

## ACTEMRA SC (S)

### Products Affected

- Actemra INJ 162MG/0.9ML
- Actemra Actpen

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Actemra therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Trial and failure, contraindication, or intolerance to a glucocorticoid (i.e., prednisone). Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. Trial and failure, contraindication, or intolerance to one of the following: NSAID or systemic glucocorticoid. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Actemra therapy.
Age Restrictions	N/A
Prescriber Restrictions	RA, GC, SJIA, PJIA (initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	RA, GC, SJIA, PJIA (initial, reauth): 12 months
Other Criteria	RA, GC, SJIA, PJIA (Reauth): Documentation of positive clinical response to Actemra therapy.

## ACTIMMUNE (S)

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### Products Affected

- Actimmune

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

## ADCETRIS (S)

### Products Affected

- Adcetris

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hodgkin Lymphoma (HL): Diagnosis of HL. One of the following: failure of autologous hematopoietic stem cell transplant (auto-HSCT) or failure of at least two prior multi-agent chemotherapy regimens or used as post-auto-HSCT consolidation therapy for patients at high risk of relapse or progression. Systemic Anaplastic Large Cell Lymphoma (sALCL): Diagnosis of sALCL. Failure of at least one prior multi-agent chemotherapy regimen.
Age Restrictions	N/A
Prescriber Restrictions	HL, sALCL: Prescribed by or in consultation with an oncologist/hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## ADCIRCA (S)

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### Products Affected

- Alyq
- Tadalafil TABS 20MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

## ADDERALL XR (S)

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### Products Affected

- Amphetamine/dextroamphetamine  
CP24

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) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## ADEMPAS (S)

### Products Affected

- Adempas

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	PAH, CTEPH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH, CTEPH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH, CTEPH (Reauth): Documentation of positive clinical response to therapy.

# AFINITOR (S)

## Products Affected

- Afinitor

- Everolimus TABS 2.5MG, 5MG, 7.5MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

## AFINITOR DISPERZ (S)

### Products Affected

- Afinitor Disperz

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Subependymal Giant Cell Astrocytoma (SEGA): Diagnosis of SEGA associated with tuberous sclerosis complex (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.
Age Restrictions	N/A
Prescriber Restrictions	SEGA: Prescribed by or in consultation with an oncologist. TSC-associated partial-onset seizures: Prescribed by or in consultation with a neurologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.



# AIMOVIG (S)

## Products Affected

- Aimovig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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. 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.
Age Restrictions	EM, CM (initial): 18 years of age or older.
Prescriber Restrictions	EM, CM (initial, reauth): Prescribed by or in consultation with a neurologist or pain specialist.
Coverage Duration	EM, CM (initial): 6 months. EM, CM (reauth): 12 months.
Other Criteria	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], triptans) has decreased since the start of CGRP therapy. CM (reauth): Patient continues to be monitored for medication overuse headache.

## ALDURAZYME (S)

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### Products Affected

- Aldurazyme

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## ALECENSA (S)

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### Products Affected

- Alecensa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
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.

## ALIQOPA (S)

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### Products Affected

- Aliqopa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Relapsed Follicular Lymphoma: Diagnosis of relapsed follicular lymphoma AND patient has received at least two prior systemic therapies.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# ALPHA-1 PROTEINASE INHIBITOR, NON-PREFERRED (S)

## Products Affected

- Aralast Np INJ 1000MG, 500MG

- Zemaira

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: Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. Continued optimal 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-causing alleles associated with serum AAT level less than 11 µM/L [e.g., Pi(Malton, Malton)]. Circulating serum concentration of AAT level less than 11 µM/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry). One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment. Trial and failure, or intolerance to Prolastin.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# 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: Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. Continued optimal 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-causing alleles associated with serum AAT level less than 11 $\mu$ M/L [e.g., Pi(Malton, Malton)]. Circulating serum concentration of 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). One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## ALUNBRIG (S)

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### Products Affected

- Alunbrig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
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.

## AMPHETAMINE (S)

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### Products Affected

- Amphetamine/dextroamphetamine  
TABS

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) diagnosis of ADHD, OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible).
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A



## AMPYRA (S)

### Products Affected

- Dalfampridine Er

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	MS (initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	MS (Initial): 6 months. (Reauth): 12 months.
Other Criteria	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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Anemia (reauth): Documentation of a positive clinical response to Anadrol-50 therapy as evidenced by an improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions).

# ANDROXY (S)

## Products Affected

- Androxy

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 in a male patient at birth. 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: Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and 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). Delayed puberty (DP): Dx of DP in males at birth. Breast cancer (BC): Dx for the palliative treatment of inoperable BC in females at birth. Gender Dysphoria (GD) (off-label): Dx of GD. Patient is a female-to-male transsexual.
<b>Age Restrictions</b>	N/A
<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.

## APOKYN (S)

### Products Affected

- Apokyn INJ 30MG/3ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	PD (Initial): Patient is using Apokyn with any 5-HT3 antagonist (eg, ondansetron, granisetron, dolasetron, palonosetron, alosetron)
Required Medical Information	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). Patient is receiving Apokyn in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, etc.).
Age Restrictions	N/A
Prescriber Restrictions	PD (Initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	PD (Initial, reauth): 12 months
Other Criteria	PD (Reauth): Documentation of positive clinical response to Apokyn therapy.

## ARANESP (S)

### Products Affected

- Aranesp Albumin Free INJ  
100MCG/0.5ML, 100MCG/ML,  
10MCG/0.4ML, 150MCG/0.3ML,  
200MCG/0.4ML, 200MCG/ML,  
25MCG/0.42ML, 25MCG/ML,  
300MCG/0.6ML, 300MCG/ML,  
40MCG/0.4ML, 40MCG/ML,  
500MCG/ML, 60MCG/0.3ML,  
60MCG/ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused in part by cancer chemo. CKD (init, reauth), Chemo (init), MDS (init): Verify iron evaluation for adequate iron stores. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.
Age Restrictions	N/A
Prescriber Restrictions	N/A

<b>Coverage Duration</b>	CKD (Init): 6 mo. CKD (reauth): 12 mo. Chemo(init, reauth): 3 mo. MDS: (init) 3 mo,(reauth) 12 mo.
<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 mo is 33% or less (Hgb 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused in part by cancer chemo. 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more 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%.</p>

# ARCALYST (S)

## Products Affected

- Arcalyst

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	CAPS (Initial): 12 years of age or older
Prescriber Restrictions	CAPS (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist.
Coverage Duration	CAPS (initial, reauth): 12 months
Other Criteria	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.

## ARZERRA (S)

### Products Affected

- Arzerra

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Refractory chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Disease is refractory to both fludarabine and alemtuzumab. Previously untreated CLL: Diagnosis of CLL. Patient is previously untreated for CLL. Patient is not an appropriate candidate for fludarabine-based therapy. Used in combination with chlorambucil. Recurrent or progressive Chronic Lymphocytic Leukemia (CLL): Diagnosis of chronic lymphocytic leukemia (CLL). Disease is recurrent or progressive. Arzerra is used for an extended treatment for patients who are in complete or partial response after at least two lines of therapy. Relapsed Chronic Lymphocytic Leukemia (CLL): Diagnosis of CLL. Disease has relapsed. Used in combination with fludarabine and cyclophosphamide.
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.



## AURYXIA (S)

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### Products Affected

- Auryxia

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

# AUSTEDO (S)

## Products Affected

- Austedo

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>	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: 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.
<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 Austedo therapy.

## AYVAKIT (S)

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### Products Affected

- Ayvakit

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

## BAFIERTAM (S)

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### Products Affected

- Bafiertam

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): 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: Aubagio (teriflunomide), Gilenya (fingolimod), or Tecfidera (dimethyl fumarate), OR b) for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## BALVERSA (S)

### Products Affected

- Balversa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 chemotherapy or immunotherapy OR 2) Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.
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.

## BAVENCIO (S)

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### Products Affected

- Bavencio

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Merkel Cell Carcinoma (MCC): Diagnosis of metastatic Merkel cell carcinoma. Urothelial Carcinoma (UC): Diagnosis of locally advanced or metastatic urothelial carcinoma. One of the following: 1) Patient has disease progression during or following platinum-containing chemotherapy, OR 2) Patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
Age Restrictions	MCC: Patient is 12 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## BELEODAQ (S)

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### Products Affected

- Beleodaq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Peripheral T-cell lymphoma (PTCL): Diagnosis of PTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (e.g., conventional chemotherapy).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## BENLYSTA (S)

### Products Affected

- Benlysta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)]).
Age Restrictions	N/A
Prescriber Restrictions	SLE (init): Prescribed by or in consultation with a rheumatologist
Coverage Duration	SLE (init, reauth): 6 months
Other Criteria	SLE (reauth): Documentation of positive clinical response to Benlysta therapy.



## BENZODIAZEPINES (S)

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### Products Affected

- Alprazolam TABS
- Lorazepam CONC
- Lorazepam INJ 2MG/ML, 4MG/ML
- Lorazepam TABS
- Lorazepam Intensol
- Temazepam CAPS 15MG, 30MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Verify the medication is being used for an FDA-approved diagnosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## BERINERT (S)

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### Products Affected

- Berinert

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

## BESPONSA (S)

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### Products Affected

- Besponsa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	B-cell precursor acute lymphoblastic leukemia (ALL): Diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL). Disease is relapsed or refractory.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## BLINCYTO (S)

### Products Affected

- Blincyto

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL); Diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia/acute lymphoblastic lymphoma. Minimal residual disease (MRD)-positive B-cell precursor ALL (MRD+ ALL); Diagnosis of B-cell precursor ALL. Patient is in their first or second complete remission. Documentation of MRD greater than or equal to 0.1%.
Age Restrictions	N/A
Prescriber Restrictions	All Indications: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	ALL: 12 months. MRD+ ALL: 6 months.
Other Criteria	Subject to Part B vs. Part D review. All Indications: Approve for continuation of prior therapy.

## BORTEZOMIB (S)

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### Products Affected

- Bortezomib

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. Mantle cell lymphoma (MCL): Diagnosis of MCL AND patient has received at least one prior therapy for MCL.
Age Restrictions	N/A
Prescriber Restrictions	MM, MCL: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## BOSULIF (S)

### Products Affected

- Bosulif

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

# BOTOX (S)

## Products Affected

- Botox

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Neuromuscular Disorders (init): Strabismus, blepharospasm associated with dystonia (eg, benign essential blepharospasm), treatment of upper or lower limb spasticity, VII cranial nerve disorders (hemifacial spasms), cervical dystonia Hyperhidrosis(HH): (Init) Dx of primary axillary HH. Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) or skin maceration with secondary infection. Migraine:(Init) Dx of chronic migraines (greater than or equal to 15 migraine headache days per month with headache lasting 4 hours a day or longer). TF/C/I to prophylactic therapy with at least two of the following agents, each given for a trial of at least two months: antidepressants [ie, Effexor (venlafaxine)], antiepileptics [ie, Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [eg, atenolol, Inderal (propranolol), nadolol, timolol, Toprol XL (metoprolol)] Achalasia:(Init) High risk of complication from or failure to pneumatic dilation or myotomy, or prior dilation caused esophageal perforation, or patient has an epiphrenic diverticulum or hiatal hernia. Anal Fissure (AF)(Init): Dx of chronic AF. At least 2 months of either nocturnal pain and bleeding or postdefecation pain. Chronic Back Pain (CBP):(Init) Dx of low back pain lasting greater than or equal to six months. Urinary incont (UI):(init) Neurogenic detrusor overactivity associated with a neurologic condition (eg, spinal cord injury [SCI], multiple sclerosis) or detrusor sphincter dyssynergia with SCI. Overactive bladder (OAB): (init) Dx of OAB. One of the following symptoms: urge urinary incontinence, urgency, frequency.</p>
Age Restrictions	N/A
Prescriber Restrictions	<p>Migraine (initial): Prescribed by a neurologist or pain specialist. CBP (initial): Prescribed by a neurologist, neurosurgeon, orthopedist, or pain specialist. UI, OAB (initial): Prescribed by a neurologist, neurosurgeon, or urologist.</p>

<b>Coverage Duration</b>	Achalasia: 6moCBP:1 tx(series of injxs)UI:3mo(1 dose,200units)Other:3mo
<b>Other Criteria</b>	UI, OAB, CBP, Neuromuscular Disorders:(Reauth) Confirmed improvement in symptoms with initial Botox treatment. At least 3 months have or will have elapsed since the last treatment with Botox HH:(Reauth) At least a 2-point improvement in HDSS. Migraine:(Reauth) Reduction in headache frequency or intensity. Confirmation of decreased utilization of pain medications (eg, narcotic analgesics, NSAIDs) or triptans, or a reduction in the number of ER visits. Achalasia:(Reauth) Documentation of improvement or reduction in symptoms of achalasia (ie, dysphagia, regurgitation, chest pain). At least 6 months have or will have elapsed since last series of injections AF: (Reauth) Incomplete healing of fissure or recurrence of fissure. Improved symptoms with prior treatment with Botox.



## BRAFTOVI (S)

### Products Affected

- Braftovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
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

## BRIVIACT (S)

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### Products Affected

- Briviact

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

## BRUKINSA (S)

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### Products Affected

- Brukinsa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of relapsed or refractory mantle cell lymphoma (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).
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.

## BYNFEZIA (S)

### Products Affected

- Bynfezia Pen

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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. All indications (initial): Trial and failure, or intolerance to generic octreotide.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	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.

