at max tolerated dose, OR (3) Pt is unable to tolerate low-, moderate-, or high-intensity statins as evidenced by one of the following intolerable and persistent (ie, more than 2 weeks) symptoms: myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times ULN), OR (4) Pt has a labeled contraindication to all statins, OR (5) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx with CK elevations greater than 10 times ULN. AND Pt has been receiving at least 12 weeks of generic ezetimibe tx as adjunct to max tolerated statin tx or pt has a history of contraindication or intolerance to ezetimibe. Reauth: Documentation of positive clinical response to therapy (eg reduction in LDL-C levels). Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at the max tolerated dose or pt has a documented inability to take other lipid-lowering therapy (eg statins, ezetimibe).</p> |

# NEXLIZET (S)

## Products Affected

- Nexlizet

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: One of the following diagnoses: A) Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age), AND b) One of the following: i) Family history (hx) of myocardial infarction in 1st-degree relative less than 60 years of age, ii) Family hx of myocardial infarction in 2nd-degree relative less than 50 years of age, iii) Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, iv) Family hx of FH in 1st- or 2nd-degree relative, or v) Family hx of tendinous xanthomas and/or arcus cornealis in 1st- or 2nd-degree relative, or (2) Both of the following: a) Untreated/pre-treatment LDL-C greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age), AND b) One of the following: i) Functional mutation in the LDL receptor, ApoB, or PCSK9 gene, ii) Tendinous xanthomata, or iii) Arcus cornealis before age 45 OR B) Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, hx of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization (eg, percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG] surgery), stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin, or clinically significant coronary heart disease diagnosed by invasive or noninvasive testing (e.g., coronary angiography, stress test using treadmill, stress echocardiography or nuclear imaging). One of the following LDL-C values while on max tolerated statin tx within the last 120 days: (1) LDL-C greater than or equal to 70 mg/dL with ASCVD or (2) LDL-C greater than or equal to 100 mg/dL without ASCVD. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |

|                          |   |
|--------------------------|---|
| <b>Coverage Duration</b> | Initial: 6 months. Reauth: 12 months  |
| <b>Other Criteria</b>    | <p>Initial, cont: One of the following: (1) Pt has been receiving at least 12 weeks of one high-intensity statin (HIS) therapy (tx) [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIS at max tolerated dose, OR (2) Both of the following: a) Pt is unable to tolerate HIS as evidenced by one of the following intolerable and persistent (ie, more than 2 wks) symptoms: myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN) AND b) Pt has been receiving at least 12 weeks of one moderate-intensity statin (MIS) [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] or one low-intensity statin (LIS) [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] tx and will continue to receive a MIS or LIS at max tolerated dose, OR (3) Pt is unable to tolerate low-, moderate-, or high-intensity statins as evidenced by one of the following intolerable and persistent (ie, more than 2 weeks) symptoms: myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times ULN), OR (4) Pt has a labeled contraindication to all statins, OR (5) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx with CK elevations greater than 10 times ULN. AND Pt has been receiving at least 12 weeks of generic ezetimibe tx as adjunct to max tolerated statin tx or pt has a history of contraindication or intolerance to ezetimibe. Reauth: Documentation of positive clinical response to therapy (eg reduction in LDL-C levels). Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at the max tolerated dose or pt has a documented inability to take other lipid-lowering therapy (eg statins, ezetimibe).</p> |

## NINLARO (S)

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### Products Affected

- Ninlaro

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with Revlimid (lenalidomide) and dexamethasone. Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)]. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# NORTHERA (S)

## Products Affected

- Droxidopa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Neurogenic orthostatic hypotension (NOH) (init): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (eg, Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy. Trial and failure, contraindication, or intolerance to one of the following agents: fludrocortisone acetate, midodrine. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist  |
| <b>Coverage Duration</b>            | NOH (init): 1 month (reauth): 12 months   |
| <b>Other Criteria</b>               | NOH (reauth): Documentation of positive clinical response to therapy.   |

# NOXAFIL SUSPENSION (S)

## Products Affected

- Noxafil SUSP

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Prophylaxis of systemic fungal infections (SFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Oropharyngeal Candidiasis (OPC): Diagnosis of OPC. One of the following: 1) Trial and failure, contraindication, or intolerance to fluconazole OR 2) Susceptibility results demonstrate resistance to fluconazole. |
| <b>Age Restrictions</b>             | Prophylaxis of SFI, OPC: Patient is 13 years or older.   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Prophylaxis of SFI: 6 months. OPC: 1 month.  |
| <b>Other Criteria</b>               | N/A  |

## NUBEQA (S)

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### Products Affected

- Nubeqa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-metastatic castration-resistant or castration-recurrent prostate cancer (nmCRPC): Diagnosis of non-metastatic castration-resistant (chemical or surgical) or castration-recurrent prostate cancer. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or urologist   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |



# NUCALA (S)

## Products Affected

- Nucala

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | <p>Asthma (init): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by one of the following: baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter or peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months. Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months or Patient has had a prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and ii) additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Diagnosis of EGPA. Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy). Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone).</p> |
| Age Restrictions             | Asthma (init): Age greater than or equal to 6 years  |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | Asthma (init, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (init, reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist. HES (init): Prescribed by or in consultation with an allergist/immunologist or hematologist.   |
| <b>Coverage Duration</b>       | Asthma (init): 6 mo, Asthma (reauth): 12 months. CRSwNP, EGPA, HES (init, reauth): 12 months   |
| <b>Other Criteria</b>          | Hypereosinophilic Syndrome (HES) (init): Diagnosis of HES. Patient has been diagnosed for at least 6 months. Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy). Patient is FIP1L1-PDGFR $\alpha$ -negative. Patient has uncontrolled HES defined as both of the following: a) History of 2 or more flares within the past 12 months AND b) Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter. Trial and failure, contraindication, or intolerance to corticosteroid therapy (e.g., prednisone) or cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib). Asthma (reauth): Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second (FEV1), decreased use of rescue medications). Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. CRSwNP (reauth): Documentation of positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS, 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS, 0-10 scale]). Used in combination with another agent for CRSwNP. EGPA (reauth): Documentation of positive clinical response to therapy (e.g., increase in remission time). HES (reauth): Documentation of positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose). |

# NUEDEXTA (S)

## Products Affected

- Nuedexta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome, c) Known hypersensitivity to dextromethorphan (e.g., rash, hives), d) Taking monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, selegiline, tranylcypromine) or have taken MAOIs within the preceding 14 days, e) Has prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or has heart failure, f) Receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), g) Has complete atrioventricular (AV) block without implanted pacemakers, or at high risk of complete AV block.</p> <p>PBA (reauth): Documentation of clinical benefit from ongoing therapy as demonstrated by a decrease in inappropriate laughing or crying episodes.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | PBA (initial): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist.  |
| <b>Coverage Duration</b>            | PBA (initial/reauth): 12 months  |
| <b>Other Criteria</b>               | N/A  |

## NUPLAZID (S)

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### Products Affected

- Nuplazid

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# NUVIGIL (S)

## Products Affected

- Armodafinil

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: a) 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or b) both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), AND 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial):Dx of SWD confirmed by one of the following: 1) symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | OSA, SWD: Initial, Reauth: 6 mo. Narcolepsy: Initial, Reauth: 12 mo  |
| <b>Other Criteria</b>               | OSA, Narcolepsy (Reauth): Documentation of positive clinical response to armodafinil therapy. SWD (Reauth): Documentation of positive clinical response to armodafinil therapy.  |

# OCREVUS (S)

## Products Affected

- Ocrevus

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Relapsing forms of multiple sclerosis (initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesion). One of the following: 1) Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Kesimpta (ofatumumab), C) Lemtrada (alemtuzumab), D) Mavenclad (cladribine), E) Plegridy (peginterferon beta-1a), F) Tysabri (natalizumab), G) Any one of the interferon beta-1a injections (eg, Avonex), H) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), I) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), J) Any one of the glatiramer acetates (eg, Copaxone, Glatopa, generic glatiramer acetate), K) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya [fingolimod], Mayzent [siponimod], Zeposia [ozanimod]), OR 2) For continuation of prior therapy. Primary progressive MS (initial): Diagnosis of primary progressive multiple sclerosis (PPMS). All indications (initial, reauth): Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]). Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | All uses (initial, reauth): Prescribed by or in consultation with a neurologist   |
| <b>Coverage Duration</b>            | All uses (initial, reauth): 12 months   |

|                       |  |
|-----------------------|--|
| <b>Other Criteria</b> | All indications (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). |
|-----------------------|--|

# ODOMZO (S)

## Products Affected

- Odomzo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma AND One of the following: 1) Cancer has recurred following surgery or radiation therapy or 2) Patient is not a candidate for surgery or radiation therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or dermatologist  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



# OFEV (S)

## Products Affected

- Ofev

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (initial): Diagnosis of SSc-ILD as documented by all of the following: a) exclusion of other known causes of ILD (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on HRCT revealing SSc-ILD or probable SSc-ILD, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD. Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype (initial): 1) diagnosis of chronic fibrosing interstitial lung disease, AND 2) patient has a high-resolution computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features, AND 3) disease has a progressive phenotype as observed by one of the following: decline of forced vital capacity (FVC), worsening of respiratory symptoms, or increased extent of fibrosis seen on imaging.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (initial): Prescribed by or in consultation with a pulmonologist   |

|                          |   |
|--------------------------|---|
| <b>Coverage Duration</b> | Initial, reauth: 12 months  |
| <b>Other Criteria</b>    | IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (reauth): Documentation of positive clinical response to therapy. |

# ONUREG (S)

## Products Affected

- Onureg

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML). Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin, etc.). Patient has achieved one of the following: a) first complete remission (CR) or b) complete remission with incomplete blood count recovery (CRi). Patient is not able to complete intensive curative therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## OPDUALAG (S)

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### Products Affected

- Opdualag

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | One of the following diagnoses: unresectable melanoma or metastatic melanoma. Both of the following: patient is 12 years of age or older AND patient weighs at least 40 kg (88 lbs). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# OPSUMIT (S)

## Products Affected

- Opsumit

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.   |
| <b>Coverage Duration</b>            | PAH: Initial: 6 months. Reauth: 12 months.  |
| <b>Other Criteria</b>               | PAH (Reauth): Documentation of positive clinical response to therapy.   |

## OPZELURA (S)

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### Products Affected

- Opzelura

| <b>PA Criteria</b>                  | <b>Criteria Details</b> |
|-------------------------------------|-------------------------|
| <b>Indications</b>                  | Pending CMS Review      |
| <b>Off-Label Uses</b>               | Pending CMS Review      |
| <b>Exclusion Criteria</b>           | Pending CMS Review      |
| <b>Required Medical Information</b> | Pending CMS Review      |
| <b>Age Restrictions</b>             | Pending CMS Review      |
| <b>Prescriber Restrictions</b>      | Pending CMS Review      |
| <b>Coverage Duration</b>            | Pending CMS Review      |
| <b>Other Criteria</b>               | Pending CMS Review      |

## ORENITRAM (S)

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### Products Affected

- Orenitram TBCR 0.25MG, 1MG, 2.5MG, 5MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.   |
| <b>Coverage Duration</b>            | PAH: Initial: 6 months. Reauth: 12 months.  |
| <b>Other Criteria</b>               | PAH (Reauth): Documentation of positive clinical response to therapy.   |

# ORGOVYX (S)

## Products Affected

- Orgovyx

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Prostate Cancer: Diagnosis of advanced prostate cancer. Disease is one of the following: 1) Evidence of biochemical or clinical relapse following local primary intervention with curative intent or 2) Newly diagnosed androgen-sensitive metastatic disease or 3) Advanced localized disease unlikely to be cured by local primary intervention with curative intent. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an urologist or oncologist.   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



# ORILISSA (S)

## Products Affected

- Orilissa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Endometriosis (EM) (initial - 150 mg): Diagnosis of moderate to severe pain associated with EM. One of the following: 1) History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progesterone) oral contraceptive, or progestins, or 2) Patient has had surgical ablation to prevent recurrence. EM (200 mg): Diagnosis of moderate to severe pain associated with EM. One of the following: 1) History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following: danazol, combination (estrogen/progesterone) oral contraceptive, or progestins, or 2) Patient has had surgical ablation to prevent recurrence. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | EM (init, reauth-150mg): 6 mo. EM (200mg): 6 mo.  |
| <b>Other Criteria</b>               | EM (reauthorization - 150 mg): Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain). Treatment duration has not exceeded a total of 24 months.  |

# ORKAMBI (S)

## Products Affected

- Orkambi TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | CF (Initial): Patient is 6 years of age or older  |
| <b>Prescriber Restrictions</b>      | CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist  |
| <b>Coverage Duration</b>            | CF (initial, reauth): 12 months   |
| <b>Other Criteria</b>               | CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).   |

# ORKAMBI GRANULES (S)

## Products Affected

- Orkambi PACK 125MG; 100MG, 188MG; 150MG

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: A) Patient is 2 through 5 years of age, OR B) Both of the following: Patient is 6 years of age or greater AND Patient is unable to swallow oral tablets. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | CF (Initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist   |
| Coverage Duration            | CF (initial, reauth): 12 months  |
| Other Criteria               | CF (Reauth): Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). One of the following: A) Patient is 2 through 5 years of age, OR B) Both of the following: Patient is 6 years of age or greater AND Patient is unable to swallow oral tablets.  |

