ACTIMMUNE

PRODUCTS AFFECTED
- ACTIMMUNE

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

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ADALIMUMAB-AATY

PRODUCTS AFFECTED

- *adalimumab-aaty (1 pen) subcutaneous auto-injector kit 40 mg/0.4ml, 80 mg/0.8ml*
- *adalimumab-aaty (2 pen)*
- *adalimumab-aaty (2 syringe) subcutaneous prefilled syringe kit 20 mg/0.2ml, 40 mg/0.4ml*
- *adalimumab-aaty cd/uc/hs start*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque Psoriasis (PsO) (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene),

PA Criteria	Criteria Details
	tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.
Age Restrictions	
Prescriber Restrictions	RA, AS, PJIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. PsO, 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.
Coverage Duration	UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo.
Other Criteria	Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. Hidradenitis Suppurativa (HS) (Initial): Diagnosis of moderate to severe HS (ie, Hurley Stage

PA Criteria	Criteria Details
	II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. HS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the abscess and inflammatory nodule count from baseline, reduced formation of new sinus tracts and scarring, improvement in symptoms (eg, pain, suppuration) from baseline. Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. PsO (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ADALIMUMAB-ADBM

PRODUCTS AFFECTED

- *adalimumab-adbm (2 pen)*
- *adalimumab-adbm (2 syringe) subcutaneous prefilled syringe kit 10 mg/0.2ml, 20 mg/0.4ml, 40 mg/0.4ml, 40 mg/0.8ml*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque Psoriasis (PsO) (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Ankylosing

PA Criteria	Criteria Details
	Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.
Age Restrictions	
Prescriber Restrictions	RA, AS, PJIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. PsO, 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.
Coverage Duration	UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo.
Other Criteria	Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. Hidradenitis Suppurativa (HS) (Initial): Diagnosis of moderate to severe HS (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to

PA Criteria	Criteria Details
	therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. HS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the abscess and inflammatory nodule count from baseline, reduced formation of new sinus tracts and scarring, improvement in symptoms (eg, pain, suppuration) from baseline. Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. PsO (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ADBRY

PRODUCTS AFFECTED

- ADBRY SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- ADBRY SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of moderate to severe atopic dermatitis. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least two of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment.
Age Restrictions	Initial: Patient is 12 years of age or older.
Prescriber Restrictions	Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist.
Coverage Duration	Initial: 6 months. Reauth: 12 months.

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Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ADCIRCA

PRODUCTS AFFECTED

- ALYQ
- *tadalafil (pah)*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ADEMPAS

PRODUCTS AFFECTED
- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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.

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PA Criteria	Criteria Details
Other Criteria	PAH, CTEPH (Reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AFINITOR

PRODUCTS AFFECTED

- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. Renal cell carcinoma: Diagnosis of advanced 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. Breast Cancer: Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole). 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	SEGA associated with TSC: Patient is 1 year of age or older.

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PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AFINITOR DISPERZ

PRODUCTS AFFECTED

- *everolimus oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. TSC-associated partial-onset seizures: Diagnosis of TSC-associated partial-onset seizures.
Age Restrictions	SEGA associated with TSC: Patient is 1 year of age or older. TSC-associated partial-onset seizures: Patient is 2 years of age or older.
Prescriber Restrictions	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.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AIMOVIG

PRODUCTS AFFECTED

- AIMOVIG SUBCUTANEOUS SOLUTION AUTO-INJECTOR 140 MG/ML, 70 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Episodic Migraines (EM) (initial): Diagnosis of EM. Patient has greater than or equal to 4 migraine 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 8 migraine days per month. All Indications (initial): Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.
Age Restrictions	EM, CM (initial): 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	EM, CM (initial): 6 months. EM, CM (reauth): 12 months.

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PA Criteria	Criteria Details
Other Criteria	EM, CM (reauth): Patient has experienced a positive response to therapy. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (reauth): Patient continues to be monitored for medication overuse headache.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AKEEGA

PRODUCTS AFFECTED
- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of prostate cancer. Disease is both of the following: a) metastatic and b) deleterious or suspected deleterious BRCA-mutated (BRCAm). Used in combination with prednisone. One of the following: a) Used in combination with a gonadotropin-releasing hormone (GnRH) analog, or b) Patient has had a bilateral orchiectomy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALECENSA

PRODUCTS AFFECTED
- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALPHA-1 PROTEINASE INHIBITOR, PROLASTIN

PRODUCTS AFFECTED

- PROLASTIN-C INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Alpha-1 antitrypsin (AAT) deficiency (initial): Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. Continued conventional treatment for emphysema (e.g., bronchodilators). One of the following: 1) PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2) other rare AAT disease genotypes associated with pre-treatment serum AAT level less than 11 -+M/L [e.g., Pi(Malton, Malton), Pi(SZ)]. Circulating pre-treatment serum AAT level less than 11 -+M/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry), unless the patient has a concomitant diagnosis of necrotizing panniculitis.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	AAT deficiency (initial, reauth): 12 months
Other Criteria	AAT deficiency (reauth): Patient demonstrates positive clinical response to therapy. Continued conventional treatment for emphysema (e.g., bronchodilators).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALUNBRIG

PRODUCTS AFFECTED

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AMPYRA

PRODUCTS AFFECTED

- *dalfampridine er*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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).