## CABLIVI (S)

### Products Affected

- Cablivi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acquired thrombocytic 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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	3 months
Other Criteria	N/A

## CABOMETYX (S)

### Products Affected

- Cabometyx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. RCC is advanced. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and failure 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.
Age Restrictions	N/A
Prescriber Restrictions	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.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## CALQUENCE (S)

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### Products Affected

- Calquence

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## CAPRELSA (S)

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### Products Affected

- Caprelsa

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



## CAYSTON (S)

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### Products Affected

- Cayston

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, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs.
Age Restrictions	CF (Initial): 7 years of age or older
Prescriber Restrictions	N/A
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).

# CERDELGA (S)

## Products Affected

- Cerdelga

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease (Initial): 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.
Age Restrictions	Gaucher disease (initial): 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease (initial, reauth): 12 months
Other Criteria	Gaucher disease (Reauth): Patient's condition has not progressed, as defined by ALL of the following: A) Hemoglobin level decreased greater than 1.5 g/dL from baseline, AND B) Platelet count decreased greater than 25% from baseline, AND C) Spleen volume increased greater than 25% from baseline, AND D) Liver volume increased greater than 20% from baseline.

## CEREZYME (S)

### Products Affected

- Cerezyme

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease: Diagnosis of type 1 Gaucher disease. Patient has evidence of symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease: 12 months
Other Criteria	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. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 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) Cholbam 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 (initial, reauth): 12 months
<b>Other Criteria</b>	All uses (reauth): documentation of positive clinical response to Cholbam therapy.

## CHORIONIC GONADOTROPIN (S)

### Products Affected

- Chorionic Gonadotropin INJ
- Novarel
- Pregnyl W/diluent Benzyl Alcohol/nacl

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prepubertal Cryptorchidism: Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction. Male Hypogonadotropic Hypogonadism (MHH) (initial): Diagnosis of male hypogonadism secondary to pituitary deficiency, and low testosterone (below normal reference value provided by the physician's laboratory) and one of the following: a) low LH (below normal reference value provided by the physician's laboratory) or b) low FSH (below normal reference value provided by the physician's laboratory).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prepubertal Cryptorchidism: 6 wks. MHH (initial, reauth): 12 months.
Other Criteria	Excluded if used to promote fertility. MHH (Reauth): Documentation of positive clinical response to therapy.

# CICLOPIROX (S)

## Products Affected

- Ciclodan SOLN
- Ciclopirox Nail Lacquer

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 great toenail, AND 5) Trial and failure, contraindication, or intolerance to oral terbinafine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	48 weeks.
Other Criteria	N/A

## CINRYZE (S)

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### Products Affected

- Cinryze

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE (prophylaxis): Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

## COMETRIQ (S)

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### Products Affected

- Cometriq

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



## COPIKTRA (S)

### Products Affected

- Copiktra

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 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.). Follicular Lymphoma: Diagnosis of follicular lymphoma. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior systemic therapies for follicular lymphoma (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 TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 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 or ARB. 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).
Age Restrictions	N/A
Prescriber Restrictions	CHF, DCM (initial): Prescribed by or in consultation with a cardiologist
Coverage Duration	CHF, DCM (initial, reauth): 12 months
Other Criteria	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>	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) OR Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Cosentyx therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Cosentyx therapy. 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.) TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, meloxicam, naproxen).
<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 rheumatologist or dermatologist. AS, nr-axSpA (initial): Prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months

<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Cosentyx therapy.
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## COTELLIC (S)

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### Products Affected

- Cotellic

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
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.

# CYRAMZA (S)

## Products Affected

- Cyramza

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>	Gastric cancer: All of the following: 1) diagnosis of one of the following: a) gastric adenocarcinoma, OR b) gastro-esophageal junction (GEJ) adenocarcinoma, AND 2) disease is one of the following: a) locally advanced, OR b) metastatic, AND 3) disease has progressed on or after one of the following first-line therapies: a) fluoropyrimidine-containing chemotherapy (eg, fluorouracil, capecitabine), OR b) platinum-containing chemotherapy (eg, cisplatin, carboplatin, oxaliplatin). Non-small cell lung cancer: All of the following: 1) diagnosis of metastatic non-small cell lung cancer, AND 2) used in combination with docetaxel, AND 3) disease has progressed on or after platinum-based chemotherapy (eg, cisplatin, carboplatin, oxaliplatin). Metastatic colorectal cancer (mCRC): 1) Diagnosis of metastatic CRC AND 2) Used in combination with irinotecan or FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), AND 3) Patient had disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.
<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.

## CYSTARAN (S)

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### Products Affected

- Cystaran

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystinosis: Diagnosis of cystinosis, confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation AND Patient is concomitantly receiving treatment with oral cysteamine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## DACOGEN (S)

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### Products Affected

- Decitabine

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.



## DALIRESP (S)

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### Products Affected

- Daliresp

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	COPD (init, reauth): 12 months
Other Criteria	COPD (reauth): Documentation of positive clinical response to Daliresp therapy.

# DARAPRIM (S)

## Products Affected

- Daraprim

- Pyrimethamine TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	12 months
Other Criteria	Toxoplasmosis only: Approve for continuation of prior therapy.

# DARZALEX (S)

## Products Affected

- Darzalex

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>	Relapsed/Refractory Multiple Myeloma (MM): Diagnosis of MM. One of the following: A) Both of the following: Used as monotherapy and Patient has received at least three prior treatment regimens which included both a proteasome inhibitor (eg, bortezomib [Velcade], carfilzomib [Kyprolis]) and an immunomodulatory agent (eg, lenalidomide [Revlimid], thalidomide [Thalomid]) or patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent. OR B) Patient has received at least one prior therapy. Darzalex will be used in combination with either 1) lenalidomide and dexamethasone or 2) bortezomib and dexamethasone. OR C) Both of the following: used in combination with both pomalidomide and dexamethasone, AND patient has received at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis]). Newly Diagnosed Multiple Myeloma: Newly diagnosed multiple myeloma, patient is ineligible for autologous stem cell transplant and used in combination with all of the following: bortezomib, melphalan, and prednisone.
<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

## DAURISMO (S)

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### Products Affected

- Daurismo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# DEFERASIROX (S)

## Products Affected

- Deferasirox
- Jadenu
- Jadenu Sprinkle

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.

## DEXMETHYLPHENIDATE (S)

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### Products Affected

- Dexmethylphenidate Hcl TABS 10MG, 5MG
- Dexmethylphenidate Hydrochloride TABS 2.5MG

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) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD).
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## DEXTROAMPHETAMINE (S)

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### Products Affected

- Dexedrine TABS
- Dextroamphetamine Sulfate SOLN
- Dextroamphetamine Sulfate TABS
- Dextroamphetamine Sulfate Er
- Zenzedi TABS 10MG, 5MG

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) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible).
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## DOJOLVI (S)

### Products Affected

- Dojolvi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Not used with any other medium-chain triglyceride (MCT) product.
Required Medical Information	Long-Chain Fatty Acid Oxidation Disorder (LC-FAOD) (initial): Diagnosis of a LC-FAOD. Disease has been molecularly confirmed (i.e., genetic testing).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.).
Coverage Duration	LC-FAOD (initial, reauth): 12 months
Other Criteria	LC-FAOD (reauth): Documentation of positive clinical response to therapy (e.g., increased cardiac efficiency, decreased left ventricular wall mass, decreased incidence of rhabdomyolysis, etc.).



# DUPIXENT (S)

## Products Affected

- Dupixent

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Atopic dermatitis (initial): Diagnosis of moderate to severe atopic dermatitis. Trial and failure, contraindication, or intolerance to one medium to high potency topical corticosteroid. One of the following: A) Trial and failure or intolerance to pimecrolimus topical cream, unless the patient is not a candidate for pimecrolimus therapy (e.g., immunocompromised, severe atopic dermatitis), B) Trial and failure or intolerance to tacrolimus topical ointment, unless the patient is not a candidate for tacrolimus ointment therapy (e.g., immunocompromised), or C) Eucrisa (crisaborole). Eosinophilic Asthma (initial): Diagnosis of moderate to 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 at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months, 2) Any prior intubation for an asthma exacerbation, or 3) Prior asthma-related hospitalization within the past 12 months. Corticosteroid Dependent Asthma (initial): Diagnosis of moderate to severe asthma. Patient is currently dependent on oral corticosteroids for the treatment of asthma. Eosinophilic Asthma, Corticosteroid Dependent Asthma (initial): 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, long-acting beta-2 agonist (LABA), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].
Age Restrictions	Asthma (initial): Age greater than or equal to 12 years. Atopic dermatitis: no age restriction.

<b>Prescriber Restrictions</b>	Atopic dermatitis (Initial): Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist. Asthma (initial, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (initial, reauth): Prescribed by or in consultation with an otolaryngologist or allergist/immunologist.
<b>Coverage Duration</b>	Atopic Dermatitis, CRSwNP (Init/Reauth): 12 months. Asthma (Init): 6 mo. Asthma (reauth): 12 mo.
<b>Other Criteria</b>	<p>Chronic rhinosinusitis with nasal polypsis (CRSwNP) (initial): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP (eg, intranasal corticosteroid). Atopic dermatitis (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity). Eosinophilic Asthma (reauth): Documentation of a 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 is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications: 1) Inhaled corticosteroid (ICS) and additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline] OR 2) A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]).</p> <p>Corticosteroid Dependent Asthma (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose). Patient is currently being treated with ONE of the following unless there is a contraindication or intolerance to these medications: 1) Inhaled corticosteroid (ICS) and additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline] OR 2) A combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]).</p> <p>CRSwNP (reauth): Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS, 0-8 scale], improvement in nasal congestion/obstruction score [NC, 0-3 scale]). Used in combination with another agent for CRSwNP (eg, intranasal corticosteroid).</p>

## ELAPRASE (S)

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### Products Affected

- Elaprase

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

## ELZONRIS (S)

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### Products Affected

- Elzonris

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# EMGALITY (S)

## Products Affected

- Emgality

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>	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. 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. Episodic Cluster Headache (ECH) (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.
<b>Age Restrictions</b>	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 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 (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], triptans) has decreased since the start of CGRP therapy. CM (reauth): Patient continues to be monitored for medication overuse headache. ECH (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity.

## EMPLICITI (S)

### Products Affected

- Empliciti

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma: Diagnosis of multiple myeloma. One of the following: 1) Both of the following: a) Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)] and b) Used in combination with both of the following: Revlimid (lenalidomide) and dexamethasone, OR 2) Both of the following: a) Patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor and b) Used in combination with both of the following: Pomalyst (pomalidomide) and dexamethasone.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# 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. Trial and failure, contraindication, or intolerance to one disease-modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Trial and failure, contraindication, or intolerance to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Trial and failure, contraindication, or intolerance to two NSAIDs.
<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.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Enbrel therapy.

## ENDARI (S)

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### Products Affected

- Endari

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Sickle cell disease (initial): Diagnosis of sickle cell disease. Used to reduce acute complications of sickle cell disease. One of the following: (a) Patient is using Endari with concurrent hydroxyurea therapy, OR (b) Patient has a contraindication or intolerance to hydroxyurea. Patient has had 2 or more painful sickle cell crises within the past 12 months.
Age Restrictions	N/A
Prescriber Restrictions	Sickle cell disease (initial): Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Sickle cell disease (initial, reauth): 12 months
Other Criteria	Sickle cell disease (reauth): Documentation of positive clinical response to Endari therapy.



## ENSPRYNG (S)

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### Products Affected

- Enspryng

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neuromyelitis Optica Spectrum Disorder (NMOSD) (initial): Diagnosis of NMOSD. Patient is anti-aquaporin-4 (AQP4) antibody positive.
Age Restrictions	N/A
Prescriber Restrictions	NMOSD (initial): Prescribed by or in consultation with a neurologist or ophthalmologist.
Coverage Duration	NMOSD (initial, reauth): 12 months
Other Criteria	NMOSD (reauth): Documentation of positive clinical response to therapy.

# 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. Trial and failure, contraindication, or intolerance (F/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), aminosalicylates [eg, mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone). F/C/I to one tumor necrosis factor (TNF) inhibitor [eg, Humira (adalimumab), infliximab]. Crohn's Disease (CD) (init): Dx of moderately to severely active CD. F/C/I to one of the following medications: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). F/C/I to one TNF inhibitor [eg, Humira (adalimumab), infliximab].
<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 Entyvio therapy.

## EPCLUSA PREFERRED (S)

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### Products Affected

- Sofosbuvir/velpatasvir

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C. Patient is not receiving sofosbuvir/velpatasvir in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)].
Age Restrictions	N/A
Prescriber Restrictions	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.
Coverage Duration	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	N/A

## EPIDIOLEX (S)

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### Products Affected

- Epidiolex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	LGS, DS, TSC: Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## EPOPROSTENOL (S)

### Products Affected

- Epoprostenol Sodium
- Veletri

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH (Initial): 6 months. (Reauth): 12 months
Other Criteria	Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.

## ERBITUX (S)

### Products Affected

- Erbitux

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Head and Neck Cancer: Diagnosis of locally or regionally advanced squamous cell head and neck cancer and used in combination with radiation therapy, or diagnosis of recurrent or metastatic squamous cell head and neck cancer and 1 of the following: trial and failure of platinum-based chemotherapy, or used in combination with 1 of the following: cisplatin (Platinol AQ), carboplatin (Paraplatin), cisplatin (Platinol AQ) plus 5-FU (Adrucil), or carboplatin (Paraplatin) plus 5-FU (Adrucil). Colorectal Cancer: Diagnosis of metastatic carcinoma of the colon or rectum. One of the following: Used in combination with either FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan), OR trial and failure or intolerance to irinotecan-based chemotherapy, oxaliplatin-based chemotherapy, or intensive therapy (eg, FOLFOX or FOLFIRI), OR used as monotherapy in patients not appropriate for intensive therapy. Tumor expresses wild-type KRAS gene and wild type NRAS gene.
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.