# OSMOLEX ER (S)

## Products Affected

- Osmolex Er

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Parkinson's Disease (PD) (initial): Diagnosis of Parkinson's disease. Trial and failure or intolerance to both of the following: A) amantadine immediate release AND B) one of the following: carbidopa-levodopa, MAO-B inhibitor (e.g., rasagiline, selegiline), or dopamine agonist (e.g., pramipexole, ropinirole). Drug-Induced Extrapyramidal Reactions (EPS) (initial): Patient is experiencing drug-induced extrapyramidal reactions. One of the following: A) Patient has persistent extrapyramidal symptoms despite a trial of dose reduction, tapering, or discontinuation of the offending medication OR B) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Trial and failure or intolerance to amantadine immediate release. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | PD (initial): Prescribed by or in consultation with a neurologist. EPS (initial): Prescribed by or in consultation with a neurologist or psychiatrist.   |
| <b>Coverage Duration</b>            | PD, EPS (initial, reauth): 12 months   |
| <b>Other Criteria</b>               | PD, EPS (Reauth): Documentation of positive clinical response to therapy   |

# OSPHERA (S)

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## Products Affected

- Ospheña

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Dyspareunia (initial): Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Vaginal dryness (initial): Diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | All uses (Initial, reauth): 12 months   |
| <b>Other Criteria</b>               | Dyspareunia, Vaginal dryness (reauth): Documentation of positive clinical response to therapy.  |

# OXANDRIN (S)

## Products Affected

- Oxandrolone TABS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Promote weight gain (initial): Used as adjunctive therapy to promote weight gain AND Diagnosis of one of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons AND a nutritional consult was performed. Counterbalance protein catabolism (initial): Used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain: Diagnosis of bone pain associated with osteoporosis. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | bone pain: 1 month. Others (initial, reauth): 3 months   |
| <b>Other Criteria</b>               | All diagnoses except bone pain (reauth): Documentation of a positive clinical response to therapy as evidenced by an improvement in weight gain or increase in lean body mass.   |

# OXBRYTA (S)

## Products Affected

- Oxbryta TBSO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Initial: Diagnosis of Sickle Cell Disease. Documentation of hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation. Trial and failure or inadequate response, contraindication, or intolerance to hydroxyurea.  |
| <b>Age Restrictions</b>             | Initial: Patient is 4 years of age or older.   |
| <b>Prescriber Restrictions</b>      | Initial: Prescribed by or in consultation with one of the following: 1) Hematologist/Oncologist or 2) Specialist w/ expertise in the diagnosis and management of sickle cell disease.  |
| <b>Coverage Duration</b>            | Initial, Reauth: 12 months.  |
| <b>Other Criteria</b>               | Reauth: Documentation of positive clinical response to therapy (e.g., an increase in hemoglobin level of 1 g/dL or greater from baseline, decreased annualized incidence rate of vaso-occlusive crises [VOCs]).<br>Documentation of hemoglobin level that does not exceed 10.5 g/dL. |

## OXLUMO (S)

### Products Affected

- Oxlumo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Primary Hyperoxaluria Type 1 (PH1) (initial): Diagnosis of PH1. Diagnosis has been confirmed by both of the following: 1) One of the following: a) Elevated urinary oxalate excretion or b) Elevated plasma oxalate concentration, AND 2) Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene. Patient has not received a liver transplant. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PH1 (initial, reauth): Prescribed by or in consultation with one of the following: nephrologist, urologist, geneticist, or specialist with expertise in the treatment of PH1.   |
| <b>Coverage Duration</b>            | PH1 (initial, reauth): 12 months.   |
| <b>Other Criteria</b>               | PH1 (reauth): Documentation of positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration). Patient has not received a liver transplant.  |



## PEGASYS (S)

### Products Affected

- Pegasys
- Pegasys Proclick INJ 180MCG/0.5ML

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.  |
| <b>Other Criteria</b>               | N/A   |

# PEMAZYRE (S)

## Products Affected

- Pemazyre

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is one of the following: unresectable locally advanced or metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has been previously treated. Myeloid/lymphoid neoplasms: Diagnosis of myeloid/lymphoid neoplasms (MLNs). Disease is relapsed or refractory. Disease has presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## PENNSAID (S)

### Products Affected

- Diclofenac Sodium EXTERNAL SOLN 1.5%

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees. Patient meets one of the following: 1) Treatment failure with at least two prescription strength topical or oral non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) OR 2) History of peptic ulcer disease/gastrointestinal bleed OR 3) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Initial, reauth: 12 months  |
| <b>Other Criteria</b>               | Osteoarthritis of the knees (reauth): Documentation of positive clinical response to therapy (e.g., improvement in pain symptoms of osteoarthritis).  |

# PHESGO (S)

## Products Affected

- Phesgo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Early Breast Cancer (EBC): Diagnosis of breast cancer. Used in combination with chemotherapy. Disease is human epidermal growth factor receptor 2 (HER2)-positive. One of the following: a) Used for neoadjuvant treatment and disease is one of the following: locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), OR b) Used for adjuvant treatment and disease is early breast cancer at high risk of recurrence. Metastatic Breast Cancer (MBC): Diagnosis of breast cancer. Used in combination with docetaxel. Disease is human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer. Patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## PIQRAY (S)

### Products Affected

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

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Breast Cancer (BC): Diagnosis of advanced or metastatic BC. Disease is hormone receptor (HR)-positive, and human epidermal growth factor receptor 2 (HER2)-negative. Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient is a postmenopausal woman or male. Used in combination with fulvestrant. Disease has progressed on or after an endocrine-based regimen. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | Prescribed by or in consultation with an oncologist.  |
| Coverage Duration            | 12 months   |
| Other Criteria               | Approve for continuation of prior therapy.  |

## POLIVY (S)

### Products Affected

- Polivy

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diffuse large B-cell lymphoma (DLBCL): Diagnosis of diffuse large B-cell lymphoma (DLBCL). Disease is relapsed or refractory. Used in combination with bendamustine and a rituximab product. Patient has received at least two prior therapies for DLBCL (e.g., RCHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone], HSCT [hematopoietic stem cell transplantation], CAR T [chimeric antigen receptor T-cell] therapy, RCEPP [rituximab, cyclophosphamide, etoposide, prednisone, procarbazine], GemOx [gemcitabine, oxaliplatin] with or without rituximab). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# POMALYST (S)

## Products Affected

- Pomalyst

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Multiple Myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone. Patient has received two prior therapies, including Revlimid (lenalidomide) and a proteasome inhibitor [eg, Velcade (bortezomib) or Kyprolis (carfilzomib)] or has a contraindication or intolerance to Revlimid and proteasome inhibitors. Patient has experienced disease progression on or within 60 days of completion of last therapy. Kaposi sarcoma (KS): One of the following: 1) Both of the following: a) Diagnosis of AIDS-related KS and b) Patient has failed highly active antiretroviral therapy (HAART) [e.g., Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide), Dovato (dolutegravir/lamivudine), Triumeq (dolutegravir/abacavir/lamivudine)], OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV-negative. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | All indications: Prescribed by or in consultation with an oncologist or hematologist.   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# POSACONAZOLE TABLET (S)

## Products Affected

- Posaconazole Dr

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Prophylaxis of systemic fungal infections (SFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Treatment (Tx) of SFI: Used as treatment of systemic fungal infections caused by Aspergillus. |
| <b>Age Restrictions</b>             | Prophylaxis of SFI: Patient is 2 years of age or older. Tx of SFI: Patient is 13 years of age or older.   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Prophylaxis of SFI: 6 months. Tx of SFI: 3 months.  |
| <b>Other Criteria</b>               | N/A   |



# PRALUENT (S)

## Products Affected

- Praluent

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | <p>HeFH/ASCVD/Primary HLD (init): One of the following dx: A)HeFH as confirmed by one of the following: 1)Both of the following: a)Untreated/pre-treatment LDL greater than 190 mg/dL in an adult, AND b)One of the following: i) Family hx of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii)Hx of myocardial infarction (MI) in 1st-degree relative less than 60 years of age, iii)Family hx of MI in 2nd-degree relative less than 50 years of age, iv)Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, v)Family hx of FH in 1st- or 2nd-degree relative, or 2)Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND submission of MR (eg chart notes, lab values) documenting one of the following: presence of tendinous xanthoma in pt, arcus cornealis before age 45, or functional mutation in the LDL receptor, ApoB, or PCSK9 gene. OR B)ASCVD as confirmed by ACS, hx of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin OR C)Primary hyperlipidemia (HLD). HoFH (init): Sub of MR (eg, chart notes, lab values) documenting dx of HoFH as confirmed by one of the following: 1)Gen confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2)either untreated LDL greater than 500 or treated LDL greater than 300, AND either xanthoma before 10 yo or evidence of HeFH in both parents. HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of the following: a)One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: 1)LDL greater than or equal to 100 mg/dL w/ASCVD, or 2)LDL greater than or equal to 130 mg/dL w/o ASCVD. AND b)One of the following: 1)Pt has been receiving at least 12 wks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] at max tolerated dose.</p> |
| Age Restrictions             | N/A   |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | Initial/Reauth: Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist   |
| <b>Coverage Duration</b>       | Initial: 6 months. Reauth: 12 months   |
| <b>Other Criteria</b>          | <p>Set A (cont, initial): OR (2) Both of the following: A) Pt unable to tolerate HI statin as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN) AND B) One of the following: a) Pt has been receiving at least 12 wks of one moderate-intensity (MI) or low-intensity (LI) statin tx and will continue to receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at max tolerated dose, OR b) Pt is unable to tolerate MI or LI statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN), OR (3) Pt has a labeled contraindication to all statins, OR (4) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin treatment w/ CK elevations greater than 10 times ULN on one statin tx. OR set B) Both of the following: a) One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: (1) LDL b/t 70 and 99 mg/dL w/ ASCVD. (2) LDL b/t 100 and 129 mg/dL w/o ASCVD. AND b) Both of the following: (1) One of the following: i) Pt has been receiving at least 12 wks of one max-tolerated statin tx and will continue to receive a statin at max tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN, iii) Patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx w/ CK elevations greater than 10 times ULN on one statin tx and (2) Pt has been receiving at least 12 weeks of ezetimibe (Zetia) tx as adjunct to max tolerated statin tx OR Pt has a hx of contraindication or intolerance to ezetimibe. HoFH (init): One of the following: 1)Pt is receiving other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD (reauth): Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at max tolerated dose (unless pt has documented inability to take these medications). HoFH (reauth): One of the following: 1)Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD/HoFH (reauth): Submission of MR (eg, lab values) documenting LDL reduction while on Praluent therapy.</p> |

# PROMACTA (S)

## Products Affected

- Promacta

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: relapsed/refractory ITP, persistent ITP, or chronic ITP. Baseline platelet count is less than 30,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. Trial and failure, intolerance, contraindication to corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytopenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) currently receiving interferon-based treatment. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy). Used in combination with standard immunosuppressive therapy (e.g., horse antithymocyte globulin, cyclosporine). Patient meets at least two of the following: 1) absolute neutrophil count less than 500/mcL, 2) platelet count less than 20,000/mcL, 3) absolute reticulocyte count less than 60,000/mcL. Refractory SAA (initial): Diagnosis of refractory severe aplastic anemia. Patient has a platelet count less than 30,000/mcL. Insufficient response to immunosuppressive therapy (e.g., horse antithymocyte globulin, cyclosporine). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | ITP and SAA: Prescribed by or in consultation with a hematologist/oncologist. Chronic hepatitis C associated thrombocytopenia: Prescribed by or in consultation with a hematologist/oncologist, gastroenterologist, hepatologist, infectious disease specialist, or HIV specialist certified through the American Academy of HIV Medicine.   |
| <b>Coverage Duration</b>            | ITP(init, reauth): 12mo. HepC: 3mo(init), 12mo(reauth). 1st line SAA: 6mo. Refract SAA: 16wk-init, 12mo-reauth   |

|                       |  |
|-----------------------|--|
| <b>Other Criteria</b> | ITP (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. Hepatitis C (reauth): One of the following: 1) For patients that started treatment with eltrombopag prior to initiation of treatment with interferon, eltrombopag will be approved when both of the following are met: a) Currently on antiviral interferon therapy for treatment of chronic hepatitis C and b) Documentation that the patient reached a threshold platelet count that allows initiation of antiviral interferon therapy with eltrombopag treatment by week 9, OR 2) For patients that started treatment with eltrombopag while on concomitant treatment with interferon, eltrombopag will be approved based on the following: Currently on antiviral interferon therapy for treatment of chronic hepatitis C. Refractory SAA (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count. |
|-----------------------|--|

# PROVIGIL (S)

## Products Affected

- Modafinil

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | <p>Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial):Dx of SWD confirmed by one of the following: 1) Symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). MS Fatigue (initial): Dx of multiple sclerosis (MS). Patient is experiencing fatigue. Depression (initial): Treatment-resistant depression defined as diagnosis of major depressive disorder (MDD) or bipolar depression, AND trial and failure, contraindication, or intolerance to at least two antidepressants from different classes (eg, SSRIs, SNRIs, bupropion). Used as adjunctive therapy. Idiopathic Hypersomnia (Initial): Diagnosis of idiopathic hypersomnia as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible).</p> |
| Age Restrictions             | N/A   |

|                                |   |
|--------------------------------|---|
| <b>Prescriber Restrictions</b> | N/A   |
| <b>Coverage Duration</b>       | Narcolepsy: Init, Reauth: 12 mo. All other indications: Init, Reauth: 6 mo.   |
| <b>Other Criteria</b>          | OSA, Narcolepsy, Idiopathic Hypersomnia (Reauth): Documentation of positive clinical response to modafinil therapy. SWD (Reauth): Documentation of positive clinical response to modafinil therapy. MS Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil therapy. Depression (reauth): Documentation of positive clinical response to modafinil therapy. Used as adjunctive therapy. |

# PULMOZYME (S)

## Products Affected

- Pulmozyme SOLN 2.5MG/2.5ML

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Cystic Fibrosis (CF) (Initial, Reauth): Diagnosis of CF.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | CF (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | Part B vs D determination applies. CF (reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). |

# PYRUKYND (S)

## Products Affected

- Pyrukynd

- Pyrukynd Taper Pack

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count). Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene: a) Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant AND b) Patients is not homozygous for the c.1436G to A (p.R479H) variant AND c) Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene. Hemoglobin is less than or equal to 10g/dL. Patient has symptomatic anemia or is transfusion dependent. Exclusion of other causes of hemolytic anemias (e. g., infections, toxins, drugs). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Initial, Reauth: Prescribed by or in consultation with a hematologist.  |
| <b>Coverage Duration</b>            | Initial: 6 months. Reauth: 12 months.   |
| <b>Other Criteria</b>               | Reauth: Documentation of positive clinical response to therapy [e.g., hemoglobin greater than or equal to 1.5g/dL from baseline, reduction in transfusions of greater than or equal to 33% in the number of red blood cell units transfused during the fixed dose period compared with the patient's historical transfusion burden, improvement in markers of hemolysis from baseline (e.g., bilirubin, lactated dehydrogenase [LDH], haptoglobin, reticulocyte count)].  |



## QINLOCK (S)

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### Products Affected

- Qinlock

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Gastrointestinal Stromal Tumor (GIST): Diagnosis of gastrointestinal stromal tumor (GIST). Disease is advanced. Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# QUALAQUIN (S)

## Products Affected

- Quinine Sulfate CAPS 324MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | Excluded if used solely for the treatment or prevention of nocturnal leg cramps.  |
| <b>Required Medical Information</b> | Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria, and trial and failure, contraindication, or intolerance to chloroquine or hydroxychloroquine, OR 2) Treatment in areas of chloroquine-resistant malaria. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 7 days  |
| <b>Other Criteria</b>               | N/A   |

## RADICAVA ORS (S)

### Products Affected

- Radicava Ors

- Radicava Ors Starter Kit

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Amyotrophic lateral sclerosis (ALS) (initial): Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support a diagnosis of “definite” or “probable” ALS per the revised El Escorial diagnostic criteria. Patient has scores of greater than or equal to 2 in all items of the ALS Functional Rating Scale-Revised (ALSFRS-R) criteria at the start of treatment. Patient has a percent forced vital capacity (%FVC) of greater than or equal to 80% at the start of treatment. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | ALS (initial): Prescribed by or in consultation with a neurologist.  |
| <b>Coverage Duration</b>            | Initial, reauth: 6 months  |
| <b>Other Criteria</b>               | ALS (reauthorization): Documentation of a benefit from therapy (e.g., slowing in the decline of functional abilities), and patient is not dependent on invasive ventilation or tracheostomy.   |

# REMICADE (S)

## Products Affected

- Infliximab

- Remicade

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | <p>Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (Initial): Diagnosis (Dx) of moderately to severely active CD or FCD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Ulcerative colitis (UC) (Initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine). Rheumatoid arthritis (RA) (Initial): Dx of moderately to severely active RA. Used in combination with methotrexate. Psoriatic arthritis (PsA) (Initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (Initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar.</p> |
| <b>Age Restrictions</b>             | N/A   |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | CD, FCD, UC (initial): Prescribed by or in consultation with a gastroenterologist. RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.   |
| <b>Coverage Duration</b>       | All uses (initial): 6 months, (reauth): 12 months  |
| <b>Other Criteria</b>          | Ankylosing spondylitis (AS) (Initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Sarcoidosis (Initial): Dx of sarcoidosis. TF/C/I to both of the following: one immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine) AND one corticosteroid (eg, prednisone). Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (Reauth): Documentation of positive clinical response to therapy. |

# RENFLEXIS (S)

## Products Affected

- Renflexis

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | <p>Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Diagnosis (Dx) of moderately to severely active CD or FCD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (eg, prednisone), methotrexate. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, 6-mercaptopurine. Rheumatoid arthritis (RA) (initial): Dx of moderately to severely active RA. Used in combination with methotrexate. Psoriatic arthritis (PsA) (initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar.</p> |
| Age Restrictions             | N/A   |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | <p>Initial: RA, AS: Prescribed by or in consultation with a rheumatologist.<br/> PsA: Prescribed or in consultation with a rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed by or in consultation with a gastroenterologist. Plaque Psoriasis: Prescribed by or in consultation with a dermatologist.<br/> Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.</p>   |
| <b>Coverage Duration</b>       | <p>All indications (initial): 6 months, (reauth): 12 months</p>  |
| <b>Other Criteria</b>          | <p>Ankylosing spondylitis (AS) (initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Sarcoidosis (initial): Dx of sarcoidosis. TF/C/I to one of the following: corticosteroid (eg, prednisone) OR immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine). All indications (initial): Trial and failure or intolerance to Remicade or Infliximab. Plaque psoriasis (reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (reauth): Documentation of positive clinical response to therapy.</p> |

# REPATHA (S)

## Products Affected

- Repatha
- Repatha Pushtronex System
- Repatha Sureclick

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | <p>HeFH/ASCVD/Primary HLD (init): One of the following dx: A)HeFH as confirmed by one of the following: 1)Both of the following: a)Untreated/pre-treatment LDL greater than 190 mg/dL in an adult, AND b)One of the following: i) Family hx of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii)Hx of myocardial infarction (MI) in 1st-degree relative less than 60 years of age, iii)Family hx of MI in 2nd-degree relative less than 50 years of age, iv)Family hx of LDL-C greater than 190 mg/dL in 1st- or 2nd-degree relative, v)Family hx of FH in 1st- or 2nd-degree relative, or 2)Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND submission of MR (eg chart notes, lab values) documenting one of the following: presence of tendinous xanthoma in pt, arcus cornealis before age 45, or functional mutation in the LDL receptor, ApoB, or PCSK9 gene. OR B)ASCVD as confirmed by ACS, hx of MI, stable or unstable angina, coronary or other arterial revascularization, stroke,TIA, or peripheral arterial disease presumed to be of atherosclerotic origin. OR C)Primary hyperlipidemia (HLD). HoFH (init): Sub of MR (eg, chart notes, lab values) documenting dx of HoFH as confirmed by one of the following: 1)Gen confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2)either untreated LDL greater than 500 or treated LDL greater than 300, AND either xanthoma before 10 yo or evidence of HeFH in both parents. HeFH/ASCVD/Primary HLD (init): One of the following: set A)Both of the following: a)One of the following LDL values while on max tolerated lipid lowering regimen w/in the last 120 days: 1)LDL greater than or equal to 100 mg/dL w/ASCVD, or 2)LDL greater than or equal to 130 mg/dL w/o ASCVD. AND b)One of the following: 1)Pt has been receiving at least 12 wks of one high-intensity (HI) statin therapy (tx) and will continue to receive a HI statin [ie, atorvastatin 40-80 mg, rosuvastatin 20-40 mg] at max tolerated dose.</p> |
| Age Restrictions             | (Initial) HeFH/HoFH: 10 years or older.   |



|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | Initial/Reauth: Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist   |
| <b>Coverage Duration</b>       | Initial: 6 months. Reauth: 12 months   |
| <b>Other Criteria</b>          | <p>Set A (cont, initial): OR (2) Both of the following: A) Pt unable to tolerate HI statin as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN) AND B) One of the following: a) Pt has been receiving at least 12 wks of one moderate-intensity (MI) or low-intensity (LI) statin tx and will continue to receive a MI or LI statin [ie, atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at max tolerated dose, OR b) Pt is unable to tolerate MI or LI statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN), OR (3) Pt has a labeled contraindication to all statins, OR (4) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin treatment w/ CK elevations greater than 10 times ULN on one statin tx. OR set B) Both of the following: a) One of the following LDL values while on max tolerated lipid lowering tx w/in the last 120 days: (1) LDL b/t 70 and 99 mg/dL w/ ASCVD. (2) LDL b/t 100 and 129 mg/dL w/o ASCVD. AND b) Both of the following: (1) One of the following: i) Pt has been receiving at least 12 wks of one max-tolerated statin tx and will continue to receive a statin at max tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms w/o CK elevations) or myositis (muscle symptoms w/ CK elevations less than 10 times ULN, iii) Patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms w/ statin tx w/ CK elevations greater than 10 times ULN on one statin tx and (2) Pt has been receiving at least 12 weeks of ezetimibe (Zetia) tx as adjunct to max tolerated statin tx OR Pt has a hx of contraindication or intolerance to ezetimibe. HoFH (init): One of the following: 1)Pt is receiving other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD (reauth): Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at max tolerated dose (unless pt has documented inability to take these medications). HoFH (reauth): One of the following: 1)Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD/HoFH (reauth): Sub of MR (eg, lab values) documenting LDL reduction while on Repatha tx.</p> |

# RETACRIT (S)

## Products Affected

- Retacrit

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial): Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is receiving chemo.</p> <p>Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% or Hgb less than 12 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa.</p> <p>Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |

|                          |  |
|--------------------------|--|
| <b>Coverage Duration</b> | CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo.   |
| <b>Other Criteria</b>    | <p>Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Documentation of a positive clinical response to therapy from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Documentation of a positive clinical response to therapy from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Documentation of a positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Documentation of a positive clinical response to therapy from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Documentation of a positive clinical response to therapy from pre-treatment level. Other Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.</p> |

# RETEVMO (S)

## Products Affected

- Retevmo

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Lung Cancer: Diagnosis of metastatic non-small cell lung cancer (NSCLC). Disease has presence of RET gene fusion-positive tumor(s).<br>Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation tumor(s). Disease requires treatment with systemic therapy.<br>Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Lung Cancer, MTC: Prescribed by or in consultation with an oncologist.<br>Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.  |
| <b>Coverage Duration</b>            | Lung Cancer, MTC, Thyroid Cancer: 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## REVATIO (S)

### Products Affected

- Sildenafil Citrate TABS 20MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.   |
| <b>Coverage Duration</b>            | PAH: Initial: 6 months. Reauth: 12 months.  |
| <b>Other Criteria</b>               | PAH (Reauth): Documentation of positive clinical response to therapy.   |

## REVCOVI (S)

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### Products Affected

- Revcovi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | N/A   |

## REVLIMID (S)

### Products Affected

- Lenalidomide

- Revlimid CAPS 2.5MG, 20MG

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Multiple myeloma (MM): Diagnosis of MM. Either used as 1) combination therapy with dexamethasone, or 2) maintenance therapy following autologous hematopoietic stem cell transplantation (auto-HSCT). Myelodysplastic syndromes (MDS): Diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q. Mantle cell lymphoma (MCL): Diagnosis of MCL. Disease has relapsed after, is refractory to, or progressed after at least one prior therapy (eg, bortezomib, bendamustine, cladribine, rituximab). Follicular Lymphoma (FL): Diagnosis of FL that has been previously treated. Used in combination with a rituximab product. Marginal Zone Lymphoma (MZL): Diagnosis of MZL that has been previously treated. Used in combination with a rituximab product. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | Prescribed by or in consultation with an oncologist/hematologist  |
| Coverage Duration            | 12 months   |
| Other Criteria               | Approve for continuation of prior therapy.  |

# REZUROCK (S)

## Products Affected

- Rezurock

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Chronic graft versus host disease (cGVHD) (initial): Diagnosis of cGVHD. Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | cGVHD (initial): Prescribed by or in consultation with one of the following: hematologist, oncologist, or physician experienced in the management of transplant patients.         |
| <b>Coverage Duration</b>            | cGVHD (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | cGVHD (reauth): Patient does not show evidence of progressive disease while on therapy.   |



## RILUTEK (S)

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### Products Affected

- Riluzole

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Amyotrophic lateral sclerosis (ALS): Diagnosis of amyotrophic lateral sclerosis (ALS). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | ALS: 12 months   |
| <b>Other Criteria</b>               | N/A  |

# RINVOQ (S)

## Products Affected

- Rinvoq

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Rheumatoid arthritis (RA) (initial - 15mg): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Psoriatic arthritis (PsA - 15mg) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS) (initial - 15 mg): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Atopic dermatitis (AD) (initial - 15mg and 30mg): Diagnosis of moderate to severe AD. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. One of the following: 1) Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of AD (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.), OR 2) Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved AD therapies: Adbry (tralokinumab-ldrm) and Dupixent (dupilumab). Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine).</p> |
| <b>Age Restrictions</b>             | AD (initial): Patient is 12 years of age or older  |

|                                |   |
|--------------------------------|---|
| <b>Prescriber Restrictions</b> | RA, AS (initial): Prescribed by or in consultation with a rheumatologist.<br>PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (initial): Prescribed by or in consultation with a dermatologist or allergist/immunologist. UC (initial): Prescribed by or in consultation with a gastroenterologist. |
| <b>Coverage Duration</b>       | RA, PsA, AS, UC, AD (initial): 6 months, (reauth): 12 months.   |

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**Other Criteria**

RA, PsA, AS (initial - 15mg): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). Not used in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). Ulcerative colitis (UC) (initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). Not used in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine). RA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. RA, PsA, AS (Reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). AD (reauth): Documentation of a positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. Not used in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine). UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (eg, azathioprine, cyclosporine).