## ERIVEDGE (S)

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### Products Affected

- Erivedge

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

## ERLEADA (S)

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### Products Affected

- Erleada

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



## ESBRIET (S)

### Products Affected

- Esbriet

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): Both of the following: 1) 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 Esbriet therapy.

## EUCRISA (S)

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### Products Affected

- Eucrisa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Atopic dermatitis (initial): Diagnosis of mild to moderate atopic dermatitis. Trial and failure, contraindication, or intolerance to one prescription strength topical corticosteroid, unless the affected area is sensitive (i.e., face, axillae, groin).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of a positive clinical response to Eucrisa 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 (HF MSE), 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 provider attests 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

<p><b>Other Criteria</b></p>	<p>SMA (Reauth): Documentation of positive clinical response to therapy from pretreatment baseline status as demonstrated by the most recent results from one of the following exams: A) One of the following HINE-2 milestones: 1) Improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick OR 2) Improvement or maintenance of a previous improvement of at least a 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp OR 3) Patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement) OR 4) Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) OR B) One of the following HFMSE milestones: 1) Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) OR C) One of the following ULM test milestones: 1) Improvement or maintenance of a previous improvement of at least a 2 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) OR D) One of the following CHOP INTEND milestones: 1) Improvement or maintenance of a previous improvement of at least a 4 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) OR E) One of the following MFM-32 milestones: 1) Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk). Patient 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. 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 provider attests 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>
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# EXONDYS 51 (S)

## Products Affected

- Exondys 51

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of Duchenne muscular dystrophy (DMD). Documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping. Patient is ambulatory. Initial/Reauth: Exondys 51 dosing for DMD is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 30 mg/kg infused once weekly. Patient's condition has been evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [documentation of the patient's most recent results must be provided].
Age Restrictions	N/A
Prescriber Restrictions	Initial/Reauth: Prescribed by or in consultation with a neurologist who has experience treating children
Coverage Duration	Initial: 6 months. Reauth: 12 months
Other Criteria	Reauth: One of the following: 1) All of the following: Patient has been on therapy for less than 12 months, patient is maintaining ambulatory status, and patient is tolerating therapy, OR 2) All of the following: Patient has been on therapy for 12 months or more, Patient is maintaining ambulatory status, patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients), and patient is tolerating therapy.

## EYLEA (S)

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### Products Affected

- Eylea

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following: A) Neovascular (wet) age-related macular degeneration OR B) Macular edema following retinal vein occlusion, OR C) Diabetic macular edema OR D) Diabetic retinopathy in patients with diabetic macular edema.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## FABRAZYME (S)

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### Products Affected

- Fabrazyme INJ 35MG

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

## FARYDAK (S)

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### Products Affected

- Farydak

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. 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)].
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.



## FASENRA (S)

### Products Affected

- Fasenra

- Fasenra 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>	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 at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months, OR 2) Any prior intubation for an asthma exacerbation, OR 3) 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, long-acting beta-2 agonist (LABA), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].
<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

<b>Other Criteria</b>	<p>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 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) inhaled corticosteroid (ICS) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].</p>
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# 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
- Ferriprox
- Ferriprox Twice-a-day

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Transfusional iron overload due to thalassemia syndromes (Initial): Diagnosis of transfusional iron overload due to thalassemia syndromes. Absolute neutrophil count (ANC) greater than $1.5 \times 10^9/L$ . One of the following: A) Trial and failure, defined as serum ferritin greater than 2,500 mcg/L, to Desferal (deferroxamine), Exjade (deferasirox) or Jadenu (deferasirox) OR B) History of contraindication or intolerance to Desferal (deferroxamine), Exjade (deferasirox) or Jadenu (deferasirox).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	All uses (reauth): Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline. ANC greater than $1.5 \times 10^9/L$ .

## FINTEPLA (S)

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### Products Affected

- Fintepla

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of seizures associated with Dravet syndrome
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## FIRAZYR (S)

### Products Affected

- Firazyr
- Icatibant Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

## FIRDAPSE (S)

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### Products Affected

- Firdapse

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lambert-Eaton Myasthenic Syndrome (LEMS) (initial): Diagnosis of LEMS.
Age Restrictions	N/A
Prescriber Restrictions	LEMS (initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	LEMS (initial): 3 months. LEMS (reauth): 12 months.
Other Criteria	LEMS (reauth): Documentation of positive clinical response to Firdapse therapy (e.g., improvement in dynamometry, Timed 25-Foot Walk Test, Timed Up and Go Test).

## FIRMAGON (S)

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### Products Affected

- Firmagon INJ 120MG/VIAL, 80MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of advanced or metastatic prostate cancer.
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.



## FOLOTYN (S)

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### Products Affected

- Folutyn

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Peripheral T-cell lymphoma: Diagnosis of relapsed or refractory PTCL.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# FORTEO (S)

## Products Affected

- Forteo INJ 600MCG/2.4ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia: 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. Treatment duration of parathyroid hormones [e.g., Forteo (teriparatide), Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses: 24 months (max 24 months of therapy per lifetime)

<b>Other Criteria</b>	<p>Glucocorticoid-Induced Osteoporosis: 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). Treatment duration of parathyroid hormones [e.g., Forteo (teriparatide), Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime.</p>
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## GALAFOLD (S)

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### Products Affected

- Galafold

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Fabry Disease (FD) (initial): Diagnosis of FD. Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. FD (initial, reauthorization): Galafold will not be used in combination with Fabrazyme (agalsidase beta).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	FD (initial, reauth): 12 months.
Other Criteria	FD (reauthorization): Documentation of positive clinical response to Galafold therapy.

## GAMASTAN S/D (S)

### Products Affected

- Gamastan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months (Approve one dose only)
Other Criteria	Subject to Part B vs D review.

## GAMIFANT (S)

### Products Affected

- Gamifant

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Primary Hemophagocytic Lymphohistiocytosis (HLH) (initial): Diagnosis of HLH. One of the following: 1) Disease is refractory, recurrent, or progressive, or 2) Trial and failure, contraindication, or intolerance to conventional HLH therapy (e.g., etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate). HLH (initial, reauth): Patient has not received hematopoietic stem cell transplantation (HSCT).
Age Restrictions	N/A
Prescriber Restrictions	HLH (initial): Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	HLH (initial, reauth): 6 months.
Other Criteria	HLH (reauth): Documentation of positive clinical response to Gamifant therapy (e.g., improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers).

## GATTEX (S)

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### Products Affected

- Gattex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	SBS (Init, reauth): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	SBS (Init): 6 months. SBS (Reauth): 12 months.
Other Criteria	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 Gattex therapy.

## GAVRETO (S)

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### Products Affected

- Gavreto

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Presence of rearranged during transfection (RET) gene fusion-positive tumor(s).
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



## GAZYVA (S)

### Products Affected

- Gazyva

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic lymphocytic leukemia (CLL): Diagnosis of CLL or small lymphocytic leukemia. Used in combination with chlorambucil. Patient is previously untreated for CLL. Follicular lymphoma (FL): One of the following: 1)All of the following: 1.1)Diagnosis of FL. 1.2) Patient has relapsed after or is refractory to a rituximab-containing regimen. 1.3) Both of the following: Used in combination with bendamustine and followed by Gazyva monotherapy. OR 2) All of the following: 2.1) Diagnosis of stage II bulky, III, or IV FL 2.2) Patient has not been treated with prior therapy 2.3) Both of the following: Used in combination with chemotherapy until patient has at least achieved a partial remission and followed by Gazyva monotherapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## GILENYA (S)

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### Products Affected

- Gilenya

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## GILOTRIF (S)

### Products Affected

- Gilotrif

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 and b) squamous NSCLC.
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.

## GLATIRAMER ACETATE (S)

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### Products Affected

- Glatiramer Acetate
- Glatopa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# 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>	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.

## GROWTH HORMONE, PREFERRED (S)

### Products Affected

- Genotropin
- Genotropin Miniquick
- Nutropin Aq Nuspin 10
- Nutropin Aq Nuspin 20
- Nutropin Aq Nuspin 5

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)].</p> <p>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>

<b>Age Restrictions</b>	N/A
<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

<p><b>Other Criteria</b></p>	<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], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L],[macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins following macimorelin administration]) 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. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level.</p> <p>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,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], 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, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. 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 by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).</p>
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## HAEGARDA (S)

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### Products Affected

- Haegarda

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

## HALAVEN (S)

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### Products Affected

- Halaven

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer: Diagnosis of recurrent or metastatic breast cancer. Previous treatment with both of the following: one anthracycline [eg, doxorubicin, Ellence (epirubicin)] and one taxane [eg, paclitaxel, Taxotere (docetaxel)]. Liposarcoma: Diagnosis of unresectable or metastatic liposarcoma. Previous treatment with one anthracycline-containing regimen.
Age Restrictions	N/A
Prescriber Restrictions	All uses: prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# HERCEPTIN (S)

## Products Affected

- Herceptin

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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) Adrucil (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# HETLIOZ (S)

## Products Affected

- HetlioZ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-24-Hour Sleep-Wake Disorder (Non-24) (initial): Both of the following: 1) Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernycthemeral syndrome), AND 2) patient is totally blind (has no light perception).
Age Restrictions	N/A
Prescriber Restrictions	Non-24 (initial): Prescribed by or in consultation with a specialist in sleep disorders or neurologist
Coverage Duration	Non-24 (initial): 6 mo. (reauth): 12 mo
Other Criteria	Non-24 (reauth): Documentation of positive clinical response to HetlioZ therapy.

# HIZENTRA (S)

## Products Affected

- Hizentra

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). Patient does not have hyperprolinemia.
<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.

## HRM - ANTIHISTAMINES

### Products Affected

- Cyproheptadine Hydrochloride TABS
- Dexchlorpheniramine Maleate SYRP
- Hydroxyzine Hcl INJ 25MG/ML
- Hydroxyzine Hcl SYRP
- Hydroxyzine Hcl TABS 50MG
- Hydroxyzine Hydrochloride INJ
- Hydroxyzine Hydrochloride TABS 10MG, 25MG
- Hydroxyzine Pamoate CAPS
- Promethazine Hcl INJ 25MG/ML
- Promethazine Hcl TABS 12.5MG
- Promethazine Hcl Plain
- Promethazine Hydrochloride INJ
- Promethazine Hydrochloride TABS 25MG, 50MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## HRM - ANTIPSYCHOTICS

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### Products Affected

- Thioridazine Hcl TABS 100MG, 10MG, 25MG, 50MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The drug is being used for an FDA-approved diagnosis 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. Trial and failure, contraindication or intolerance to one of the following: haloperidol, fluphenazine, or an atypical antipsychotic.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only.

## HRM - ENDOCRINE

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### Products Affected

- Megestrol Acetate SUSP
- Megestrol Acetate TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only.



## HRM - PHENOBARBITAL, PENTOBARBITAL

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### Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	The drug is being used for an FDA-approved diagnosis 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.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only.

## HRM - SKELETAL MUSCLE RELAXANTS

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### Products Affected

- Chlorzoxazone TABS 250MG, 500MG
- Cyclobenzaprine Hydrochloride TABS 10MG, 5MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## HRM - TCA

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### Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only.

# HUMIRA (S)

## Products Affected

- Humira
- Humira Pediatric Crohns Disease Starter Pack

- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-ps/uv Starter

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 of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)].</p> <p>Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall).</p> <p>Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall), or failure (ie, lost response) or intolerance to infliximab. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, reauth): 12 mo.
<b>Other Criteria</b>	RA, JIA, PsA, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira 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 Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.

# HYDROXYPROGESTERONE (S)

## Products Affected

- Hydroxyprogesterone Caproate INJ 1.25GM/5ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	All uses (initial): Pregnant patients.
Required Medical Information	Amenorrhea/Abnormal Uterine Bleeding: Diagnosis of one of the following: 1) primary or secondary amenorrhea or 2) abnormal uterine bleeding. Amenorrhea or abnormal uterine bleeding is due to hormonal imbalance in the absence of organic pathology (e.g., submucous fibroids or uterine cancer). Secretory endometrium and desquamation: Used for production of secretory endometrium and desquamation in patients with endometrial disorder. Adenocarcinoma: Diagnosis of Stage III or IV adenocarcinoma of the uterine corpus. Estrogen production test: Used for the testing of endogenous estrogen production.
Age Restrictions	N/A
Prescriber Restrictions	Adenocarcinoma (initial): Prescribed by or in consultation with an oncologist
Coverage Duration	Amenorrhea/Abnormal Uterine Bleeding: 4 mo. Estrogen testing: 2 mo. All other uses: 12 months
Other Criteria	Approve for continuation of prior therapy.

## IBRANCE (S)

### Products Affected

- Ibrance

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
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.

# ICLUSIG (S)

## Products Affected

- Iclusig

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 myelogenous leukemia: Diagnosis of chronic myelogenous leukemia AND One of the following: A) Trial and failure, resistance, relapse, 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)

### Products Affected

- Idhifa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# ILARIS (S)

## Products Affected

- Ilaris

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>	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 AND The medication will not be used in combination with another biologic.
<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
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	SJIA (initial): Trial and failure, contraindication, or intolerance to non-steroidal anti-inflammatory drugs (NSAIDs), methotrexate, or corticosteroids. Periodic Fever Syndrome (CAPS, TRAPS, HIDS/MKD, FMF) and SJIA (Reauth): Documentation of positive clinical response to therapy.

## ILUMYA (S)

### Products Affected

- Ilumya

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque Psoriasis (initial): Diagnosis of moderate-to-severe plaque psoriasis. One of the following: set A) Both of the following: 1) Trial and failure, contraindication, or intolerance to Enbrel (etanercept) or Humira (adalimumab) AND 2) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab), or set B) For continuation of prior Ilumya therapy.
Age Restrictions	N/A
Prescriber Restrictions	Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Plaque Psoriasis (Reauth): Documentation of positive clinical response to Ilumya therapy.

# IMBRUVICA (S)

## Products Affected

- Imbruvica

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, 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.

## IMFINZI (S)

### Products Affected

- Imfinzi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Urothelial carcinoma: 1) Diagnosis of locally advanced or metastatic urothelial carcinoma AND 2) One of the following: a) Patient has experienced disease progression during or following platinum-containing chemotherapy OR b) Patient has experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Non-Small Cell Lung Cancer (NSCLC): 1) Diagnosis of NSCLC AND 2) Disease is stage III and unresectable AND 3) Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
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.

## IMVEXXY (S)

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### Products Affected

- Imvexxy Maintenance Pack
- Imvexxy Starter Pack

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

## INCRELEX (S)

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### Products Affected

- Increlex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with a pediatric endocrinologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	(Reauth): Evidence of positive response to therapy.

# INFLECTRA (S)

## Products Affected

- Inflectra

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>	Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Dx of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): Diagnosis (Dx) of moderately to severely active RA. Ankylosing spondylitis (AS) (initial): Dx of active AS. Psoriatic arthritis (PsA) (initial): Dx of active PsA. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs. All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Inflectra therapy.
<b>Age Restrictions</b>	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.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months



<b>Other Criteria</b>	Reauth (all indications): Documentation of positive clinical response to infliximab therapy.
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## INLYTA (S)

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### Products Affected

- Inlyta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: (1) disease has relapsed or (2) diagnosis of stage IV disease.
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.

# INQOVI (S)

## Products Affected

- Inqovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## INREBIC (S)

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### Products Affected

- Inrebic

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

# INTRON A (S)

## Products Affected

- Intron A

- Intron A W/diluent INJ 10MU

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 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, as maintenance therapy for the treatment of multiple myeloma.
<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)

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### Products Affected

- Iressa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
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.

# ISOTRETINOIN (S)

## Products Affected

- Amnesteem
- Claravis
- Isotretinoin CAPS
- Myorisan
- Zenatane

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>	Acne (initial): Diagnosis of acne. One of the following: A) Prescribed by a dermatologist or, B) Trial and failure, contraindication or intolerance to an adequate trial (at least 6 weeks) on both of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)] AND b) combination therapy with benzoyl peroxide and one of the following: 1) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)] OR 2) topical antibiotic [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)].
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Acne (initial): 5 months. Acne (reauth): Retreatment - 5 months, Dose Titration - 1 month
<b>Other Criteria</b>	Acne, Retreatment (reauth): After more than 2 months off therapy, persistent or recurring acne is still present. Acne, Dose Titration (reauth): Confirmation that the total cumulative dose is less than 150 mg/kg.

# ISTODAX (S)

## Products Affected

- Istodax (overfill)

- Romidepsin

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>	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), Cytosan (cyclophosphamide)] Peripheral T-cell lymphoma (PTCL): Diagnosis of PTCL. Trial and failure, contraindication, or intolerance to at least one therapy for the treatment of PTCL (e.g., conventional chemotherapy such as CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone), Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin), HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	CTCL, PTCL: 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.



## ISTURISA (S)

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### Products Affected

- Isturisa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Patient is not a candidate for pituitary surgery, OR b) Pituitary surgery has not been curative for the patient.
Age Restrictions	N/A
Prescriber Restrictions	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Cushing's disease (initial, reauth): 12 months
Other Criteria	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).

## IVIG (S)

### Products Affected

- Bivigam
- Carimune Nanofiltered INJ 12GM, 6GM
- Flebogamma Dif
- Gammagard Liquid
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked
- Gammaplex INJ 10GM/100ML, 10GM/200ML, 20GM/200ML, 20GM/400ML, 5GM/100ML, 5GM/50ML
- Gamunex-c
- Octagam
- Panzyga
- Privigen

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	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. Gammaplex only: Hereditary intolerance to fructose. Infants for whom sucrose or fructose tolerance has not been established.

<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 $10 \times 10^9/L$ . 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.

<p><b>Other Criteria</b></p>	<p>[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).</p> <p>[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, Gammagard Liquid, 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.</p>
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## JAKAFI (S)

### Products Affected

- Jakafi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Myelofibrosis, Polycythemia vera: Prescribed by or in consultation with a hematologist/oncologist. Acute graft versus host disease: Prescribed by or in consultation with one of the following: hematologist, oncologist, physician experienced in the management of transplant patients.
Coverage Duration	12 months.
Other Criteria	Approve for continuation of prior therapy.

## JEVTANA (S)

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### Products Affected

- Jevtana

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of castration-resistant metastatic prostate cancer AND patient has been previously treated with a docetaxel-containing regimen AND patient is receiving concurrent prednisone.
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.

# JUXTAPID (S)

## Products Affected

- Juxtapid

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>	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 Juxtapid therapy. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

## KADCYLA (S)

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### Products Affected

- Kadcyla

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: A) Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive recurrent or metastatic breast cancer AND B) Patient has been previously treated with Herceptin (trastuzumab) and a taxane (eg, docetaxel, paclitaxel).
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.



## KALBITOR (S)

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### Products Affected

- Kalbitor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	12 years of age or older
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

# KALYDECO (S)

## Products Affected

- Kalydeco

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>	Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has one of the following mutations on at least one allele in the cystic fibrosis transmembrane conductance regulator 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): A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, G178R, G551D, G551S, G1069R, G1244E, G1349D, K1060T, L206W, P67L, R74W, R117C, R117H, R347H, R352Q, R1070Q, R1070W, S549N, S549R, S945L, S977F, S1251N, S1255P, 711+3A-G, 2789+5G-A, 3272-26A-G, or 3849+10kbC-T.
<b>Age Restrictions</b>	CF (Initial): 6 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) to Kalydeco therapy.

## KANUMA (S)

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### Products Affected

- Kanuma

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, gastroenterologist, or lipidologist
Coverage Duration	12 months
Other Criteria	N/A

# KESIMPTA (S)

## Products Affected

- Kesimpta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Relapsing forms of multiple sclerosis (RRMS) (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). Both of the following: Set A) Patient has not been previously treated with alemtuzumab and patient has not been previously treated with ofatumumab AND Set B) One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Mavenclad (cladribine), Mayzent (siponimod), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), Vumerity (diroximel fumarate) OR b) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their multiple sclerosis, OR c) 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]). Not used in combination with laquinimod.
Age Restrictions	N/A
Prescriber Restrictions	RRMS (Initial, Reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	Initial, Reauth: 12 months

<b>Other Criteria</b>	RRMS (Reauth): Documentation of positive clinical response to therapy (e.g., improvement 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]). Not used in combination with laquinimod.
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## KEYTRUDA (S)

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### Products Affected

- Keytruda INJ 100MG/4ML

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

## KISQALI (S)

### Products Affected

- Kisqali

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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) Kisqali is used in combination with an aromatase inhibitor [e.g., Femara (letrozole)] OR B) Used in combination with Faslodex (fulvestrant).
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

## KISQALI-FEMARA PACK (S)

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### Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of advanced or metastatic breast cancer. Cancer is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative.
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.



## KORLYM (S)

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### Products Affected

- Korlym

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial, reauth: 6 months
Other Criteria	Reauth: Documentation of one of the following: patient has improved glucose tolerance while on Korlym therapy or patient has stable glucose tolerance while on Korlym therapy.

# KOSELUGO (S)

## Products Affected

- Koselugo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: oncologist or neurologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## KRYSTEXXA (S)

### Products Affected

- Krystexxa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gout (initial): Diagnosis of treatment failure gout characterized by one of the following symptoms: a) greater than or equal to 3 flares in previous 18 months, b) greater than or equal to 1 gout tophus or c) gouty arthritis. History of failure or intolerance to both of the following conventional therapies: xanthine oxidase inhibitor (ie., allopurinol, febuxostat) and uricosuric agent (e.g., probenecid).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Gout (initial, reauth): 12 months
Other Criteria	Gout (reauth): Serum urate level has decreased since initiating therapy. Clinical improvement in the signs and symptoms of gout (e.g., decrease in tophi size or frequency of gouty flares per year from baseline or improvement in chronic arthropathy or quality of life).

## KUVAN (S)

### Products Affected

- Kuvan

- Sapropterin Dihydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PKU (Init): 2 months (Reauth): 12 months
Other Criteria	PKU (reauth): Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline. Patient will continue to have blood Phe levels measured periodically during therapy.

## KYPROLIS (S)

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### Products Affected

- Kyprolis

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. Disease is relapsed or refractory. Patient has received at least one prior therapy for MM.
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.

## LARTRUVO (S)

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### Products Affected

- Lartruvo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of soft tissue sarcoma (STS). One of the following: Disease is not amenable to curative treatment with radiotherapy OR Disease is not amenable to curative treatment with surgery. Used in combination with doxorubicin for the first 8 cycles of treatment AND Physician is aware that the phase 3 ANNOUNCE trial does not support initiating treatment with Lartruvo.
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.

# LEMTRADA (S)

## Products Affected

- Lemtrada

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses). 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: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Mavenclad (cladribine), Mayzent (siponimod), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Zinbryta (daclizumab), 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	MS: 12 months, max 2 yrs of therapy.
Other Criteria	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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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. Treatment follows one prior anti-angiogenic therapy. 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.
Age Restrictions	N/A
Prescriber Restrictions	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.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.



## LETAIRIS (S)

### Products Affected

- Ambrisentan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH (Initial): 6 months. PAH (Reauth): 12 months
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

## LIBTAYO (S)

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### Products Affected

- Libtayo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cutaneous Squamous Cell Carcinoma (CSCC): Diagnosis of CSCC. Disease is metastatic or locally advanced. Patient is not a candidate for curative surgery or curative radiation.
Age Restrictions	N/A
Prescriber Restrictions	CSCC: Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# LIDODERM (S)

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## Products Affected

- Lidocaine PTCH 5%

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

# 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>	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., Avastin) 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 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: fluoropyrimidine-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).
<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)

### Products Affected

- Lorbrena

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic and anaplastic lymphoma kinase (ALK)-positive. Metastatic disease has progressed on one of the following: 1) Xalkori (crizotinib) and at least one other ALK inhibitor [e.g., Alunbrig (brigatinib)], 2) Alecensa (alectinib) as the first ALK inhibitor therapy, or 3) Zykadia (ceritinib) as the first ALK inhibitor therapy.
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.

# LOTRONEX (S)

## Products Affected

- Alosetron Hydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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].
Age Restrictions	Initial: 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	IBS (initial): 12 weeks. IBS (reauth): 6 mo.
Other Criteria	IBS (reauthorization): Symptoms of IBS continue to persist, AND documentation of positive clinical response to therapy.

## LUMIZYME (S)

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### Products Affected

- Lumizyme

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pompe disease: Diagnosis of Pompe disease [acid alpha-glucosidase (GAA) deficiency].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## LUMOXITI (S)

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### Products Affected

- Lumoxiti

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hairy cell leukemia (HCL): Diagnosis of HCL. Disease is relapsed or refractory. Patient has received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA).
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.



# LUPRON (S)

## Products Affected

- Leuprolide Acetate INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. 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.
Age Restrictions	N/A
Prescriber Restrictions	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (initial, reauth), Prostate CA: 12 months
Other Criteria	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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 and one oral contraceptive. 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prostate CA: 12 mo. Endomet (init, reauth):6mo. UL (anemia):3 mo (fibroids):4 mo
Other Criteria	Approve for continuation of prior therapy.

# LUPRON DEPOT PED (S)

## Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (init, reauth): 12 months
Other Criteria	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.

## LYNPARZA (S)

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### Products Affected

- Lynparza CAPS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Ovarian Cancer: 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).
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.

# 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	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). 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 Clinical Laboratory Improvement Amendments (CLIA). Disease is human epidermal growth factor receptor 2 (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 hormone receptor (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.
Age Restrictions	N/A
Prescriber Restrictions	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). Lynparza 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). Lynparza 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

- Hydroxyprogesterone Caproate INJ 250MG/ML
- Makena INJ 275MG/1.1ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Preterm birth prophylaxis: Prescribed by or in consultation with a specialist in obstetrics and gynecology
Coverage Duration	Preterm birth prophylaxis: 21 weeks
Other Criteria	N/A

## MARINOL (S)

### Products Affected

- Dronabinol

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CINV: 6 months. AIDS anorexia: 3 months.
Other Criteria	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.



# MAVENCLAD (S)

## Products Affected

- Mavenclad

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 (e.g., relapsing-remitting MS, secondary-progressive MS with relapses). One of the following: 1) Patient has not been previously treated with cladribine AND Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: Aubagio (teriflunomide), Avonex (interferon beta-1a), Bafiertam (monomethyl fumarate), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Mayzent (siponimod), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), Tysabri (natalizumab), Vumerity (diroximel fumarate), Zeposia (ozanimod), Zinbryta (daclizumab), OR 2) Patient has previously received treatment with cladribine AND Patient has not already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine. Not used in combination with another disease-modifying therapy for MS.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	MS: 1 month
<b>Other Criteria</b>	N/A

## MAVYRET (S)

### Products Affected

- Mavyret

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
Age Restrictions	N/A
Prescriber Restrictions	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.
Coverage Duration	8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	N/A

## MAYZENT (S)

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### Products Affected

- Mayzent

- Mayzent Starter Pack

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# 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>	<p>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).</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.