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# ROZLYTREK (S)

## Products Affected

- Rozlytrek

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer (NSCLC). Patient has ROS1 rearrangement positive tumor(s). Solid Tumors: Patient has solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.). Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions). Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) or disease has no satisfactory alternative treatments. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# RUBRACA (S)

## Products Affected

- Rubraca

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Ovarian cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) Both of the following: a) Presence of deleterious BRCA mutation as detected by a U.S. Food and Drug Administration (FDA)-approved diagnostic test (e.g., FoundationFocus CDxBRCA Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Trial and failure, contraindication, or intolerance to two or more chemotherapies (e.g., cisplatin, carboplatin), OR 2) Both of the following: a) Disease is recurrent and b) Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer. Presence of deleterious BRCA mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received previous treatment with both of the following: 1) Androgen receptor-directed therapy [e.g., Erleada (apalutamide), Xtandi (enzalutamide), Zytiga (abiraterone)], AND 2) A taxane-based chemotherapy [e.g., docetaxel, Jevtana (cabazitaxel)]. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Ovarian cancer: Prescribed by or in consultation with an oncologist.<br>Prostate cancer: Prescribed by or in consultation with an oncologist or urologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy   |

# RUXIENCE (S)

## Products Affected

- Ruxience

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Non-Hodgkin's Lymphoma (NHL): One of the following: 1) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Used as first-line treatment in combination with chemotherapy, 2) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy. Used as monotherapy for maintenance therapy, 3) Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma. One of the following: a) Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy or, b) Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy, 4) Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma, 5) Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma. Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens, OR 6) Diagnosis of one of the following previously untreated, advanced stage indications: a) CD-20-positive diffuse large B-cell lymphoma, b) Burkitt lymphoma, c) Burkitt-like lymphoma, or d) mature B-cell acute leukemia. Patient is 6 months of age or older. Used in combination with chemotherapy. Chronic Lymphocytic Leukemia (CLL): Diagnosis of chronic lymphocytic leukemia. Used in combination with fludarabine and cyclophosphamide.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | NHL, CLL: Prescribed by or in consultation with a hematologist/oncologist. RA: Prescribed by or in consultation with a rheumatologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.  |

|                          |  |
|--------------------------|--|
| <b>Coverage Duration</b> | NHL, CLL: 12 months. WG, MPA: 3 months. RA: 1 month.   |
| <b>Other Criteria</b>    | Rheumatoid Arthritis (RA): Diagnosis of moderately to severely active RA. Used in combination with methotrexate. Trial and failure, contraindication, or intolerance (TF/C/I) to a TNF antagonist (eg, adalimumab, etanercept, infliximab). Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): Diagnosis of WG or MPA. Patient is concurrently on glucocorticoids (eg, prednisone) OR contraindication or intolerance to glucocorticoids (eg, prednisone). All uses: Approve for continuation of prior therapy. |



# RYBREVANT (S)

## Products Affected

- Rybrevant

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) locally advanced or b) metastatic. Patient's disease has epidermal growth factor receptor (EGFR) exon 20 insertion mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed on or after platinum-based chemotherapy (e.g., carboplatin, cisplatin). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# RYDAPT (S)

## Products Affected

- Rydapt

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Acute Myeloid Leukemia (AML): Newly diagnosed acute myeloid leukemia (AML), FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with a hematologist or oncologist.  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## SABRIL (S)

### Products Affected

- Vigabatrin

- Vigadrone

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Complex Partial Seizures (CPS): For use as adjunctive therapy. Failure, contraindication, or intolerance to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)].<br>Infantile Spasms (IS): Diagnosis of infantile spasms. |
| <b>Age Restrictions</b>             | IS: 1 month to 2 years of age. CPS: 2 years or older.  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# SANDOSTATIN (S)

## Products Affected

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

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Acromegaly (initial): Diagnosis of acromegaly. One of the following: A) Inadequate response to surgical resection and/or pituitary irradiation OR B) Patient is not a candidate for surgical resection or pituitary irradiation. Trial and failure, contraindication or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | All uses (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | Acromegaly (reauth): Documentation of positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): Patient has improvement in number of diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (reauth): Patient has improvement in number of diarrhea episodes.  |

## SAPHNELO (S)

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### Products Affected

- Saphnelo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Systemic lupus erythematosus (SLE) (initial): Diagnosis of moderate to severe SLE. Currently receiving standard of care treatment for SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | SLE (initial): Prescribed by or in consultation with a rheumatologist.   |
| <b>Coverage Duration</b>            | SLE (initial, reauth): 6 months.   |
| <b>Other Criteria</b>               | SLE (reauth): Documentation of positive clinical response to therapy.  |

# SARCLISA (S)

## Products Affected

- Sarclisa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of multiple myeloma. One of the following: 1) Both of the following: a) Patient has received at least two prior treatment regimens which included lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib), and b) Used in combination with pomalidomide and dexamethasone, OR 2) All of the following: a) Disease is relapsed or refractory, b) Patient has received one to three prior lines of therapy, and c) Used in combination with carfilzomib and dexamethasone. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist/hematologist.  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## SCSEMBLIX (S)

### Products Affected

- Scemblix

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of chronic myelogenous/myeloid leukemia (CML). Disease is Philadelphia chromosome-positive (Ph+). Disease is in chronic phase. One of the following: 1) Patient has been previously treated with two or more alternative tyrosine kinase inhibitors (TKI) [e.g., Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tassigna (nilotinib), Iclusig (ponatinib)], OR 2) Disease is T315I mutation positive. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or hematologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## SCIG (S)

### Products Affected

- Cutaquig
- Cuvitru
- Hizentra
- Hyqvia INJ 10GM/100ML;  
800UNIT/5ML, 20GM/200ML;  
1600UNIT/10ML, 30GM/300ML;  
2400UNIT/15ML, 5GM/50ML;  
400UNIT/2.5ML
- Xembify

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).   |
| <b>Required Medical Information</b> | Initial: Immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Medication is being used subcutaneously. Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) OR one of the following FDA-approved or literature supported diagnoses: 1) Common variable immunodeficiency (CVID), OR 2) Congenital agammaglobulinemia (X-linked or autosomal recessive), OR 3) Severe combined immunodeficiencies (SCID), OR 4) Wiskott-Aldrich syndrome, OR 5) Other primary immunodeficiency with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on SCIG therapy (e.g., immunologist, hematologist, neurologist).  |
| <b>Coverage Duration</b>            | Initial, reauth: 12 months   |



|                       |   |
|-----------------------|---|
| <b>Other Criteria</b> | Subject to Part B vs. Part D review. All uses (reauth): Patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy. |
|-----------------------|---|

## SIGNIFOR (S)

### Products Affected

- Signifor

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Pituitary surgery has not been curative for the patient or b) Patient is not a candidate for pituitary surgery.                  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.   |
| <b>Coverage Duration</b>            | Cushing's disease (initial, reauth): 12 months   |
| <b>Other Criteria</b>               | Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease). |

# SIGNIFOR LAR (S)

## Products Affected

- Signifor Lar

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Acromegaly (initial): Diagnosis of acromegaly. One of the following: a) Inadequate response to surgery or b) Patient is not a candidate for surgery.<br>Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Pituitary surgery has not been curative for the patient or b) Patient is not a candidate for pituitary surgery.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.  |
| <b>Coverage Duration</b>            | Acromegaly: Initial: 6 months, Reauth: 12 months. Cushing's disease (init, reauth): 12 months   |
| <b>Other Criteria</b>               | Acromegaly (reauth): Documentation of positive clinical response to therapy (e.g., patient's growth hormone (GH) level or insulin-like growth factor 1 (IGF-1) level for age and gender has normalized/improved).<br>Cushing's disease (reauth): Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease). |

# SKYRIZI (S)

## Products Affected

- Skyrizi INJ 150MG/ML, 360MG/2.4ML, 75MG/0.83ML

- Skyrizi Pen

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.   |
| <b>Coverage Duration</b>            | All uses (initial): 6 months, (reauth): 12 months  |
| <b>Other Criteria</b>               | Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline.   |

# SKYTROFA (S)

## Products Affected

- Skytrofa

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Pediatric Growth Hormone Deficiency (PGHD) (initial): One of the following: A) History of neonatal hypoglycemia associated with pituitary disease, B) Diagnosis of panhypopituitarism, OR C) Both of the following: 1) Diagnosis of PGHD as confirmed by one of the following: a) Height is documented by one of the following (utilizing age and gender growth charts related to height): i) height is greater than 2.0 standard deviations (SD) below midparental height OR ii) height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender), b) Growth velocity is greater than 2 SD below mean for age and gender, or c) Delayed skeletal maturation of greater than 2 SD below mean for age and gender (eg, delayed greater than 2 years compared with chronological age), AND 2) Documentation of one of the following: a) Patient is male with bone age less than 16 years, OR b) Patient is female with bone age less than 14 years. Patient weight is 11.5 kg or greater. Trial and failure or intolerance to both of the following: a) Genotropin AND b) Nutropin, Nutropin AQ, or Nutropin AQ NuSpin. |
| <b>Age Restrictions</b>             | PGHD (initial): 1 year of age or older.  |
| <b>Prescriber Restrictions</b>      | PGHD (initial, reauth): Prescribed by or in consultation with an endocrinologist.  |
| <b>Coverage Duration</b>            | PGHD (initial, reauth): 12 months.   |
| <b>Other Criteria</b>               | PGHD (reauth): Both of the following: 1) Expected adult height not attained AND 2) Documentation of expected adult height goal.  |

# SOMATULINE DEPOT (S)

## Products Affected

- Somatuline Depot

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Acromegaly: Diagnosis of acromegaly. One of the following: A) Inadequate response to one of the following: surgery or radiotherapy, OR B) Not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (120mg/0.5mL strength only): Diagnosis of GEP-NETs. Disease is one of the following: (a) unresectable, locally advanced or (b) metastatic. Carcinoid syndrome (120mg/0.5mL strength only): Diagnosis of carcinoid syndrome. Used to reduce the frequency of short-acting somatostatin analog rescue therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Acromegaly (initial): Prescribed by or in consultation with an endocrinologist. GEP-NETs (initial): Prescribed by or in consultation with an oncologist. Carcinoid syndrome (initial): Prescribed by or in consultation with an endocrinologist or oncologist.  |
| <b>Coverage Duration</b>            | All uses: 12 months   |
| <b>Other Criteria</b>               | All Indications: Approve for continuation of prior therapy.   |

# SOMAVERT (S)

## Products Affected

- Somavert

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Acromegaly (initial): Diagnosis of acromegaly AND Failure to surgery and/or radiation therapy and/or other medical therapies (such as dopamine agonists [e.g., bromocriptine, cabergoline]) unless patient is not a candidate for these treatment options AND trial and failure or intolerance to generic octreotide (a somatostatin analogue) |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an endocrinologist   |
| <b>Coverage Duration</b>            | Initial and reauth: 12 months  |
| <b>Other Criteria</b>               | Acromegaly (reauth): Patient has experienced a positive clinical response to therapy (biochemical control, decrease or normalization of IGF-1 levels).   |

# SPRAVATO (S)

## Products Affected

- Spravato 56mg Dose
- Spravato 84mg Dose

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | One of the following: A) Both of the following: 1) Diagnosis of major depressive disorder (treatment-resistant) and 2) Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode OR B) Both of the following: 1) Diagnosis of major depressive disorder and 2) Patient has both of the following: a) depressive symptoms and b) acute suicidal ideation or behavior. Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline). |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | Prescribed by or in consultation with a psychiatrist   |
| Coverage Duration            | 12 months  |
| Other Criteria               | Approve for continuation of prior therapy.   |



# SPRYCEL (S)

## Products Affected

- Sprycel

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Philadelphia chromosome positive (Ph+)/BCR ABL chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML. Ph+/BCR ABL acute lymphoblastic leukemia (ALL): Diagnosis of Ph+/BCR ABL ALL. One of the following: 1) Patient has resistance or intolerance to any prior therapy OR 2) Both of the following: i) Patient is 1 year of age or older with newly diagnosed disease, and ii) Used in combination with chemotherapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | All Uses: Prescribed by or in consultation with an oncologist or hematologist   |
| <b>Coverage Duration</b>            | All Uses: 12 months   |
| <b>Other Criteria</b>               | All Uses: Approve for continuation of prior therapy.  |