## MEKTOVI (S)

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### Products Affected

- Mektovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
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

## METADATE ER-RITALIN SR (S)

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### Products Affected

- Metadate Er TBCR 20MG
- Methylphenidate Hydrochloride Er TBCR 10MG, 20MG

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) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible).
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# METHOTREXATE INJECTION (S)

## Products Affected

- Rasuvo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (initial): Diagnosis of severe, active RA. Polyarticular juvenile idiopathic arthritis (PJIA) (initial): Diagnosis of active PJIA. Psoriasis (initial): Diagnosis of severe psoriasis. All Indications (initial): Trial and failure or intolerance to oral methotrexate.
Age Restrictions	N/A
Prescriber Restrictions	RA, PJIA (initial): Prescribed by or in consultation with a rheumatologist. Psoriasis (initial): Prescribed by or in consultation with a dermatologist.
Coverage Duration	All Indications (Initial, reauth): 12 months
Other Criteria	All Indications (reauth): Documentation of positive clinical response to therapy.

# METHYLIN CHEW (S)

## Products Affected

- Methylphenidate Hydrochloride CHEW

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) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible).
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A



# METHYLPHENIDATE (S)

## Products Affected

- Methylphenidate Hydrochloride SOLN
- Methylphenidate Hydrochloride TABS

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) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible).
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# MOZOBIL (S)

## Products Affected

- Mozobil

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hematopoietic Stem Cell (HSC) Mobilization: Patient with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) who will be undergoing autologous HSC transplantation. Used in combination with granulocyte-colony stimulating factor (G-CSF) [e.g., Neupogen (filgrastim), Zarxio (filgrastim)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	One course of therapy up to 4 days
Other Criteria	N/A

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

### Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to Rebif, or 2) for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## MS INTERFERONS (PREFERRED) (S)

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### Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## MYALEPT (S)

### Products Affected

- Myalept

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lipodystrophy (initial): Diagnosis of congenital or acquired generalized lipodystrophy AND one of the following: 1) Diabetes mellitus or insulin resistance despite optimized insulin therapy at maximum tolerated doses OR 2) Hypertriglyceridemia despite optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins).
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Lipodystrophy (reauth): Patient has experienced an objective response to therapy, such as A) Sustained reduction in hemoglobin A1c (HbA1c) level from baseline OR B) Sustained reduction in triglyceride (TG) levels from baseline.

## MYCAPSSA (S)

### Products Affected

- Mycapssa

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: 1) Inadequate response to surgical resection and/or pituitary irradiation, or 2) Patient is not a candidate for surgical resection or pituitary irradiation. Patient has responded to and tolerated treatment with octreotide or lanreotide.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Acromegaly (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)

# MYLOTARG (S)

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## Products Affected

- Mylotarg

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute myeloid leukemia (AML): One of the following diagnoses: Newly diagnosed AML or relapsed/refractory (R/R) AML. Disease is CD33-positive.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## NAGLAZYME (S)

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### Products Affected

- Naglazyme

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



## NATPARA (S)

### Products Affected

- Natpara

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypocalcemia (Initial): Diagnosis of hypocalcemia due to chronic hypoparathyroidism. NATPARA is not being 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. NATPARA will be used as an adjunct treatment.
Age Restrictions	N/A
Prescriber Restrictions	Hypocalcemia (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial: 6 months. Reauth: 12 months
Other Criteria	Hypocalcemia (Reauth): One of the following: A) Patient has achieved and maintained serum calcium levels in the ideal range (7.5 - 10.6 mg/dL ), OR B) Patient has experienced a 50% or greater reduction in oral calcium intake, OR C) Patient has experienced a 50% or greater reduction in oral vitamin D intake.

## NERLYNX (S)

### Products Affected

- Nerlynx

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
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.

# 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>	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.
<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

- Nexavar

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: Relapsed disease OR both medically/surgically unresectable tumor and dx of Stage IV disease. 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).
Age Restrictions	N/A
Prescriber Restrictions	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.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## NINLARO (S)

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### Products Affected

- Ninlaro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## NON-PREFERRED TIRF (S)

### Products Affected

- Abstral
- Fentanyl Citrate TABS
- Lazanda

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). Trial and failure or intolerance to generic fentanyl lozenge.
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

## NORTHERA (S)

### Products Affected

- Northera

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist
Coverage Duration	NOH (init): 1 month (reauth): 12 months
Other Criteria	NOH (reauth): Documentation of positive clinical response to therapy.

## NPLATE (S)

### Products Affected

- Nplate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Immune (idiopathic) thrombocytopenic purpura (ITP): All of the following: A) Diagnosis of one of the following: a) chronic ITP or b) relapsed/refractory ITP AND B) Baseline platelet count is less than 30,000/mcL AND C) Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding AND D) One of the following: 1) Patient had an insufficient response, intolerance, or contraindication to corticosteroids or immune globulin or 2) Patient had an inadequate response or contraindication to splenectomy.
Age Restrictions	N/A
Prescriber Restrictions	ITP (initial): Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	ITP (initial, reauth): 12 months
Other Criteria	ITP (reauth): After at least 4 weeks of therapy at the maximum weekly dose (10 mcg/kg) the platelet count increased to a sufficient level to avoid clinically important bleeding.



## NUBEQA (S)

### Products Affected

- Nubeqa

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

# NUCALA (S)

## Products Affected

- Nucala

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>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 at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months or Patient has had any prior intubation for an asthma exacerbation 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, long-acting beta-2 agonist (LABA), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].</p> <p>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>
<b>Age Restrictions</b>	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. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist.
<b>Coverage Duration</b>	Asthma (init): 6 mo, Asthma (reauth): 12 months. EGPA (init, reauth): 12 months

<b>Other Criteria</b>	<p>Asthma (reauth): Documentation of positive clinical response to therapy (eg, reduction in exacerbations, improvement in forced expiratory volume in 1 second (FEV1), decreased use of rescue medications). 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) inhaled corticosteroid (ICS) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]. EGPA (reauth): Documentation of positive clinical response to therapy (e.g., increase in remission time).</p>
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## NUEDEXTA (S)

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### Products Affected

- Nuedexta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. (Reauthorization): Documentation of clinical benefit from ongoing therapy with Nuedexta.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PBA (initial/reauth): 12 months
Other Criteria	N/A

## NULOJIX (S)

### Products Affected

- Nulojix

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Kidney transplant: The medication is being used for prevention of kidney transplant organ rejection AND The patient is immune to the Epstein-Barr virus (i.e. EBV seropositive) AND The patient is prescribed concurrent therapy with mycophenolate and corticosteroids.
Age Restrictions	Kidney transplant: 18 years of age or older
Prescriber Restrictions	Kidney transplant: Prescriber is experienced in immunosuppressive therapy and management of transplant patients
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## NUPLAZID (S)

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### Products Affected

- Nuplazid

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

# NURTEC (S)

## Products Affected

- Nurtec

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 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. If patient has 4 or more headache days per month, patient must meet one of the following: a) currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications, OR b) currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications, OR c) currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications. 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, pain specialist, or headache 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.

## ODOMZO (S)

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### Products Affected

- Odomzo

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



## OFEV (S)

### Products Affected

- Ofev

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Idiopathic pulmonary fibrosis (IPF) (initial): Both of the following: 1) 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, AND 2) not used in combination with Esbriet (pirfenidone). Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (initial): Both of the following: 1) 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, AND 2) not used in combination with Esbriet (pirfenidone). 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>
Age Restrictions	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 Ofev therapy.

# OLUMIANT (S)

## Products Affected

- Olumiant

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR F40.2 for specific phobia diagnostic criteria), OR for continuation of prior Olumiant therapy. Patient is not receiving Olumiant in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Reauth: Documentation of positive clinical response to Olumiant therapy. Patient is not receiving Olumiant in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).

## ONMEL (S)

### Products Affected

- Onmel

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	All of the following: 1) Diagnosis of onychomycosis of the toenail as confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) fungal culture, OR c) nail biopsy, AND 2) patient has had a trial and failure, contraindication, or intolerance to oral terbinafine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

## OPDIVO (S)

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### Products Affected

- Opdivo

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

## OPSUMIT (S)

### Products Affected

- Opsumit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

## ORENCIA IV (S)

### Products Affected

- Orencia INJ 250MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Orencia therapy.
Age Restrictions	N/A
Prescriber Restrictions	RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Orencia therapy.

# ORENCIA SC (S)

## Products Affected

- Orenia INJ 125MG/ML, 50MG/0.4ML, 87.5MG/0.7ML
- Orenia Clickject

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Orenia therapy.
Age Restrictions	N/A
Prescriber Restrictions	RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Orenia therapy.



## ORENITRAM (S)

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### Products Affected

- Orenitram

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

## ORIAHNN (S)

### Products Affected

- Oriahnn

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 at least 3 months, or history of intolerance or contraindication to one of the following: combination (estrogen/progesterone) oral 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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	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.

# ORILISSA (S)

## Products Affected

- Orilissa

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>	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 of Orilissa has not exceeded a total of 24 months.

# ORKAMBI (S)

## Products Affected

- Orkambi TABS

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).
Age Restrictions	CF (Initial): Patient is 6 years of age or older
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).

# ORKAMBI GRANULES (S)

## Products Affected

- Orkambi 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>	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.
<b>Age Restrictions</b>	N/A
<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). 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.

## OSPHERA (S)

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### Products Affected

- Osphena

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses (Initial, reauth): 12 months
Other Criteria	Dyspareunia, Vaginal dryness (reauth): Documentation of positive clinical response to therapy.

# OXANDRIN (S)

## Products Affected

- Oxandrolone TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	bone pain: 1 month. Others (initial, reauth): 3 months
Other Criteria	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)

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### Products Affected

- Oxbryta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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, contraindication, or intolerance to hydroxyurea.
Age Restrictions	Initial: Patient is 12 years of age or older.
Prescriber Restrictions	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.
Coverage Duration	Initial, Reauth: 12 months.
Other Criteria	Reauth: Documentation of positive clinical response to Oxbryta therapy (e.g., an increase in hemoglobin level of 1 g/dL or greater from baseline, decreased annualized incidence rate of VOCs). Documentation of hemoglobin level that does not exceed 10.5 g/dL.



## OXERVATE (S)

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### Products Affected

- Oxervate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neurotrophic keratitis (NK): Diagnosis of NK.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or optometrist.
Coverage Duration	8 weeks.
Other Criteria	N/A

## PEGASYS (S)

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### Products Affected

- Pegasys
- Pegasys Proclicik

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.
Other Criteria	N/A

## PEG-INTRON (S)

### Products Affected

- Pegintron INJ 50MCG/0.5ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Hepatitis C:Criteria will be applied consistent with current AASLD-IDSA guidance.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HepC: Initial: 28 wks. Reauth: 20 wks.
Other Criteria	HepC (reauth): patient has an undetectable HCV RNA at week 24, additional treatment weeks of peginterferon are required to complete treatment regimen, and patient has not exceeded 48 wks of therapy with peginterferon.

## PEMAZYRE (S)

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### Products Affected

- Pemazyre

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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. Patient has been previously treated.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## PENNSAID (S)

### Products Affected

- Diclofenac Sodium EXTERNAL SOLN 1.5%
- Klofensaid II

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 oral non-steroidal anti-inflammatory drugs (NSAIDs) OR 2) Documented swallowing disorder OR 3) History of peptic ulcer disease/gastrointestinal bleed OR 4) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Osteoarthritis of the knees (reauth): Documentation of positive clinical response to therapy (e.g., improvement in pain symptoms of osteoarthritis).

# PERJETA (S)

## Products Affected

- Perjeta

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 breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer. One of the following: a) patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease AND used in combination with Herceptin (trastuzumab) and a taxane (eg, docetaxel, paclitaxel), OR b) patient was previously treated with chemotherapy and Herceptin (trastuzumab) without Perjeta AND used in combination with Herceptin (trastuzumab). Non-metastatic breast cancer: One of the following diagnoses: HER2-positive early stage breast cancer, HER2-positive locally advanced breast cancer, or HER2-positive inflammatory breast cancer. Used in combination with both Herceptin (trastuzumab) and chemotherapy. Early Breast Cancer Adjuvant Treatment: Diagnosis of HER2-positive early breast cancer. Patient is at high risk of recurrence. Used in combination with both of the following: Herceptin (trastuzumab) and chemotherapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	All uses: Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Non-metastatic breast cancer: 6 months. All others: 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.

# 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), 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>	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.



## PORTRAZZA (S)

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### Products Affected

- Portrazza

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

# POTELIGEO (S)

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## Products Affected

- Poteligeo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mycosis fungoides (MF)/Sezary syndrome (SS): Diagnosis of one of the following: MF or SS. Disease is relapsed or refractory. Patient has received at least one prior systemic therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## PROCYSBI (S)

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### Products Affected

- Procysbi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Nephropathic cystinosis: Diagnosis of nephropathic cystinosis, confirmed by elevated leukocyte cystine levels (LCL) or genetic analysis of the CTNS gene or demonstration of cysteine corneal crystals by slit lamp examination AND Trial and failure or intolerance to therapy with Cystagon (immediate-release cysteamine bitartrate).
Age Restrictions	1 year of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# PROMACTA (S)

## Products Affected

- Promacta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: relapsed/refractory 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 or immunoglobulins 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. 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.
Age Restrictions	N/A
Prescriber Restrictions	Chronic 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.
Coverage Duration	ITP(init, reauth): 12mo. HepC: 3mo(init), 12mo(reauth). 1st line SAA: 6mo. Refract SAA: 16wk-init, 12mo-reauth

<b>Other Criteria</b>	<p>ITP (reauth): Documentation of positive clinical response to Promacta 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 Promacta prior to initiation of treatment with interferon, Promacta 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 Promacta treatment by week 9, OR 2) For patients that started treatment with Promacta while on concomitant treatment with interferon, Promacta will be approved based on the following: Currently on antiviral interferon therapy for treatment of chronic hepatitis C.</p> <p>Refractory SAA (reauth): Documentation of positive clinical response to Promacta therapy as evidenced by an increase in platelet count.</p>
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# 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/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS 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 sleep disorder (SWSD) (Initial): Dx of SWSD 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). No other medical condition or medication accounts for the symptoms. 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>	OSAHS, Narcolepsy, Idiopathic Hypersomnia (Reauth): Documentation of positive clinical response to modafinil therapy. SWSD (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)

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### Products Affected

- Pulmozyme

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, Reauth): Diagnosis of CF.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	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).



## QINLOCK (S)

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### Products Affected

- Qinlock

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
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.

## QUALAQUIN (S)

### Products Affected

- Quinine Sulfate CAPS 324MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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. Not used solely for the treatment or prevention of nocturnal leg cramps.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	N/A

## RADICAVA (S)

### Products Affected

- Radicava

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	ALS (initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	Initial, reauth: 6 months
Other Criteria	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.

## RAVICTI (S)

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### Products Affected

- Ravicti

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Urea cycle disorders (UCDs) (Initial): Diagnosis of UCDs.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	UCDs (Initial, reauth): 12 months
Other Criteria	UCDs (reauth): Documentation of positive clinical response to Ravicti therapy.

## REMODULIN (S)

### Products Affected

- Treprostinil

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	Subject to Part B vs. D Review. PAH (Reauth): Documentation of positive clinical response to therapy.

# RENFLEXIS (S)

## Products Affected

- Renflexis

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>	Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Dx of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): Diagnosis (Dx) of moderately to severely active RA. Ankylosing spondylitis (AS) (initial): Dx of active AS. Psoriatic arthritis (PsA) (initial): Dx of active PsA. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs. All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Renflexis therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Initial: RA, AS: Prescribed by or in consultation with a rheumatologist. 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.
<b>Coverage Duration</b>	All indications (initial, reauth): 12 months

<b>Other Criteria</b>	Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy.
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# 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	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

<p><b>Other Criteria</b></p>	<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) Submission of MR documenting 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.</p> <p>OR set B) Both of the following: a) One of the following LDL values while on max tolerated statin 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) Submission of MR documenting 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): Pt is receiving 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): Pt continues to receive 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. HeFH/ASCVD/Primary HLD/HoFH (Init, reauth): Prescriber attests that the info provided is true and accurate to the best of their knowledge and they understand that OptumRx may perform a routine audit and request the medical info necessary to verify the accuracy of the info provided. HoFH (Init, reauth): Not used in combo w/ Juxtapid.</p>
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# RETACRIT (S)

## Products Affected

- Retacrit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 concurrently on chemo, or will receive concomitant chemo for a minimum of 2 mos, or anemia is caused in part by cancer chemo. 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. 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.
Age Restrictions	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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused in part by cancer 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more 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. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more 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). 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. 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. 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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

## REVATIO INJECTION (S)

### Products Affected

- Sildenafil INJ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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. Patient is unable to take oral medications.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

## REVCovi (S)

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### Products Affected

- Rencovi

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



## REVLIMID (S)

### Products Affected

- Revlimid

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.

## RILUTEK (S)

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### Products Affected

- Riluzole

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

# RINVOQ (S)

## Products Affected

- Rinvoq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA) (initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29/F40.2 for specific phobia diagnostic criteria), OR for continuation of prior Rinvoq therapy. Patient is not receiving Rinvoq in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).
Age Restrictions	N/A
Prescriber Restrictions	RA (initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	RA (initial, reauth): 12 months.
Other Criteria	RA (reauth): Documentation of positive clinical response to therapy. Patient is not receiving Rinvoq in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine).

# RITUXAN (S)

## Products Affected

- Rituxan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Non-Hodgkin's Lymphoma (NHL): As first-line treatment of diffuse large B-cell, CD20-positive, NHL in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens, or as first-line treatment of follicular, CD20-positive, B-cell NHL in combination with chemotherapy, or for the treatment of follicular, CD20-positive, B-cell NHL in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, used as monotherapy for maintenance therapy, or for the treatment of low-grade, CD20-positive, B-cell NHL in patients with stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/prednisone) chemotherapy or who achieve a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/prednisone) chemotherapy, or diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma. Rheumatoid Arthritis (RA) (init): Diagnosis of moderately to severe active RA, Concurrently on or contraindication, or intolerance to 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). Immune or idiopathic thrombocytopenic purpura (ITP): Diagnosis of ITP, TF/C/I to one of the following: corticosteroids, immunoglobulins, or splenectomy. Documented platelet count of less than <math>50 \times 10^9 /L</math>. Chronic Lymphocytic Leukemia (CLL): Diagnosis of CLL, used in combination with fludarabine and cyclophosphamide. Pemphigus Vulgaris (PV): Diagnosis of moderate to severe PV, used in combination with a tapering course of glucocorticoids.</p>
Age Restrictions	N/A

<b>Prescriber Restrictions</b>	ITP, CLL, NHL: Prescribed by or in consultation with a hematologist or oncologist. RA: Prescribed by or in consultation with a rheumatologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist. PV: Prescribed by or in consultation with a dermatologist
<b>Coverage Duration</b>	All uses except RA, WG, MPA: 12 mos. RA: 3 months. WG, MPA: 3 months only.
<b>Other Criteria</b>	Approve for continuation of prior therapy.

# RITUXAN HYCELA (S)

## Products Affected

- Rituxan Hycela

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<p>Follicular Lymphoma: Diagnosis of follicular lymphoma. One of the following: 1) Disease is relapsed or refractory OR 2) Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy OR 3) Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy OR 4) Both of the following: a) Disease is previously untreated AND b) Medication is used in combination with first-line chemotherapy. Patient receives a full induction dose of intravenous rituximab prior to initiation of therapy.</p> <p>Diffuse Large B-Cell Lymphoma: 1) Diagnosis of diffuse large B-cell lymphoma AND 2) Disease is previously untreated AND 3) Medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy AND 4) Patient receives a full induction dose of intravenous rituximab prior to initiation of therapy.</p> <p>Chronic Lymphocytic Leukemia: 1) Diagnosis of chronic lymphocytic leukemia AND 2) Medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy AND 3) Patient receives a full induction dose of intravenous rituximab prior to initiation of therapy.</p>
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## ROZLYTREK (S)

### Products Affected

- Rozlytrek

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
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.

# 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. 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



## RUCONEST (S)

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### Products Affected

- Ruconest

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

## RUZURGI (S)

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### Products Affected

- Ruzurgi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lambert-Eaton Myasthenic Syndrome (LEMS) (initial): Diagnosis of LEMS.
Age Restrictions	N/A
Prescriber Restrictions	LEMS (initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	LEMS (initial): 3 months. LEMS (reauth): 12 months.
Other Criteria	LEMS (reauth): Documentation of positive clinical response to therapy (e.g., improvement in dynamometry, Timed 25-Foot Walk Test, Timed Up and Go Test).

# RYDAPT (S)

## Products Affected

- Rydapt

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>	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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)]. Infantile Spasms (IS): Diagnosis of infantile spasms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# SANDOSTATIN (S)

## Products Affected

- Octreotide Acetate

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.

## SCIG (S)

### Products Affected

- Cuvitru

- 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.

## SECUADO (S)

### Products Affected

- Secuado

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of schizophrenia. Both of the following: 1) Trial and failure of Saphris (asenapine) and 2) Trial and failure, contraindication, or intolerance to one of the following generic formulary atypical antipsychotic agents: aripiprazole, olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## SIGNIFOR (S)

### Products Affected

- Signifor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Cushing's disease (initial, reauth): 12 months
Other Criteria	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).



## SIKLOS (S)

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### Products Affected

- Siklos

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Sickle Cell Anemia: Diagnosis of sickle cell anemia. Patient has moderate to severe painful crises. One of the following: 1) Patient is less than 18 years of age or 2) Trial and failure, or intolerance to Droxia.
Age Restrictions	Patient is 2 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# SIMPONI (S)

## Products Affected

- Simponi

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. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall) OR trial and failure, contraindication, or intolerance (TF/C/I) to methotrexate (Rheumatrex/Trexall). One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Patient is corticosteroid dependent (ie, an inability to successfully taper corticosteroids without a return of the symptoms of UC), OR TF/C/I to one of the following: oral aminosalicylate, oral corticosteroid, azathioprine, 6-mercaptopurine. One of the following: TF/C/I to Humira (adalimumab), OR for continuation of prior Simponi therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	UC (Initial): 12 weeks. UC (Reauth): 12 months. RA, AS, PsA (Initial, reauth): 12 months

<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Simponi therapy.
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# SIMPONI ARIA (S)

## Products Affected

- Simponi Aria

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. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), OR trial and failure, contraindication, or intolerance (TF/C/I) to methotrexate (Rheumatrex/Trexall). One of the following: trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist.
<b>Coverage Duration</b>	RA, AS, PsA (Initial, reauth): 12 months
<b>Other Criteria</b>	All Indications (Reauth): Documentation of positive clinical response to Simponi therapy.

## SKYRIZI (S)

### Products Affected

- Skyrizi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept) or Humira (adalimumab), OR b) for continuation of prior Skyrizi therapy.
Age Restrictions	N/A
Prescriber Restrictions	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist.
Coverage Duration	Plaque psoriasis (Initial, reauth): 12 months
Other Criteria	Plaque psoriasis (Reauth): Documentation of positive clinical response to Skyrizi therapy.

# SOLIRIS (S)

## Products Affected

- Soliris

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>	Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS) (initial): Diagnosis of PNH or aHUS. Generalized Myasthenia Gravis (gMG) (initial): Diagnosis of gMG. Patient is anti-acetylcholine (AChR) antibody positive. One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), or 2) TF/C/I to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), and TF/C/I to chronic plasmapheresis/plasma exchange (PE) or intravenous immunoglobulin (IVIG).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	gMG (initial): Prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	All uses (initial, reauth): 12 months
<b>Other Criteria</b>	PNH (reauth): Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to Soliris therapy. aHUS (reauth): Documentation of positive clinical response (e.g., increase in mean platelet counts, hematologic normalization) to Soliris therapy. gMG (reauth): Documentation of positive clinical response to Soliris therapy.

# SOMATULINE DEPOT (S)

## Products Affected

- Somatuline Depot

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	N/A
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

# SOMAVERT (S)

## Products Affected

- Somavert

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial and reauth: 12 months
Other Criteria	Acromegaly (reauth): Patient has experienced a positive clinical response to therapy (biochemical control, decrease or normalization of IGF-1 levels).



## SPINRAZA (S)

### Products Affected

- Spinraza

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 either of the following: 1) Invasive ventilation or tracheostomy or 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 (HFMSE), Upper Limb Module (ULM) Test (Non ambulatory), or Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND). Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	SMA (initial, reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis of SMA
<b>Coverage Duration</b>	Initial: 3 months. Reauth: 6 months.

<p><b>Other Criteria</b></p>	<p>SMA (reauth): Documentation of positive clinical response to Spinraza therapy from pretreatment baseline status as demonstrated by the most recent results (less than 1 month prior to request) from one of the following exams: A) Both of the following HINE milestones: 1) One of the following: a) Improvement or maintenance of a previous improvement of at least a 2 point (or maximal score) increase in ability to kick or b) Improvement or maintenance of a previous improvement of at least a 1 point increase in any other HINE milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp AND 2) One of the following: a) Improvement or maintenance of a previous improvement in more HINE motor milestones than worsening from pretreatment baseline (net positive improvement) or b) Patient has achieved and maintained any new motor milestones from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk) OR B) One of the following HFMSE milestones: 1) Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so OR C) One of the following ULM test milestones: 1) Improvement or maintenance of a previous improvement of at least a 2 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so OR D) One of the following CHOP INTEND milestones: 1) Improvement or maintenance of a previous improvement of at least a 4 point increase in score from pretreatment baseline OR 2) Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so. Patient continues to not be dependent on either of the following: 1) Invasive ventilation or tracheostomy or 2) use of non-invasive ventilation beyond use for naps and nighttime sleep. Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.</p>
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# SPORANOX (S)

## Products Affected

- Itraconazole CAPS
- Itraconazole SOLN

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: 1) patient has a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), OR 2) all of the following: a) patient has a diagnosis of onychomycosis confirmed by one of the following (CAPSULE ONLY): i) positive potassium hydroxide (KOH) preparation, OR ii) fungal culture, OR iii) nail biopsy, AND b) patient has had a trial and failure, contraindication, or intolerance to oral terbinafine, OR 3) patient has a diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole (ORAL SOLUTION ONLY).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Systemic fungal infxn:6mo.Candidiasis:1mo.Fingernail onycho:5wks.Toenail onycho, other:3mo.
Other Criteria	N/A

## SPRAVATO (S)

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### 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	Treatment-resistant depression (TRD): Diagnosis of major depressive disorder (treatment-resistant). 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. Used in combination with an oral antidepressant.
Age Restrictions	N/A
Prescriber Restrictions	TRD: Prescribed by or in consultation with a psychiatrist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## SPRYCEL (S)

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### Products Affected

- Sprycel

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	All Uses: Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	All Uses: 12 months
Other Criteria	All Uses: Approve for continuation of prior therapy.