## STELARA (IV) (S)

### Products Affected

- Stelara INJ 130MG/26ML

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Crohn's Disease (CD): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, methotrexate, corticosteroid (eg, prednisone). Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), or an aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | Prescribed by or in consultation with a gastroenterologist.  |
| Coverage Duration            | One time   |
| Other Criteria               | Stelara is to be administered as an intravenous induction dose. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.  |

# STELARA (S)

## Products Affected

- Stelara INJ 45MG/0.5ML, 90MG/ML

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | <p>Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial): One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, calcineurin inhibitors (eg, tacrolimus, pimecrolimus), anthralin, OR coal tar. Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn's disease. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, methotrexate, or a corticosteroid (eg, prednisone).</p> |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | <p>Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist.</p>  |
| <b>Coverage Duration</b>            | All uses (Initial): 6 months. All uses (reauth): 12 months  |

|                       |  |
|-----------------------|--|
| <b>Other Criteria</b> | <p>Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), or an aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD (Reauth), UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.</p> |
|-----------------------|--|

# STIVARGA (S)

## Products Affected

- Stivarga

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Metastatic colorectal cancer (mCRC): All of the following: 1) diagnosis of mCRC, AND 2) trial and failure, contraindication or intolerance to fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI), AND 3) trial and failure, contraindication or intolerance to an anti-VEGF therapy (e.g., bevacizumab), AND 4) one of the following: a) RAS mutation, OR b) both of the following: RAS wild-type (RAS mutation negative tumor) and trial and failure, contraindication or intolerance to an anti-EGFR therapy [e.g., Vectibix (panitumumab), Erbitux (cetuximab)]. Gastrointestinal stromal tumor (GIST): All of the following: 1) diagnosis of locally advanced, unresectable or metastatic GIST, AND 2) trial and failure, contraindication or intolerance to both of the following: a) Gleevec (imatinib mesylate), AND b) Sutent (sunitinib malate). Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Trial and failure or intolerance to Nexavar (sorafenib tosylate). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | mCRC, GIST: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# STRENSIQ (S)

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## Products Affected

- Strensiq

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Hypophosphatasia: Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia AND for patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Hypophosphatasia: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist   |
| <b>Coverage Duration</b>            | Hypophosphatasia: 12 months   |
| <b>Other Criteria</b>               | N/A   |

# SUPPRELIN LA (S)

## Products Affected

- Supprelin La

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.  |
| <b>Coverage Duration</b>            | CPP (init, reauth): 12 months  |
| <b>Other Criteria</b>               | CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.  |

# SUTENT (S)

## Products Affected

- Sunitinib Malate

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma. Gastrointestinal stromal tumor (GIST): Diagnosis of GIST after disease progression on, or contraindication or intolerance to Gleevec (imatinib). Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease. Adjuvant treatment of renal cell carcinoma: Diagnosis of renal cell carcinoma (RCC). Used as adjuvant therapy. Patient is at high risk of recurrent RCC following nephrectomy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | All uses: 12 months  |
| <b>Other Criteria</b>               | All Indications: Approve for continuation of prior therapy.  |



## SYLATRON (S)

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### Products Affected

- Sylatron

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Melanoma: Diagnosis of melanoma with microscopic or gross nodal involvement AND The prescribed medication will be used as adjuvant therapy within 84 days of definitive surgical resection, including complete lymphadenectomy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or dermatologist  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# SYMDEKO (S)

## Products Affected

- Symdeko

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Initial: Diagnosis of cystic fibrosis. One of the following: 1) Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR 2) Patient has at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| Age Restrictions             | Initial: Patient is 6 years of age or older   |
| Prescriber Restrictions      | Initial: Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center   |
| Coverage Duration            | 12 months   |
| Other Criteria               | Reauth: Documentation of a positive clinical response to therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).   |

## SYMLIN (S)

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### Products Affected

- Symlinpen 120
- Symlinpen 60

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes. Patient has failed to achieve desired glucose control despite optimal insulin therapy. Patient is taking concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Reauth: Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline. Patient is receiving concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog).  |

# SYNAGIS (S)

## Products Affected

- Synagis INJ 100MG/ML, 50MG/0.5ML

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Patient will use palivizumab for immunoprophylaxis of respiratory syncytial virus (RSV) during the peak months of infection in the patient's geographic region AND Patient meets one of the following criteria: 1) Infants born at 28 weeks, six days gestation or earlier and who are younger than 12 months of age at the start of the RSV season OR 2) Diagnosis of chronic lung disease of prematurity, born before 32 weeks, 0 days gestation, received greater than 21% oxygen for at least the first 28 days after birth, and one of the following: a) 12 months of age or younger at the start of the RSV season OR b) greater than 12 months of age to 24 months of age at the start of the RSV season and received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season. OR 3) Patient is 12 months of age or younger at the start of the RSV season and has one of the following: a) acyanotic heart failure that will require a cardiac surgical procedure and the patient is receiving medication to control congestive heart failure, OR b) moderate to severe pulmonary hypertension OR c) cyanotic heart defect. OR 4) patient is younger than 24 months of age and will or has undergone a cardiac transplantation during the RSV season. OR 5) Patient is 12 months of age or younger at the start of the RSV season with a congenital abnormality or neuromuscular disorder and has an impaired ability to clear secretions from the upper airway due to an ineffective cough. OR 6) Patient is younger than 24 months of age with a lymphocyte count below the normal range for patient's age and has received or will receive a solid organ transplant, hematopoietic stem cell transplant recipient, or chemotherapy during the RSV season.</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a pediatric specialist (i.e., pulmonologist, neonatologist, neurologist, cardiologist, pediatric intensivist, or infectious disease specialist).   |

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|                          |                                       |
|--------------------------|---------------------------------------|
| <b>Coverage Duration</b> | 5 months (5 doses) during RSV season. |
| <b>Other Criteria</b>    | N/A                                   |

# SYNRIBO (S)

## Products Affected

- Synribo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic myelogenous leukemia (CML): Diagnosis of CML in the chronic or accelerated phase AND Patient has tried and has had resistance, relapse, inadequate response, intolerance or is contraindicated to TWO tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel, Tasisna, and Bosulif, Iclusig). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | CML: Prescribed by or in consultation with a hematologist/oncologist   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## SYPRINE (S)

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### Products Affected

- Clovique
- Trientine Hydrochloride

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Initial: Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration).<br>Trial and failure, contraindication, or intolerance to a penicillamine product (e.g., Depen, Cuprimine) |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Reauth: Documentation of a positive clinical response to therapy   |

# TABRECTA (S)

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## Products Affected

- Tabrecta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of non-small cell lung cancer (NSCLC). Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



# TAFAMIDIS (S)

## Products Affected

- Vyndamax

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) (initial): Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM). One of the following: 1) Patient has a transthyretin (TTR) mutation (e.g., V122I), 2) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, OR 3) All of the following: i) echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis, ii) scintigraphy scan suggestive of cardiac TTR amyloidosis, and iii) absence of light-chain amyloidosis. One of the following: 1) History of heart failure (HF), with at least one prior hospitalization for HF, OR 2) Presence of clinical signs and symptoms of HF (e.g., dyspnea, edema). Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist  |
| <b>Coverage Duration</b>            | ATTR-CM (initial, reauth): 12 months   |
| <b>Other Criteria</b>               | ATTR-CM (reauth): Documentation of positive clinical response to therapy. Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure.  |

# TAFINLAR (S)

## Products Affected

- Tafinlar

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | <p>Melanoma: Diagnosis of unresectable or metastatic melanoma AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR both of the following: cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and medication is used in combination with Mekinist (trametinib). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Mekinist (trametinib). Non-small Cell Lung Cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic anaplastic thyroid cancer. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Mekinist (trametinib) .</p> |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |

|                          |  |
|--------------------------|--|
| <b>Coverage Duration</b> | 12 months                                  |
| <b>Other Criteria</b>    | Approve for continuation of prior therapy. |

# TAGRISSO (S)

## Products Affected

- Tagrisso

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): One of the following: A) All of the following: Diagnosis of metastatic NSCLC. One of the following: 1) Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), OR 2) Both of the following: a) Patient has known active EGFR T790M mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), or Vizimpro (dacomitinib). OR B) All of the following: Diagnosis of NSCLC. Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Both of the following: 1) Patient is receiving as adjuvant therapy, and 2) Patient has had a complete surgical resection of the primary NSCLC tumor. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# TALZENNA (S)

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## Products Affected

- Talzenna

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) locally advanced or b) metastatic. Presence of a deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease is human epidermal growth factor receptor 2 (HER2)-negative. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# TARCEVA (S)

## Products Affected

- Erlotinib Hydrochloride

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of locally advanced or metastatic (Stage III or IV) NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).<br>Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND erlotinib will be used in combination with gemcitabine. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | All uses: 12 months  |
| <b>Other Criteria</b>               | All Indications: Approve for continuation of prior therapy.  |

# TARGRETIN (S)

## Products Affected

- Bexarotene

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Cutaneous T-Cell Lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [eg, corticosteroids {ie, clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}] or systemic therapies [eg, interferons]). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or dermatologist   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# TARPEYO (S)

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## Products Affected

- Tarpeyo

| <b>PA Criteria</b>                  | <b>Criteria Details</b> |
|-------------------------------------|-------------------------|
| <b>Indications</b>                  | Pending CMS Review      |
| <b>Off-Label Uses</b>               | Pending CMS Review      |
| <b>Exclusion Criteria</b>           | Pending CMS Review      |
| <b>Required Medical Information</b> | Pending CMS Review      |
| <b>Age Restrictions</b>             | Pending CMS Review      |
| <b>Prescriber Restrictions</b>      | Pending CMS Review      |
| <b>Coverage Duration</b>            | Pending CMS Review      |
| <b>Other Criteria</b>               | Pending CMS Review      |



# TASIGNA (S)

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## Products Affected

- Tasigna

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.                                 |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML    |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or hematologist |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.                          |

# TAVALISSE (S)

## Products Affected

- Tavalisse

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic Idiopathic Thrombocytopenic Purpura (ITP) (initial): Diagnosis of chronic immune ITP or relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], splenectomy, thrombopoietin receptor agonists (e.g., Nplate, Promacta), or Rituxan (rituximab). Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | ITP (initial): Prescribed by or in consultation with a hematologist/oncologist.  |
| <b>Coverage Duration</b>            | ITP (initial, reauth): 12 months   |
| <b>Other Criteria</b>               | ITP (reauth): Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.   |

# TAVNEOS (S)

## Products Affected

- Tavneos

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: a) Granulomatosis with polyangiitis (GPA) OR b) Microscopic polyangiitis (MPA). Diagnosis is confirmed by one of the following: a) ANCA test positive for proteinase 3 (PR3) antigen, b) ANCA test positive for myeloperoxidase (MPO) antigen, OR c) Tissue biopsy. Patient is receiving concurrent immunosuppressant therapy with one of the following: a) cyclophosphamide OR b) rituximab. One of the following: a) Patient is concurrently on glucocorticoids (e.g., prednisone) OR b) History of contraindication or intolerance to glucocorticoids (e.g., prednisone). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Initial, Reauth: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist   |
| <b>Coverage Duration</b>            | Initial, Reauth: 12 months  |
| <b>Other Criteria</b>               | Reauth: Patient does not show evidence of progressive disease while on therapy. Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab).  |

# TAZVERIK (S)

## Products Affected

- Tazverik

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Epithelioid sarcoma: Diagnosis of epithelioid sarcoma. Disease is one of the following: metastatic or locally advanced. Patient is not eligible for complete resection. Follicular lymphoma: Diagnosis of follicular lymphoma. Disease is one of the following: relapsed or refractory. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Epithelioid sarcoma: Prescribed by or in consultation with an oncologist. Follicular lymphoma: Prescribed by or in consultation with an oncologist or hematologist.   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# TECFIDERA (S)

## Products Affected

- Dimethyl Fumarate Starterpack MISC 0
- Dimethyl Fumarate CPDR

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| <b>Required Medical Information</b> | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | MS (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).                                      |

# TEGSEDI (S)

## Products Affected

- Tegsedi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) (initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Patient has a transthyretin (TTR) mutation (e.g., V30M). One of the following: 1) Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb, 2) Patient has baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2, OR 3) Patient has a baseline neuropathy impairment score (NIS) between 10 and 130. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | hATTR amyloidosis (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | hATTR amyloidosis (reauth): Patient has demonstrated a benefit from therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment). One of the following: 1) Patient continues to have a PND score less than or equal to IIIb, 2) Patient continues to have a FAP stage of 1 or 2, OR 3) Patient continues to have a NIS between 10 and 130.  |

# TEPMETKO (S)

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## Products Affected

- Tepmetko

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# TERIPARATIDE (S)