# STELARA (S)

## Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<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). 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. Plaque psoriasis (Initial): One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept) OR Humira (adalimumab) OR b) for continuation of prior Stelara therapy. PsA (Initial): One of the following: a) TF/C/I to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept) or Humira (adalimumab), OR b) for continuation of prior Stelara therapy. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn's disease. One of the following: a) TF/C/I to Humira (adalimumab) OR b) TF/C/I to treatment with at least one immunomodulator or corticosteroid [e.g., Purinethol (6-mercaptopurine), Imuran (azathioprine), Sandimmune (cyclosporine A), Prograf (tacrolimus), MTX (methotrexate)], OR c) for continuation of prior Stelara therapy. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: a) TF/C/I to Humira (adalimumab) OR b) TF/C/I to treatment with at least one immunomodulator or corticosteroid (e.g., Purinethol [6-mercaptopurine], Imuran [azathioprine], aminosaliclates [e.g., mesalamine {Asacol, Pentasa, Rowasa}, olsalazine {Dipentum}, sulfasalazine {Azulfidine, Sulfazine}]), OR c) for continuation of prior Stelara therapy.</p>
Age Restrictions	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. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	All uses (Initial, reauth): 12 months
<b>Other Criteria</b>	Reauth (all indications): Documentation of positive clinical response to Stelara therapy.

# 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, AND 3) trial and failure, contraindication or intolerance to an anti-VEGF therapy (e.g., Avastin [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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Hypophosphatasia: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist
Coverage Duration	Hypophosphatasia: 12 months
Other Criteria	N/A

## SUPPRELIN LA (S)

### Products Affected

- Supprelin La

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (init, reauth): 12 months
Other Criteria	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.

## SUTENT (S)

### Products Affected

- Sutent

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

## SYLATRON (S)

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### Products Affected

- Sylatron

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

## SYLVANT (S)

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### Products Affected

- Sylvant

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multicentric Castleman's disease (MCD) (Initial): Diagnosis of MCD. Patient is human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.
Age Restrictions	N/A
Prescriber Restrictions	MCD (initial): Prescribed by or in consultation with hematologist/oncologist or rheumatologist.
Coverage Duration	MCD (initial, reauth): 6 months
Other Criteria	MCD (reauth): Documentation of positive clinical response to Sylvant therapy. Patient is HIV negative and HHV-8 negative.

# SYMDEKO (S)

## Products Affected

- Symdeko TBPK 75MG; 50MG

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 cystic fibrosis. One of the following: 1) Patient is homozygous for the F508del mutation 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 one of the following mutations on at least one allele 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): E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A-G, E831X, S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G-A, 3272-26A-G, 3849+10kbC-T.
<b>Age Restrictions</b>	Initial: Patient is 6 years of age or older
<b>Prescriber Restrictions</b>	Initial: Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Reauth: Documentation of a positive clinical response to Symdeko (tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations).

# SYNAGIS (S)

## Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<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>
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pediatric specialist (i.e., pulmonologist, neonatologist, neurologist, cardiologist, pediatric intensivist, or infectious disease specialist).

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



## SYNDROS (S)

### Products Affected

- Syndros

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>	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance (TF/C/I) to a 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). TF/C/I 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 chemotherapy.

## SYNRIBO (S)

### Products Affected

- Synribo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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, Tasigna, and Bosulif, Iclusig).
Age Restrictions	CML: 18 years of age or older
Prescriber Restrictions	CML: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## SYPRINE (S)

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### Products Affected

- Clovique
- Trientine Hydrochloride

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

## TABRECTA (S)

### Products Affected

- Tabrecta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: recurrent, advanced, 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).
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.

# TAFAMIDIS (S)

## Products Affected

- Vyndamax

- Vyndaqel

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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	<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>
Age Restrictions	N/A
Prescriber Restrictions	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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): 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).
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.



## TAKHZYRO (S)

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### Products Affected

- Takhzyro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	HAE (prophylaxis): Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

# TALTZ (S)

## Products Affected

- Taltz

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: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept) or Humira (adalimumab), OR b) for continuation of prior Taltz therapy. Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept) or Humira (adalimumab), OR b) for continuation of prior Taltz therapy. Ankylosing spondylitis (AS) (initial): Diagnosis of active AS. One of the following: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab) AND one of the following: Enbrel (etanercept) or Humira (adalimumab), OR b) for continuation of prior Taltz therapy. 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.) TF/C/I to one non-steroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, meloxicam, naproxen). One of the following: a) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab), OR b) for continuation of prior Taltz therapy.</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. AS, nr-axSpA (initial): Prescribed by or in consultation with a rheumatologist.</p>
<b>Coverage Duration</b>	Initial, reauth: 12 months

<b>Other Criteria</b>	All indications (Reauth): Documentation of positive clinical response to Taltz therapy.
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## TALZENNA (S)

### Products Affected

- Talzenna

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
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.

# TARCEVA (S)

## Products Affected

- Erlotinib Hydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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). Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND erlotinib will be used in combination with gemcitabine.
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

# TARGRETIN (S)

## Products Affected

- Bexarotene

- Targretin GEL

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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]).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## TASIGNA (S)

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### Products Affected

- Tasigna

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

## TAZVERIK (S)

### Products Affected

- Tazverik

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Epithelioid sarcoma: Prescribed by or in consultation with an oncologist. Follicular lymphoma: Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.



## TECENTRIQ (S)

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### Products Affected

- Tecentriq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 Months
Other Criteria	Approve for continuation of prior therapy.

## TECFIDERA (S)

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### Products Affected

- Dimethyl Fumarate CPDR
- Dimethyl Fumarate Starterpack MISC 0
- Tecfidera
- Tecfidera Starter Pack

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): 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).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# TERIPARATIDE (S)

## Products Affected

- Teriparatide

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia: 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. Treatment duration of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses: 24 months (max 24 months of therapy per lifetime)

<b>Other Criteria</b>	<p>Glucocorticoid-Induced Osteoporosis: 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). Treatment duration of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime.</p>
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# TESTOSTERONE (S)

## Products Affected

- Androderm PT24 2MG/24HR, 4MG/24HR
- Testosterone GEL 1.62%, 20.25MG/1.25GM, 25MG/2.5GM, 40.5MG/2.5GM, 50MG/5GM
- Testosterone SOLN
- Testosterone Cypionate INJ 100MG/ML, 200MG/ML
- Testosterone Pump
- Testosterone Topical Solution

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). Gender Dysphoria (GD) (off-label): Dx of GD. Patient is a female-to-male transsexual.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	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>	<p>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.</p>
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# 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). 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) (off-label): Dx of GD. Patient is a female-to-male transsexual.
<b>Age Restrictions</b>	N/A
<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.

## THALOMID (S)

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### Products Affected

- Thalomid

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. Used in combination with dexamethasone, unless the patient has an intolerance to steroids. 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.
Age Restrictions	N/A
Prescriber Restrictions	MM: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.



# TIBSOVO (S)

## Products Affected

- Tibsovo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Relapsed or refractory Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. 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). Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). 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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## TIGLUTIK (S)

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### Products Affected

- Tiglutik

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Amyotrophic Lateral Sclerosis (ALS): Diagnosis of ALS. Trial and failure or intolerance to generic riluzole tablets.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## TOPICAL RETINOID (S)

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### Products Affected

- Avita
- Tretinoin CREA
- Tretinoin GEL

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

## TRELSTAR (S)

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### Products Affected

- Trelstar
- Trelstar Mixject

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

# TREMFYA (S)

## Products Affected

- Tremfya

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: set A) 1) Trial and failure, contraindication, or intolerance (TF/C/I) to Enbrel (etanercept) or Humira (adalimumab) AND 2) TF/C/I to Cosentyx (secukinumab), OR set B) for continuation of prior Tremfya therapy. Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: set A) 1) TF/C/I to Enbrel (etanercept) or Humira (adalimumab) AND 2) TF/C/I to Cosentyx (secukinumab), OR set B) for continuation of prior Tremfya therapy.
Age Restrictions	N/A
Prescriber Restrictions	Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	All indications (Initial, reauth): 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Tremfya therapy.

## TRIKAFTA (S)

### Products Affected

- Trikafta

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 has at least one F508del mutation 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.
Age Restrictions	CF (initial): 12 years of age or older.
Prescriber Restrictions	CF (initial): Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center.
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	CF (reauth): Documentation of a positive clinical response to Trikafta 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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	CPP (initial): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (Initial, reauth): 12 months
Other Criteria	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.

## TUKYSA (S)

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### Products Affected

- Tukysa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
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.



## TURALIO (S)

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### Products Affected

- Turalio

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## TYKERB (S)

### Products Affected

- Lapatinib Ditosylate
- Tykerb

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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)].
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.

# TYMLOS (S)

## Products Affected

- Tymlos

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>	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., Forteo [teriparatide], Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	24 months (max 24 months of therapy per lifetime)
<b>Other Criteria</b>	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): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following disease-modifying therapies for MS: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Mavenclad (cladribine), Mayzent (siponimod), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), or Zinbryta (daclizumab), 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. Not used in combination with another disease-modifying therapy for MS. Crohn's Disease (CD) (initial): Diagnosis of moderate to severe 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, 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate, aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). TF/C/I to a TNF-inhibitor (eg, Cimzia [certolizumab pegol], Humira [adalimumab], Remicade [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 Remicade [infliximab]).</p>
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	MS: 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Otherwise, 3 mo.

<b>Other Criteria</b>	CD (reauth): Documentation of positive clinical response (eg, improved disease activity index) to Tysabri therapy.
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# UBRELVY (S)

## Products Affected

- Ubrelevy

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 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 less 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. If patient has 4 or more headache days per month, patient must meet one of the following: a) currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications, OR b) currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications, OR c) currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications.
<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 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.

# UDENYCA (S)

## Products Affected

- Udenyca

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). 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).</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

# ULTOMIRIS (S)

## Products Affected

- Ultomiris

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Paroxysmal nocturnal hemoglobinuria (PNH) (initial): Diagnosis of PNH.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PNH (initial, reauth): 12 months
Other Criteria	PNH (reauth): Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to Ultomiris therapy.



## VALCHLOR (S)

### Products Affected

- Valchlor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## VELCADE (S)

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### Products Affected

- Velcade

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. Mantle cell lymphoma (MCL): Diagnosis of MCL.
Age Restrictions	N/A
Prescriber Restrictions	MM, MCL: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## VENCLEXTA (S)

### Products Affected

- Venclexta

- Venclexta Starting Pack

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## VENTAVIS (S)

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### Products Affected

- Ventavis

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH (Initial): 6 months. (Reauth): 12 months
Other Criteria	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
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 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.
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.

## VIMIZIM (S)

### Products Affected

- Vimizim

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Reauth: Documentation of positive clinical response to Vimizim therapy.

## VITRAKVI (S)

### Products Affected

- Vitrakvi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
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.

## VIZIMPRO (S)

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### Products Affected

- Vizimpro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
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.



## VOSEVI (S)

### Products Affected

- Vosevi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 patient is not receiving Vosevi in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
Age Restrictions	N/A
Prescriber Restrictions	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.
Coverage Duration	12 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	N/A

## VOTRIENT (S)

### Products Affected

- Votrient

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## VPRIV (S)

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### Products Affected

- Vpriv

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease: Diagnosis of type 1 Gaucher disease. Patient has evidence of symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease: 12 months
Other Criteria	N/A

## VYXEOS (S)

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### Products Affected

- Vyxeos

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Newly diagnosed therapy related acute myeloid leukemia (t-AML): Diagnosis of t-AML. Acute myeloid leukemia myelodysplasia-related changes (AML-MRC): Diagnosis of AML-MRC.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## XALKORI (S)

### Products Affected

- Xalkori

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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 rearrangements-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	NSCLC: Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## XCOPRI (S)

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### Products Affected

- Xcopri

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of partial onset seizures.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	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>	Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. RA/PsA (initial): One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29/F40.2 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Trial and failure, contraindication or intolerance to one of the following conventional therapies: 6-mercaptopurine (Purinethol), aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], azathioprine (Imuran), or corticosteroids (e.g., prednisone, methylprednisolone). Trial and failure, contraindication, or intolerance to Humira (adalimumab), OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR F40.2 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy. All indications: Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA (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/PsA (initial, reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.

<b>Other Criteria</b>	All Indications (Reauth): Documentation of positive clinical response to tofacitinib therapy. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).
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## 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. 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.

## XGEVA (S)

### Products Affected

- Xgeva

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma (MM)/Bone metastasis from solid tumors (BMST): One of the following: 1) Diagnosis of multiple myeloma OR 2) diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer), AND 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 intravenous bisphosphonate (eg, pamidronate, Zometa (zoledronic acid).
Age Restrictions	N/A
Prescriber Restrictions	GCTB, HCM: Prescribed by or in consultation with an oncologist
Coverage Duration	MM/BMST, GCTB: 12 mo. HCM: 2 mo.
Other Criteria	Approve for continuation of prior therapy.