## Products Affected

- Forteo INJ 600MCG/2.4ML
- Teriparatide

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia (initial): Diagnosis of one of the following: a) postmenopausal osteoporosis or osteopenia or b) primary or hypogonadal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Glucocorticoid-Induced Osteoporosis: See Other Criteria section. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | All uses (initial): 24 months. All uses (reauth): 12 months.  |



|                       |  |
|-----------------------|--|
| <b>Other Criteria</b> | <p>Glucocorticoid-Induced Osteoporosis (initial): Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: 1) BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site), or 2) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions, or 3) History of one of the following fractures resulting from minimal trauma: vertebral compression fx, fx of the hip, fx of the distal radius, fx of the pelvis, or fx of the proximal humerus. TF/C/I to one bisphosphonate (e.g., alendronate). All uses (initial, reauth): One of the following: 1) Treatment duration of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime, or 2) Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)].</p> |
|-----------------------|--|

# TESTOSTERONE (S)

## Products Affected

- Androderm PT24 2MG/24HR, 4MG/24HR
- Striant
- Testosterone GEL 20.25MG/1.25GM, 25MG/2.5GM, 40.5MG/2.5GM, 50MG/5GM
- Testosterone Cypionate INJ 100MG/ML, 200MG/ML
- Testosterone Pump

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence. Patient is a transgender male (female-to-male). |
| Age Restrictions             | Testosterone cypionate only: HG (init): 12 years of age or older. All other testosterone: HG (init): Patient is 18 years of age or older.   |
| Prescriber Restrictions      | N/A   |

|                          |  |
|--------------------------|--|
| <b>Coverage Duration</b> | HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): 12 mo. GD: 12 mo.   |
| <b>Other Criteria</b>    | HG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Follow-up calculated free or bioavailable T level within or below the normal limits of the reporting lab, or follow-up calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted. |

# TESTOSTERONE ENANTHATE (S)

## Products Affected

- Testosterone Enanthate INJ

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence. Patient is a transgender male (female-to-male). |
| <b>Age Restrictions</b>             | HG (init): Patient is 18 years of age or older.  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC, GD: 12 mo. DP: 6 mo.   |

|                       |  |
|-----------------------|--|
| <b>Other Criteria</b> | HG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Follow-up calculated free or bioavailable T level within or below the normal limits of the reporting lab, or follow-up calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted. |
|-----------------------|--|

# TEZSPIRE (S)

## Products Affected

- Tezspire

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: Diagnosis of severe asthma. Patient has a history of one of the following within the past 12 months: 1) Two or more asthma exacerbations requiring systemic corticosteroid (e.g., prednisone) treatment OR 2) Prior asthma-related hospitalization. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day) and ii) Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium), OR b) One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol]). One of the following: 1) Medication will not be used to treat eosinophilic asthma OR 2) Both of the following: a) Medication will be used to treat eosinophilic asthma AND b) Trial and failure, contraindication, or intolerance to one of the following: Nucala (mepolizumab), Fasentra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab). One of the following: 1) Medication will not be used to treat oral corticosteroid-dependent asthma OR 2) Both of the following: a) Medication will be used to treat oral corticosteroid-dependent asthma AND b) Trial and failure, contraindication, or intolerance to Dupixent (dupilumab). One of the following: 1) Medication will not be used to treat persistent allergic asthma OR 2) Both of the following: a) Medication will be used to treat persistent allergic asthma AND b) Trial and failure, contraindication, or intolerance to Xolair (omalizumab). |
| <b>Age Restrictions</b>             | Initial: Patient is 12 years of age or older  |
| <b>Prescriber Restrictions</b>      | Initial, Reauth: Prescribed by or in consultation with a pulmonologist or allergist/immunologist  |

|                          |   |
|--------------------------|---|
| <b>Coverage Duration</b> | Initial: 6 months. Reauth: 12 months  |
| <b>Other Criteria</b>    | Reauth: Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1]). Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. |

# THALOMID (S)

## Products Affected

- Thalomid

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Multiple myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone, unless the patient has an intolerance to steroids.<br>Erythema nodosum leprosum (ENL): Diagnosis of moderate to severe ENL with cutaneous manifestations. Thalomid is not used as monotherapy if moderate to severe neuritis is present. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MM: Prescribed by or in consultation with an oncologist/hematologist   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |



# TIBSOVO (S)

## Products Affected

- Tibsovo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Relapsed or refractory Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. One of the following: 1) patient is greater than or equal to 75 years old OR 2) patient has comorbidities that preclude use of intensive induction chemotherapy. Locally Advanced or Metastatic Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is locally advanced or metastatic. Patient has been previously treated. All indications: Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Relapsed or refractory AML, Newly-Diagnosed AML: Prescribed by or in consultation with a hematologist/oncologist. Locally Advanced or Metastatic Cholangiocarcinoma: Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## TIVDAK (S)

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### Products Affected

- Tivdak

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of cervical cancer. Disease is one of the following: a) recurrent or b) metastatic. Disease has progressed on or after chemotherapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## TOPICAL RETINOID (S)

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### Products Affected

- Tretinoin CREA 0.025%, 0.05%

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                                 |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.                     |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne). |
| <b>Age Restrictions</b>             | PA applies to members 26 years of age or older          |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | N/A   |

# TRACLEER (S)

## Products Affected

- Bosentan

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.   |
| <b>Coverage Duration</b>            | PAH (Initial): 6 months. PAH (Reauth): 12 months  |
| <b>Other Criteria</b>               | PAH (Reauth): Documentation of positive clinical response to therapy.   |

# TRAZIMERA (S)

## Products Affected

- Trazimera

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-overexpressing breast cancer. One of the following treatment regimens: a) As adjuvant treatment, b) metastatic disease and one of the following: 1) used in combination with a taxane (eg, docetaxel, paclitaxel), or 2) used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease, or c) used in combination with Perjeta (pertuzumab). Gastric Cancer: Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic). Used in combination with one of the following treatment regimens: a) Platinol (cisplatin) and Adrucil (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## TRELSTAR (S)

### Products Affected

- Trelstar Mixject INJ 11.25MG, 22.5MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to any brand Lupron formulation. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## TRIKAFTA (S)

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### Products Affected

- Trikafta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Cystic Fibrosis (CF) (initial): Diagnosis of CF. Patient has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility: F508del mutation OR a mutation in the CFTR gene that is responsive based on in vitro data. |
| <b>Age Restrictions</b>             | CF (initial): 6 years of age or older.   |
| <b>Prescriber Restrictions</b>      | CF (initial): Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center.  |
| <b>Coverage Duration</b>            | CF (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | CF (reauth): Documentation of positive clinical response to therapy (e.g., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations).   |

# TRIPTODUR (S)

## Products Affected

- Triptodur

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range. Trial and failure or intolerance to Lupron Depot-Ped. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.  |
| <b>Coverage Duration</b>            | CPP (Initial, reauth): 12 months   |
| <b>Other Criteria</b>               | CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.  |



# TRODELVY (S)

## Products Affected

- Trodelvy

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Triple Negative Breast Cancer (TNBC): Diagnosis of TNBC. Disease is one of the following: a) unresectable locally advanced or b) metastatic. Patient has received at least two prior therapies for at least one of which is for metastatic disease (e.g., carboplatin, cisplatin, gemcitabine, paclitaxel, docetaxel, capecitabine, etc.). Urothelial Cancer: Diagnosis of urothelial cancer. Disease is one of the following: a) locally advanced or b) metastatic. Patient has previously received both of the following: 1) Platinum-containing chemotherapy (e.g., cisplatin, carboplatin) AND 2) One of the following: a) programmed death receptor-1 (PD-1) inhibitor [e.g., Keytruda (pembrolizumab)], or b) programmed death-ligand 1 (PD-L1) inhibitor [e.g., Bavencio (avelumab)]. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# TRUSELTIQ (S)

## Products Affected

- Truseltiq

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of cholangiocarcinoma. Disease is one of the following: a) unresectable locally advanced or b) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has been previously treated. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# TUKYSA (S)

## Products Affected

- Tukysa

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) advanced unresectable or b) metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Used in combination with trastuzumab and capecitabine. Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## TURALIO (S)

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### Products Affected

- Turalio

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Tenosynovial Giant Cell Tumor (TGCT): Diagnosis of TGCT. Patient is symptomatic. Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# TYKERB (S)

## Products Affected

- Lapatinib Ditosylate

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Breast Cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic or recurrent breast cancer. Used in combination with one of the following: Trastuzumab, Xeloda (capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# TYMLOS (S)

## Products Affected

- Tymlos

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Diagnosis of postmenopausal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) one of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: a) major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime. |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | 24 months (max 24 months of therapy per lifetime)   |
| Other Criteria               | N/A   |

# TYSABRI (S)

## Products Affected

- Tysabri

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | <p>Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following disease-modifying therapies for MS: A) Aubagio (teriflunomide), B) Lemtrada (alemtuzumab), C) Mavenclad (cladribine), D) Plegridy (peginterferon beta-1a), E) Any one of the inteferon beta-1a injections (eg, Avonex), F) Any one of the interferon beta-1b injections (eg, Betaseron, Extavia), G) Any one of the glatiramer acetate injections (eg, Copaxone, Glatopa, generic glatiramer acetate), H) Any one of the oral fumarates (eg, brand Tecfidera, generic dimethyl fumarate), I) Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (eg, Gilenya, Mayzent, Zeposia), J) Any one of the B-cell targeted therapies (eg, Ocrevus, Kesimpta), 2) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their MS, or 3) for continuation of prior therapy. MS (init, reauth): Not used in combination with another disease-modifying therapy for MS. Crohn's Disease (CD) (initial): Diagnosis of moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone, methylprednisolone), 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate (Rheumatrex, Trexall), aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). TF/C/I to a TNF-inhibitor (eg, Humira [adalimumab], infliximab). CD (initial and reauth): Not used in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate). Not used in combination with a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or infliximab).</p> |
| Age Restrictions             | N/A  |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | MS (init, reauth): Prescribed by or in consultation with a neurologist. CD (initial): Prescribed by or in consultation with a gastroenterologist.  |
| <b>Coverage Duration</b>       | MS (init, reauth): 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Otherwise, 3 mo.   |
| <b>Other Criteria</b>          | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). CD (reauth): Documentation of positive clinical response (eg, improved disease activity index) to therapy. |



## UBRELVY (S)

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### Products Affected

- Ubrelvy

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Will not be used for preventive treatment of migraine. Patient has fewer than 15 headache days per month. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another oral CGRP inhibitor. |
| <b>Age Restrictions</b>             | Initial: 18 years of age or older.  |
| <b>Prescriber Restrictions</b>      | Initial, Reauth: Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.  |
| <b>Coverage Duration</b>            | Initial: 3 months. Reauth: 12 months.   |
| <b>Other Criteria</b>               | Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). Will not be used for preventive treatment of migraine. Medication will not be used in combination with another oral CGRP inhibitor.   |

## UDENYCA (S)

### Products Affected

- Udenyca

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with a hematologist/oncologist   |
| <b>Coverage Duration</b>            | ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.   |
| <b>Other Criteria</b>               | N/A   |

# UKONIQ (S)

## Products Affected

- Ukoniq

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Marginal zone lymphoma (MZL): Diagnosis of MZL. Disease is one of the following: relapsed or refractory. Patient has received at least one prior anti-CD20-based regimen (e.g., bendamustine + rituximab, bendamustine + obinutuzumab, etc.). Follicular lymphoma (FL): Diagnosis of FL. Disease is one of the following: relapsed or refractory. Patient has received at least three prior lines of systemic therapy (e.g., bendamustine + rituximab, bendamustine + obinutuzumab, etc.). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MZL/FL: Prescribed by or in consultation with a hematologist/oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## VALCHLOR (S)

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### Products Affected

- Valchlor

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) (initial): All of the following: 1) diagnosis of Stage IA MF-CTCL, OR diagnosis of Stage IB MF-CTCL, AND 2) patient has received at least one prior skin-directed therapy [e.g., topical corticosteroids, bexarotene topical gel (Targretin topical gel), etc.]. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist or dermatologist  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## VARIZIG (S)

### Products Affected

- Varizig INJ 125UNIT/1.2ML

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Presence of contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).   |
| <b>Required Medical Information</b> | Immune globulin is being used intramuscularly. The immune globulin is being used for passive immunization or post exposure-prophylaxis of varicella. Patient is considered a high risk individual (i.e., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 months (approve one dose only)   |
| <b>Other Criteria</b>               | N/A  |

## VASCEPA (S)

### Products Affected

- Icosapent Ethyl CAPS 1GM

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Severe Hypertriglyceridemia (init): Diagnosis (dx) of hypertriglyceridemia and patient has a pre-treatment triglyceride (TG) level greater than or equal to 500 mg/dL. Prevention of CV Events (init): Dx of hypertriglyceridemia and patient has a pre-treatment TG level of 150 to 499 mg/dL. One of the following: 1) Patient has established cardiovascular disease (CVD) (e.g., coronary artery disease, cerebrovascular or carotid disease, peripheral artery disease, etc.) OR 2) Both of the following: a) Dx of diabetes mellitus AND b) Patient has two or more risk factors for developing CVD. Medication will be used as an adjunct to maximally tolerated statin therapy unless there is a contraindication or intolerance to statin therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Initial/Reauth: 12 months   |
| <b>Other Criteria</b>               | Severe Hypertriglyceridemia (reauth): Documentation of positive clinical response to therapy. Prevention of CV Events (Reauth): Documentation of positive clinical response to therapy. Medication continues to be used as an adjunct to maximally tolerated statin therapy unless there is a contraindication or intolerance to statin therapy.  |