## XIAFLEX (S)

### Products Affected

- Xiaflex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Dupuytren's contracture (DC) (initial, reauth): Diagnosis of Dupuytren's contracture with a palpable cord AND Prescriber is enrolled in the Xiaflex REMS program for Dupuytren's contracture AND Patient has a positive "table top test" (defined as the inability to simultaneously place the affected finger and palm flat against a table top) AND Patient has a documented contracture of at least 20 degrees flexion for a metacarpophalangeal joint or a proximal interphalangeal joint AND Patient has a flexion deformity that results in functional limitations. Peyronie's disease (PD) (initial, reauth): Diagnosis of Peyronie's disease AND Prescriber is enrolled in the Xiaflex REMS program for Peyronie's disease AND Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy AND The plaques do not involve the penile urethra AND Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse).
Age Restrictions	Initial (DC, PD): 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	DC, PD (Initial and reauth): 12 months
Other Criteria	Peyronie's disease (reauth): patient has a new plaque that results in a curvature deformity.

## 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)

## Products Affected

- Xolair

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>Asthma (init): Diagnosis of moderate to severe persistent allergic asthma. Positive skin test or in vitro reactivity to a perennial aeroallergen. Pretreatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL for patients 12 years of age and older OR 30 to 1300 IU/mL for patients 6 years to less than 12 years of age. 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, long-acting beta-2 agonist (LABA), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]. Chronic Idiopathic Urticaria (CIU) (init): Diagnosis of CIU. Persistent symptoms (itching and hives) for at least 4 consecutive weeks despite titrating to an optimal dose with a second generation H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines. Patient has tried and had an inadequate response or intolerance or contraindication to at least one of the following additional therapies: H2 antagonist, leukotriene receptor antagonist, H1 antihistamine, hydroxyzine, doxepin. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines.</p>
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	<p>Asthma (init/reauth): Prescribed by or in consultation with an allergist/immunologist, or pulmonologist. CIU (init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist</p>
<b>Coverage Duration</b>	<p>Asthma (init): 6 months, Asthma (reauth): 12 months. CIU (init): 3 months, (reauth) 6 months</p>

<b>Other Criteria</b>	<p>Asthma (reauth): Documentation of positive clinical response to therapy (e.g., Reduction in number of asthma exacerbations, improvement in forced expiratory volume in 1 second (FEV1), or decreased use of rescue medications). 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) inhaled corticosteroid (ICS) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)].</p> <p>CIU (reauth): Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment. Patient has experienced one or both of the following: Reduction in itching severity from baseline or Reduction in the number of hives from baseline.</p>
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## XOSPATA (S)

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### Products Affected

- Xospata

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# XPOVIO (S)

## Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma (MM): Diagnosis of relapsed or refractory multiple myeloma (RRMM). Patient has received at least four prior therapies. 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.
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.



## XTANDI (S)

### Products Affected

- Xtandi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic castration-sensitive prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	CRPC, M-CSPC: Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	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	N/A
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with Xyrem therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy.

## YERVOY (S)

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### Products Affected

- Yervoy

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

## YONSA (S)

### Products Affected

- Yonsa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer. Used in combination with methylprednisolone. Trial and failure or intolerance to Xtandi (enzalutamide).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

## ZALTRAP (S)

### Products Affected

- Zaltrap

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Colon and/or rectal cancer: Diagnosis of metastatic colon and/or rectal cancer. Ziv-aflibercept is being used in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) regimen. Patient has disease that is resistant to or has progressed following an oxaliplatin-containing regimen [e.g., 5-fluorouracil, leucovorin, and oxaliplatin (FOLFOX)].
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.

## ZAVESCA (S)

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### Products Affected

- Miglustat

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease. Patient is unable to receive enzyme replacement therapy due to one of the following conditions: allergy or hypersensitivity to enzyme replacement therapy, poor venous access, unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease: 12 months
Other Criteria	N/A

# ZEJULA (S)

## Products Affected

- Zejula

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 epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of 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 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).
<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.

## ZELBORAF (S)

### Products Affected

- Zelboraf

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
Age Restrictions	N/A
Prescriber Restrictions	Melanoma: Prescribed by or in consultation with an oncologist. Erdheim-Chester Disease: Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	All indications: Approve for continuation of therapy.



## ZEPOSIA (S)

### Products Affected

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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive MS). 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: Aubagio (teriflunomide), Gilenya (fingolimod), or Tecfidera (dimethyl fumarate), OR b) for continuation of prior therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

## ZOLINZA (S)

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### Products Affected

- Zolinza

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## ZORBTIVE (S)

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### Products Affected

- Zorbtive

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	SBS: 4 weeks.
Other Criteria	N/A

# ZYDELIG (S)

## Products Affected

- Zydelig

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 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]). Follicular Lymphoma (FL): Diagnosis of FL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]). Small lymphocytic lymphoma (SLL): Diagnosis of SLL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	All uses: 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

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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).
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.

## ZYTIGA (PREFERRED) (S)

### Products Affected

- Abiraterone Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	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.
Age Restrictions	N/A
Prescriber Restrictions	mCRPC, mCSPC: Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	mCRPC, mCSPC: 12 months
Other Criteria	Approve for continuation of prior therapy

## PART B VERSUS PART D

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### Products Affected

- Abelcet
- Acetylcysteine SOLN
- Acyclovir Sodium INJ 1000MG, 500MG, 50MG/ML
- Akynzeo CAPS
- Albuterol Sulfate NEBU
- Ambisome
- Amino Acid INJ 50MG/ML; 50MG/ML
- Aminosyn INJ 148MEQ/L; 1280MG/100ML; 980MG/100ML; 1280MG/100ML; 300MG/100ML; 720MG/100ML; 940MG/100ML; 720MG/100ML; 400MG/100ML; 440MG/100ML; 860MG/100ML; 420MG/100ML; 520MG/100ML; 160MG/100ML; 44MG/100ML; 800MG/100ML
- Aminosyn 7%/electrolytes INJ 124MEQ/L; 900MG/100ML; 690MG/100ML; 96MEQ/L; 900MG/100ML; 210MG/100ML; 510MG/100ML; 660MG/100ML; 510MG/100ML; 10MEQ/L; 280MG/100ML; 310MG/100ML; 30MMOLE/L; 65MEQ/L; 610MG/100ML; 300MG/100ML; 65MEQ/L; 370MG/100ML; 120MG/100ML; 44MG/100ML; 560MG/100ML
- Aminosyn 8.5%/electrolytes INJ 142MEQ/L; 1100MG/100ML; 850MG/100ML; 98MEQ/L; 1100MG/100ML; 260MG/100ML; 620MG/100ML; 810MG/100ML; 624MG/100ML; 10MEQ/L; 340MG/100ML; 380MG/100ML; 30MEQ/L; 65MEQ/L; 750MG/100ML; 370MG/100ML; 65MEQ/L; 460MG/100ML; 150MG/100ML; 44MG/100ML; 680MG/100ML
- Aminosyn II INJ 50.3MEQ/L; 695MG/100ML; 713MG/100ML; 490MG/100ML; 517MG/100ML; 350MG/100ML; 210MG/100ML; 462MG/100ML; 700MG/100ML; 735MG/100ML; 120MG/100ML; 209MG/100ML; 505MG/100ML; 371MG/100ML; 31.3MEQ/L; 280MG/100ML; 140MG/100ML; 189MG/100ML; 350MG/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
- Aminosyn II 8.5%/electrolytes
- Aminosyn M INJ 65MEQ/L; 448MG/100ML; 343MG/100ML; 40MEQ/L; 448MG/100ML; 105MG/100ML; 252MG/100ML; 329MG/100ML; 252MG/100ML; 3MEQ/L; 140MG/100ML; 154MG/100ML; 3.5MMOLE/L; 13MEQ/L; 300MG/100ML; 147MG/100ML; 40MEQ/L; 182MG/100ML; 56MG/100ML; 31MG/100ML; 280MG/100ML
- Aminosyn-hbc INJ 7.1MEQ/100ML; 660MG/100ML; 507MG/100ML; 660MG/100ML; 154MG/100ML; 789MG/100ML; 1576MG/100ML; 265MG/100ML; 206MG/100ML; 1.12GM/100ML; 228MG/100ML; 448MG/100ML; 221MG/100ML; 272MG/100ML; 88MG/100ML; 33MG/100ML; 789MG/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; 3.4MEQ/L; 70MG/100ML; 512MG/100ML; 180MG/100ML; 44MG/100ML; 673MG/100ML
- Aminosyn-pf 7%
- Aminosyn-rf INJ 113MEQ/L; 600MG/100ML; 429MG/100ML; 462MG/100ML; 726MG/100ML; 535MG/100ML; 726MG/100ML; 726MG/100ML; 330MG/100ML; 165MG/100ML; 528MG/100ML
- Amphotericin B INJ
- Anzemet TABS
- Aprepitant
- Azasan
- Azathioprine INJ
- Azathioprine TABS
- Baclofen INJ
- Bleomycin
- Bleomycin Sulfate INJ
- Budesonide SUSP
- Cladribine
- Clinimix 2.75%/dextrose 5%
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 20%
- Clinimix 4.25%/dextrose 25%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%
- Clinimix 5%/dextrose 20%
- Clinimix 5%/dextrose 25%
- Clinimix 6/5
- Clinimix 8/10
- Clinimix 8/14
- Clinimix E 2.75%/dextrose 10% INJ 570MG/100ML; 317MG/100ML; 33MG/100ML; 10GM/100ML; 283MG/100ML; 132MG/100ML; 165MG/100ML; 201MG/100ML; 159MG/100ML; 51MG/100ML; 110MG/100ML; 454MG/100ML; 154MG/100ML; 261MG/100ML; 187MG/100ML; 138MG/100ML; 217MG/100ML; 112MG/100ML; 116MG/100ML; 50MG/100ML; 11MG/100ML; 160MG/100ML
- Clinimix E 2.75%/dextrose 5%
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 25%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Clinimix E 5%/dextrose 25%
- Clinimix E 8/10
- Clinimix E 8/14
- Clinimix N14g30e
- Clinimix N9g15e
- Clinimix N9g20e
- Clinolipid
- Clonidine Hydrochloride INJ
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclosporine CAPS
- Cyclosporine Modified
- Cytarabine INJ 100MG/ML, 20MG/ML
- Cytarabine Aqueous
- Deferoxamine Mesylate
- Dobutamine Hcl INJ 250MG/20ML, 500MG/40ML
- Dobutamine Hcl/d5w INJ 5%; 1MG/ML
- Dobutamine Hydrochloride/dextrose
- Dobutamine/dextrose 5% INJ 5%; 2MG/ML, 5%; 4MG/ML
- Dopamine Hcl INJ 160MG/ML, 80MG/ML
- Dopamine Hydrochloride INJ
- Dopamine Hydrochloride/dextrose



- Dopamine/d5w INJ 5%; 3.2MG/ML
- Emend SUSR
- Engerix-b
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG
- Fentanyl Citrate INJ 1000MCG/20ML, 100MCG/2ML, 2500MCG/50ML, 250MCG/5ML, 500MCG/10ML
- Floxuridine INJ
- Freamine Hbc 6.9%
- Freamine III INJ 89MEQ/L; 710MG/100ML; 950MG/100ML; 3MEQ/L; 24MG/100ML; 1400MG/100ML; 280MG/100ML; 690MG/100ML; 910MG/100ML; 730MG/100ML; 530MG/100ML; 560MG/100ML; 10MMOLE/L; 120MG/100ML; 1120MG/100ML; 590MG/100ML; 10MEQ/L; 400MG/100ML; 150MG/100ML; 660MG/100ML
- Gablofen
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf
- Granisetron Hcl TABS
- Hepagam B
- Hepatamine
- Heplisav-b
- Hyperhep B S/d
- Hyperrab
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- Levalbuterol Hydrochloride
- Lioresal Intrathecal
- Milrinone In Dextrose INJ 5%; 20MG/100ML, 5%; 40MG/200ML
- Milrinone Lactate INJ 10MG/10ML, 20MG/20ML, 50MG/50ML
- Morphine Sulfate INJ 10MG/ML, 150MG/30ML, 1MG/ML, 4MG/ML, 5MG/ML, 8MG/ML
- Mycophenolate Mofetil
- Mycophenolic Acid Dr
- Nabi-hb
- Nebupent
- Nephramine
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hcl TABS 24MG
- Ondansetron Hydrochloride TABS
- Ondansetron Odt
- Pentamidine Isethionate INHALATION SOLR
- Perforomist
- Premasol
- Procalamine
- Prograf PACK
- Prosol
- Rabavert
- Recombivax Hb
- Sandimmune SOLN
- Sirolimus SOLN
- Sirolimus TABS
- Synthamin 17
- Tacrolimus CAPS
- Tobramycin NEBU 300MG/5ML
- Travasol INJ 52MEQ/L; 1760MG/100ML; 880MG/100ML; 34MEQ/L; 1760MG/100ML; 372MG/100ML; 406MG/100ML; 526MG/100ML; 492MG/100ML; 492MG/100ML; 526MG/100ML; 356MG/100ML; 500MG/100ML; 356MG/100ML; 390MG/100ML; 34MG/100ML; 152MG/100ML

- Trophamine INJ 97MEQ/L;  
0.54GM/100ML; 1.2GM/100ML;  
0.32GM/100ML; 0; 0; 0.5GM/100ML;  
0.36GM/100ML; 0.48GM/100ML;  
0.82GM/100ML; 1.4GM/100ML;  
1.2GM/100ML; 0.34GM/100ML;  
0.48GM/100ML; 0.68GM/100ML;  
0.38GM/100ML; 5MEQ/L;  
0.025GM/100ML; 0.42GM/100ML;  
0.2GM/100ML; 0.24GM/100ML;  
0.78GM/100ML
- Xopenex
- Xopenex Concentrate
- Zortress

## 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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