## VENCLEXTA (S)

### Products Affected

- Venclexta

- Venclexta Starting Pack

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL. Acute Myeloid Leukemia (AML): Diagnosis of newly diagnosed AML. Used in combination with azacitidine, or decitabine, or low-dose cytarabine. One of the following: 1) age 75 years or older OR 2) comorbidities that preclude use of intensive induction chemotherapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist or oncologist   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## VENTAVIS (S)

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### Products Affected

- Ventavis

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.   |
| <b>Coverage Duration</b>            | PAH (Initial): 6 months. (Reauth): 12 months  |
| <b>Other Criteria</b>               | Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.  |



# VERZENIO (S)

## Products Affected

- Verzenio

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Advanced or Metastatic Breast Cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) and patient is male or a postmenopausal woman, OR b) used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy, OR c) used as monotherapy and disease has progressed following endocrine therapy and patient has already received at least one prior chemotherapy regimen. Early Breast Cancer: Diagnosis of early breast cancer at high risk of recurrence. Disease is hormone receptor (HR)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Disease is node-positive. Used as adjunctive therapy. Used in combination with one of the following endocrine therapies: 1) tamoxifen or 2) aromatase inhibitor (e.g., anastrozole, letrozole, exemestane). Patient has a Ki-67 score of greater than or equal to 20% as determined by an FDA approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## VIJOICE (S)

### Products Affected

- Vioice

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Initial: Diagnosis of PIK3CA-related overgrowth spectrum (PROS). Documentation of mutation in the PIK3CA gene. Documentation of severe clinical manifestations (e.g., congenital lipomatous overgrowth, vascular malformations, epidermal nevi, scoliosis/skeletal and spinal [CLOVES], facial infiltrating lipomatosis [FIL], klippel-trenaunay syndrome [KTS], megalencephaly-capillary malformation polymicrogyria [MCAP]). |
| <b>Age Restrictions</b>             | Initial: Patient is 2 years of age or older.   |
| <b>Prescriber Restrictions</b>      | Initial, Reauth: Prescribed by or in consultation with a physician who specializes in the treatment of PROS.   |
| <b>Coverage Duration</b>            | Initial: 6 months. Reauth: 12 months.  |
| <b>Other Criteria</b>               | Reauth: Documentation of positive clinical response to therapy.  |

# VIMIZIM (S)

## Products Affected

- Vimizim

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Mucopolysaccharidosis (initial): Diagnosis of Mucopolysaccharidosis type IVA (MPS IVA, Morquio A syndrome) confirmed by both of the following: a) documented clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.) and b) documented reduced fibroblast or leukocyte GALNS enzyme activity or molecular genetic testing of GALNS. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Initial, reauth: 12 months  |
| <b>Other Criteria</b>               | Reauth: Documentation of positive clinical response to therapy.   |

## VITRAKVI (S)

### Products Affected

- Vitrakvi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Presence of solid tumors (e.g., salivary gland, soft tissue sarcoma, infantile fibrosarcoma, thyroid cancer, lung, melanoma, colon, etc.). Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.). Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]. Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy) OR Disease has no satisfactory alternative treatments. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## VIZIMPRO (S)

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### Products Affected

- Vizimpro

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletion or exon 21 L858R substitution. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## VONJO (S)

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### Products Affected

- Vonjo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Pre-treatment platelet count below $50 \times 10^9/L$ . |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist or oncologist.   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# VORICONAZOLE INJECTION (S)

## Products Affected

- Voriconazole INJ

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Invasive aspergillosis: Diagnosis of invasive aspergillosis (IA).<br>Candidemia: Diagnosis of candidemia. One of the following: (1) patient is non-neutropenic or (2) infection is located in skin, abdomen, kidney, bladder wall, or wounds. Esophageal Candidiasis: Diagnosis of esophageal candidiasis. Mycosis: Diagnosis of fungal infection caused by <i>Scedosporium apiospermum</i> (asexual form of <i>Pseudallescheria boydii</i> ) or <i>Fusarium</i> spp. including <i>Fusarium solani</i> . For fusariosis: Patient is intolerant of, or refractory to, other therapy (e.g., liposomal amphotericin B, amphotericin B lipid complex). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 weeks   |
| <b>Other Criteria</b>               | N/A  |

## VOSEVI (S)

### Products Affected

- Vosevi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier]. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine.   |
| <b>Coverage Duration</b>            | 12 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.  |
| <b>Other Criteria</b>               | N/A   |



## VOTRIENT (S)

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### Products Affected

- Votrient

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Renal cell carcinoma (RCC): Diagnosis of advanced/metastatic RCC. Soft tissue sarcoma: Diagnosis of advanced soft tissue sarcoma and patient received at least one prior chemotherapy (e.g., ifosfamide, doxorubicin, cisplatin, dacarbazine, docetaxel, oxaliplatin, etc.). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | All uses: Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

# VOXZOGO (S)

## Products Affected

- Voxzogo

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: Patient has open epiphyses. Diagnosis of achondroplasia as confirmed by one of the following: 1) Both of the following: a) Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis) and b) Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosiatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest), OR 2) Molecular genetic testing confirmed c.1138G to A or c.1138G to C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene. Patient did not have limb-lengthening surgery in the previous 18 months and does not plan on having limb-lengthening surgery while on Voxzogo therapy. |
| <b>Age Restrictions</b>             | Initial: Patient is 5 years of age or older.  |
| <b>Prescriber Restrictions</b>      | Initial, Reauth: Prescribed by or in consultation with a clinical geneticist, endocrinologist, or a physician who has specialized expertise in the management of achondroplasia.  |
| <b>Coverage Duration</b>            | Initial, Reauth: 12 months.   |
| <b>Other Criteria</b>               | Reauth: Patient continues to have open epiphyses. Documentation of a positive clinical response to therapy as evidenced by one of the following: 1) Improvement in annualized growth velocity (AGV) compared to baseline, OR 2) Improvement in height Z-score compared to baseline.   |

## VUMERITY (S)

### Products Affected

- Vumerity

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.  |
| <b>Required Medical Information</b> | MS (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS (initial, reauth): Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | MS (initial, reauth): 12 months  |
| <b>Other Criteria</b>               | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression).  |

# VYVGART (S)

## Products Affected

- Vyvgart

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Initial: Diagnosis of generalized myasthenia gravis (gMG). Patient is anti-acetylcholine receptor (AChR) antibody positive. Prior to administration, patient must be on a stable dose of at least ONE of the following therapies for the treatment of gMG: a) acetylcholinesterase (AChE) inhibitors (e.g., pyridostigmine), b) steroids (e.g., prednisone), or c) non-steroidal immunosuppressive therapies (NSISTs) (e.g., azathioprine, cyclosporine, cyclophosphamide). One of the following: a) Prescribed medication will be administered at 10mg/kg as an intravenous infusion over one hour once weekly for 4 weeks OR b) In patients weighing 120 kg or more, prescribed medication will be administered at 1200mg per infusion over one hour once weekly for 4 weeks. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Initial: Prescribed by or in consultation with a neurologist.   |
| <b>Coverage Duration</b>            | Initial: 6 months. Reauth: 12 months.   |
| <b>Other Criteria</b>               | Reauth: Documentation of positive clinical response to therapy. One of the following: a) Prescribed medication will be administered at 10mg/kg as an intravenous infusion over one hour once weekly for 4 weeks OR b) In patients weighing 120 kg or more, prescribed medication will be administered at 1200mg per infusion over one hour once weekly for 4 weeks.   |

## WELIREG (S)

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### Products Affected

- Welireg

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of von Hippel-Lindau (VHL) disease. Patient requires therapy for one of the following: a) renal cell carcinoma (RCC), b) central nervous system (CNS) hemangioblastoma, or c) pancreatic neuroendocrine tumor (pNET). Patient does not require immediate surgery. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# XALKORI (S)

## Products Affected

- Xalkori

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of advanced or metastatic NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) or B) Patient has MET amplification- or ROS1 rearrangement-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | NSCLC: Prescribed by or in consultation with an oncologist. ALCL: Prescribed by or in consultation with an oncologist or hematologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## Xcopri (S)

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### Products Affected

- Xcopri

| <b>PA Criteria</b>                  | <b>Criteria Details</b>                    |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.        |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of partial onset seizures.       |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months                                  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy. |

# XELJANZ (S)

## Products Affected

- Xeljanz

- Xeljanz Xr

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | <p>Xeljanz tab/Xeljanz XR tab: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PsA, AS (Initial): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). Not used in combination with other Janus kinase (JAK) inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine).</p> |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | RA, PJIA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.   |



|                          |   |
|--------------------------|---|
| <b>Coverage Duration</b> | RA/PJIA/PsA/AS (initial): 6 mo, (reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.   |
| <b>Other Criteria</b>    | <p>Xeljanz: Polyarticular course juvenile idiopathic arthritis (PJIA) (Initial): Diagnosis of active polyarticular course juvenile idiopathic arthritis. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Enbrel, Humira). RA, PsA, AS, PJIA (Initial): Not used in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). RA, PJIA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. RA, PsA, AS, PJIA (reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). UC (Reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine).</p> |

# XENAZINE (S)

## Products Affected

- Tetrabenazine

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Chorea associated with Huntington's Disease (HD) (Initial): Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia (Initial): Diagnosis of tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication, OR 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Tourette's syndrome (Initial): Patient has tics associated with Tourette's syndrome. Trial and failure, contraindication, or intolerance to Haldol (haloperidol). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | HD (Initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia, Tourette's syndrome (Initial): Prescribed by or in consultation with neurologist or psychiatrist.  |
| Coverage Duration            | All uses: (initial) 3 months. (Reauth) 12 months.   |
| Other Criteria               | All indications (Reauth): Documentation of clinical response and benefit from therapy.  |

# XERMELO (S)

## Products Affected

- Xermelo

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Carcinoid syndrome diarrhea (Initial): Diagnosis of carcinoid syndrome diarrhea AND diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months AND used in combination with SSA therapy. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Initial: Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist   |
| <b>Coverage Duration</b>            | Initial: 6 months. Reauth: 12 months   |
| <b>Other Criteria</b>               | Carcinoid syndrome diarrhea (Reauthorization): Documentation of a positive clinical response to therapy AND drug will continue to be used in combination with SSA therapy.   |

# XGEVA (S)

## Products Affected

- Xgeva

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Multiple Myeloma (MM)/Bone metastasis from solid tumors (BMST): One of the following: 1) Both of the following: a) Diagnosis of multiple myeloma and b) Trial and failure, contraindication (e.g., renal insufficiency), or intolerance to one bisphosphonate therapy, OR 2) Both of the following: a) Diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and b) Documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Both of the following: 1) Diagnosis of giant cell tumor of bone AND 2) One of the following: a) tumor is unresectable, OR b) surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM): Both of the following: 1) Diagnosis of hypercalcemia of malignancy, AND 2) Trial and failure, contraindication, or intolerance to one bisphosphonate therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | GCTB, HCM: Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | MM/BMST, GCTB: 12 mo. HCM: 2 mo.  |
| <b>Other Criteria</b>               | GCTB: Approve for continuation of prior therapy.  |

# XIFAXAN (S)

## Products Affected

- Xifaxan

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Travelers' diarrhea (TD) (200 mg strength only): Diagnosis of travelers' diarrhea, AND one of the following: a) Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR b) resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). Prophylaxis of hepatic encephalopathy (HE) recurrence (550mg strength only): Used for the prophylaxis of hepatic encephalopathy recurrence, AND trial and failure, contraindication or intolerance to lactulose. Treatment of HE: Used for the treatment of HE. Trial and failure, contraindication, or intolerance to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (550mg strength only) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide]. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | TD: 14 days. HE (prophylaxis, treatment): 12 months. IBS-D (initial, reauth): 2 weeks.   |
| Other Criteria               | IBS-D (reauth): Patient experiences IBS-D symptom recurrence.  |

# XOLAIR (S)

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## Products Affected

- Xolair

| <b>PA Criteria</b>                  | <b>Criteria Details</b> |
|-------------------------------------|-------------------------|
| <b>Indications</b>                  | Pending CMS Review      |
| <b>Off-Label Uses</b>               | Pending CMS Review      |
| <b>Exclusion Criteria</b>           | Pending CMS Review      |
| <b>Required Medical Information</b> | Pending CMS Review      |
| <b>Age Restrictions</b>             | Pending CMS Review      |
| <b>Prescriber Restrictions</b>      | Pending CMS Review      |
| <b>Coverage Duration</b>            | Pending CMS Review      |
| <b>Other Criteria</b>               | Pending CMS Review      |

## XOSPATA (S)

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### Products Affected

- Xospata

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis of acute myeloid leukemia (AML). Disease is relapsed or refractory. Patient has a FMS-like tyrosine kinase (FLT3) mutation as determined by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist or oncologist.   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# XPOVIO (S)

## Products Affected

- Xpovio
- Xpovio 100 Mg Once Weekly
- Xpovio 40 Mg Once Weekly
- Xpovio 40 Mg Twice Weekly
- Xpovio 60 Mg Once Weekly
- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Once Weekly
- Xpovio 80 Mg Twice Weekly

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Multiple Myeloma (MM): Diagnosis of multiple myeloma. Patient has received at least one prior therapy (e.g., lenalidomide, bortezomib, daratumumab, pomalidomide). Used in combination with bortezomib and dexamethasone. Relapsed/Refractory Multiple Myeloma (RRMM): Diagnosis of relapsed or refractory multiple myeloma (RRMM). Patient has received at least four prior therapies (e.g., lenalidomide, bortezomib, daratumumab, pomalidomide). Disease is refractory to all of the following: 1) Two proteasome inhibitors (e.g., bortezomib, carfilzomib), 2) Two immunomodulatory agents (e.g., lenalidomide, thalidomide), and 3) An anti-CD38 monoclonal antibody (e.g. daratumumab). Used in combination with dexamethasone. Diffuse large B-cell lymphoma (DLBCL): Diagnosis of one of the following: 1) Relapsed or refractory DLBCL not otherwise specified OR 2) Relapsed or refractory DLBCL arising from follicular lymphoma. Patient has previously received at least two lines of systemic therapy (e.g., CHOP: cyclophosphamide, doxorubicin, vincristine, and prednisone plus rituximab). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist/hematologist  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |



# XTANDI (S)

## Products Affected

- Xtandi

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Castration-resistant or castration-recurrent prostate cancer (CRPC):<br>Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Metastatic castration-sensitive prostate cancer (M-CSPC):<br>Diagnosis of metastatic castration-sensitive prostate cancer. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | CRPC, M-CSPC: Prescribed by or in consultation with an oncologist or urologist  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

# XYREM (S)

## Products Affected

- Xyrem

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Indications                  | All Medically-accepted Indications.  |
| Off-Label Uses               | N/A  |
| Exclusion Criteria           | N/A  |
| Required Medical Information | Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant. |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | All uses (initial): Prescribed by or in consultation with one of the following: neurologist, psychiatrist, or sleep medicine specialist.   |
| Coverage Duration            | All uses (initial): 6 months. All uses (reauth): 12 months   |
| Other Criteria               | Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy.  |

## ZAVESCA (S)

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### Products Affected

- Miglustat

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.                                    |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease. |
| <b>Age Restrictions</b>             | Gaucher disease: Patient is 18 years of age or older.                  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Gaucher disease: 12 months   |
| <b>Other Criteria</b>               | N/A  |

## ZEJULA (S)

### Products Affected

- Zejula

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: advanced epithelial ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to first-line platinum-based chemotherapy (e.g., cisplatin, carboplatin). Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Treatment of advanced ovarian cancer after three or more chemotherapies: Diagnosis of advanced ovarian cancer, advanced fallopian tube cancer, or advanced primary peritoneal cancer. Patient has been treated with three or more prior chemotherapy regimens. Patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by one of the following: (a) a deleterious or suspected deleterious BRCA mutation or (b) both of the following: (1) genomic instability and (2) cancer has progressed more than 6 months after response to the last platinum-based chemotherapy (e.g., cisplatin, carboplatin). |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | Prescribed by or in consultation with an oncologist   |
| Coverage Duration            | 12 months   |
| Other Criteria               | Approve for continuation of prior therapy.  |

# ZELBORAF (S)

## Products Affected

- Zelboraf

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (eg, cobas 4600 BRAFV600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Erdheim-Chester Disease: Diagnosis of Erdheim-Chester disease AND Disease is BRAFV600 mutant type (MT). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Melanoma: Prescribed by or in consultation with an oncologist. Erdheim-Chester Disease: Prescribed by or in consultation with a hematologist/oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | All indications: Approve for continuation of therapy.  |

## ZEPOSIA (S)

### Products Affected

- Zeposia
- Zeposia 7-day Starter Pack
- Zeposia Starter Kit

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Aubagio (teriflunomide), 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. Ulcerative Colitis (UC) (init): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. One of the following: a) Trial and failure, contraindication, or intolerance to two of the following: Humira (adalimumab), Stelara (ustekinumab), Rinvoq (upadacitinib), or Xeljanz IR (tofacitinib IR)/Xeljanz XR (tofacitinib XR), OR b) for continuation of prior therapy. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | MS (initial, reauth): Prescribed by or in consultation with a neurologist.<br>UC (init): Prescribed by or in consultation with a gastroenterologist.  |
| <b>Coverage Duration</b>            | MS (initial, reauth): 12 months. UC (init): 12 weeks, (reauth): 12 months.  |

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|-----------------------|--|
| <b>Other Criteria</b> | MS (reauth): Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). UC (reauth): Documentation of positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. |
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## ZEPZELCA (S)

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### Products Affected

- Zepzelca

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of metastatic small cell lung cancer (SCLC). Disease has progressed on or after platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |



# ZIRABEV (S)

## Products Affected

- Zirabev

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Indications                  | All Medically-accepted Indications.   |
| Off-Label Uses               | N/A   |
| Exclusion Criteria           | Non-Small Cell Lung Cancer: Excluded if squamous cell histology.  |
| Required Medical Information | <p>Colorectal Cancer: Diagnosis of metastatic colorectal cancer. One of the following: 1) Both of the following: a) used as first- or second-line treatment and b) used in combination with an intravenous 5-fluorouracil-based chemotherapy, OR 2) All of the following: a) used as second-line treatment, b) used in combination with fluoropyrimidine-irinotecan-based chemotherapy or fluoropyrimidine-oxaliplatin-based chemotherapy, and c) patient has progressed on a first-line bevacizumab-containing regimen.</p> <p>Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is unresectable, locally advanced, recurrent, or metastatic. Used as first-line treatment. Used in combination with paclitaxel and carboplatin.</p> <p>Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with interferon-alpha.</p> <p>Cervical Cancer: Diagnosis of carcinoma of the cervix. Disease is persistent, recurrent, or metastatic. Used in combination with one of the following: a) paclitaxel and cisplatin or b) paclitaxel and topotecan.</p> <p>Glioblastoma: Diagnosis of recurrent glioblastoma.</p> <p>Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) All of the following: a) disease is stage 3 or 4, b) patient has been treated with bevacizumab as a single agent, c) treatment is following surgical resection, and d) used in combination with carboplatin and paclitaxel, OR 2) All of the following: a) disease is platinum-resistant recurrent, b) patient has received no more than 2 prior chemotherapy regimens, and c) used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, OR 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, and c) used in combination with one of the following: i) carboplatin and paclitaxel or ii) carboplatin and gemcitabine.</p> |
| Age Restrictions             | N/A   |

|                                |  |
|--------------------------------|--|
| <b>Prescriber Restrictions</b> | Prescribed by or in consultation with an oncologist.   |
| <b>Coverage Duration</b>       | 12 months  |
| <b>Other Criteria</b>          | Hepatocellular Carcinoma (HCC): Diagnosis of hepatocellular carcinoma. Disease is unresectable or metastatic. Used in combination with Tecentriq (atezolizumab). Patient has not received prior systemic therapy. Approve for continuation of prior therapy. |

# ZOKINVY (S)

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## Products Affected

- Zokinvy

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | One of the following: 1) Diagnosis of Hutchinson-Gilford Progeria Syndrome, OR 2) For treatment of processing-deficient Progeroid Laminopathies with one of the following: i) Heterozygous LMNA mutation with progerin-like protein accumulation OR ii) Homozygous or compound heterozygous ZMPSTE24 mutations. Patient has a body surface area of 0.39 m <sup>2</sup> and above. |
| <b>Age Restrictions</b>             | Patient is 12 months of age or older.   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | N/A   |

## ZOLADEX (S)

### Products Affected

- Zoladex

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to any brand Lupron formulation. Endometriosis [Zoladex (3.6 mg strength)]: Treatment of endometriosis. Trial and failure to Lupron Depot (3.75 mg or 11.25 mg). Advanced Breast Cancer [Zoladex (3.6 mg strength)]: For the palliative treatment of advanced breast cancer. Endometrial thinning [Zoladex (3.6 mg strength)] For the treatment of dysfunctional uterine bleeding. Used as an endometrial thinning agent prior to endometrial ablation. |
| <b>Age Restrictions</b>             | Endometriosis: 18 years or older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## ZOLINZA (S)

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### Products Affected

- Zolinza

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Progressive, persistent or recurrent disease on or contraindication or intolerance to two systemic therapies (e.g., bexarotene, romidepsin, etc.). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist.  |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.  |

## ZORBTIVE (S)

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### Products Affected

- Zorbtive

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements). Patient has not previously received 4 weeks of treatment with Zorbtive (somatropin). |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a gastroenterologist.   |
| <b>Coverage Duration</b>            | SBS: 4 weeks.   |
| <b>Other Criteria</b>               | N/A   |

## ZYDELIG (S)

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### Products Affected

- Zydelig

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Used in combination with Rituxan (rituximab). The patient has relapsed on at least one prior therapy (eg, purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]). Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (eg, coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD]). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist/hematologist.  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## ZYKADIA (S)

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### Products Affected

- Zykadia

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC that is metastatic or recurrent. Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an oncologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |



## ZYNLONTA (S)

### Products Affected

- Zynlonta

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Indications</b>                  | All Medically-accepted Indications.  |
| <b>Off-Label Uses</b>               | N/A  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | One of the following diagnoses: 1) Diffuse large B-cell lymphoma (DLBCL), 2) DLBCL arising from low-grade lymphoma, or 3) High-grade B-cell lymphoma. Disease is one of the following: a) relapsed or b) refractory. Patient has received at least two prior systemic therapies (e.g., rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, dexamethasone, cisplatin, cytarabine). |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a hematologist/oncologist.   |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy.   |

## ZYTIGA (PREFERRED) (S)

### Products Affected

- Abiraterone Acetate

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Indications</b>                  | All Medically-accepted Indications.   |
| <b>Off-Label Uses</b>               | N/A   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Metastatic Castration-Resistant Prostate Cancer (mCRPC): Diagnosis of metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer. Used in combination with prednisone. Metastatic Castration-Sensitive Prostate Cancer (mCSPC): Diagnosis of metastatic high-risk castration-sensitive prostate cancer. Used in combination with prednisone. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | mCRPC, mCSPC: Prescribed by or in consultation with an oncologist or urologist  |
| <b>Coverage Duration</b>            | mCRPC, mCSPC: 12 months   |
| <b>Other Criteria</b>               | Approve for continuation of prior therapy   |

# PART B VERSUS PART D

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## Products Affected

- Abelcet
- Acetylcysteine SOLN
- Acyclovir Sodium INJ 50MG/ML
- Akynzeo CAPS
- Albuterol Sulfate NEBU 0.083%, 0.63MG/3ML, 1.25MG/3ML, 2.5MG/0.5ML
- Ambisome
- Aminosyn II INJ 107.6MEQ/L; 1490MG/100ML; 1527MG/100ML; 1050MG/100ML; 1107MG/100ML; 750MG/100ML; 450MG/100ML; 990MG/100ML; 1500MG/100ML; 1575MG/100ML; 258MG/100ML; 447MG/100ML; 1083MG/100ML; 795MG/100ML; 50MEQ/L; 600MG/100ML; 300MG/100ML; 405MG/100ML; 750MG/100ML, 71.8MEQ/L; 993MG/100ML; 1018MG/100ML; 700MG/100ML; 738MG/100ML; 500MG/100ML; 300MG/100ML; 660MG/100ML; 1000MG/100ML; 1050MG/100ML; 172MG/100ML; 298MG/100ML; 722MG/100ML; 530MG/100ML; 38MEQ/L; 400MG/100ML; 200MG/100ML; 270MG/100ML; 500MG/100ML, 993MG/100ML; 1018MG/100ML; 700MG/100ML; 738MG/100ML; 500MG/100ML; 300MG/100ML; 660MG/100ML; 1000MG/100ML; 1050MG/100ML; 172MG/100ML; 270MG/100ML; 298MG/100ML; 722MG/100ML; 530MG/100ML; 400MG/100ML; 200MG/100ML; 500MG/100ML
- Aminosyn-pf INJ 46MEQ/L; 698MG/100ML; 1227MG/100ML; 527MG/100ML; 820MG/100ML; 385MG/100ML; 312MG/100ML; 760MG/100ML; 1200MG/100ML; 677MG/100ML; 180MG/100ML; 427MG/100ML; 812MG/100ML; 495MG/100ML; 70MG/100ML; 512MG/100ML; 180MG/100ML; 44MG/100ML; 673MG/100ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Aprepitant CAPS
- Azathioprine TABS
- Budesonide SUSP
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclosporine CAPS
- Cyclosporine Modified
- Engerix-b
- Envarsus Xr
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Formoterol Fumarate NEBU
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Hepagam B INJ 312UNIT/ML
- Heplisav-b
- Hyperhep B
- Hyperrab S/d INJ 1500UNIT/10ML, 300UNIT/2ML
- Imogam Rabies-ht INJ 300UNIT/2ML
- Imovax Rabies (h.d.c.v.)
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Kedrab
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR

- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nabi-hb INJ 312UNIT/ML
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hydrochloride TABS
- Ondansetron Odt
- 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
- Prehevbrio
- Prograf PACK
- Rabavert
- Recombivax Hb
- Sandimmune SOLN
- Sirolimus SOLN
- Sirolimus TABS
- Tacrolimus CAPS
- Tobramycin NEBU 300MG/5ML
- Yupelri

## 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.

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