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ARFORMOTEROL

PRODUCTS AFFECTED

- *arformoterol tartrate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD): Diagnosis of COPD. Used for maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	COPD: 12 months.
Other Criteria	Subject to Part B vs. Part D review.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ARIKAYCE

PRODUCTS AFFECTED
- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Mycobacterium avium complex (MAC) lung disease: Diagnosis of Mycobacterium avium complex (MAC) lung disease. Used as part of a combination antibacterial drug regimen. Used in patients who do not achieve at least two negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g., a macrolide, a rifamycin, ethambutol, etc).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist or pulmonologist.
Coverage Duration	12 months
Other Criteria	

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUGTYRO

PRODUCTS AFFECTED
- AUGTYRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: a) locally advanced, or b) metastatic. Patient has ROS1 rearrangement positive tumor(s). Solid Tumors: Diagnosis of solid tumors. Disease has neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1). Disease is one of the following: a) Locally advanced, b) Metastatic, or c) Unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: a) Disease has progressed following previous treatment (e.g., radiation therapy, systemic therapy, tyrosine kinase inhibitor [TKI]), or b) Disease has no satisfactory alternative treatments.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	All indications: 12 months.
Other Criteria	All indications: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUSTEDO

PRODUCTS AFFECTED

- AUSTEDO
- AUSTEDO XR
- AUSTEDO XR PATIENT TITRATION ORAL TABLET EXTENDED RELEASE THERAPY PACK 12 & 18 & 24 & 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chorea associated with Huntington's disease (initial): Diagnosis of Chorea associated 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.
Age Restrictions	
Prescriber Restrictions	Huntington's disease chorea (initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist.
Coverage Duration	Initial, Reauth: 12 months.

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PA Criteria	Criteria Details
Other Criteria	All indications (Reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AVMAPKI FAKZYNJA

PRODUCTS AFFECTED
- AVMAPKI FAKZYNJA CO-PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of recurrent low-grade serous ovarian cancer (LGSOC). Presence of a KRAS-mutation as detected by a Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received prior systemic therapy (e.g., chemotherapy).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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AVTOZMA SC

PRODUCTS AFFECTED
- AVTOZMA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. Minimum duration of a one month trial of a nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated dose. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: a) TF/C/I to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq/LQ, or Xeljanz (tofacitinib), OR b) for continuation of prior therapy. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (Initial): Diagnosis of SSc-ILD as documented by the following: a) Exclusion of other known causes of ILD 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

PA Criteria	Criteria Details
	[UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (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.
Age Restrictions	
Prescriber Restrictions	RA, GC, SJIA, PJIA (initial): Prescribed by or in consultation with a rheumatologist. SSc-ILD (initial): Prescribed by or in consultation with a pulmonologist or rheumatologist.
Coverage Duration	RA, GC, SJIA, PJIA, SSc-ILD (initial): 6 months, (reauth): 12 months
Other Criteria	RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. SJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in clinical features or symptoms (eg, pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline. GC, SSc-ILD (Reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AYVAKIT

PRODUCTS AFFECTED
- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	
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. Advanced Systemic Mastocytosis (AdvSM): Diagnosis of AdvSM. Patient has one of the following: a) aggressive systemic mastocytosis (ASM), b) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or c) mast cell leukemia (MCL). Platelet count is greater than or equal to 50 x 10^9/L. Indolent Systemic Mastocytosis (ISM): Diagnosis of ISM. Platelet count is greater than or equal to 50 x 10^9/L.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months.

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BALVERSA

PRODUCTS AFFECTED
- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Urothelial Carcinoma: Diagnosis of urothelial carcinoma (UC). Disease is one of the following: Locally advanced or Metastatic. Presence of susceptible fibroblast growth factor receptor (FGFR) 3 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). Disease has progressed on or after at least one line of prior systemic therapy (e.g., chemotherapy). One of the following: 1) Patient had been treated with prior PD-1 inhibitor (e.g., Opdivo [nivolumab], Keytruda [pembrolizumab]) or PD-L1 inhibitor therapy (e.g., Bavencio [avelumab]) or 2) Patient is not a candidate for PD-1 or PD-L1 inhibitor therapy.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BENLYSTA

PRODUCTS AFFECTED
- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
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)]). Lupus Nephritis (init): Diagnosis of active lupus nephritis. Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide).
Age Restrictions	SLE, Lupus Nephritis (init): Benlysta IV (vial), SC (prefilled syringe): Patient is 5 years of age or older.
Prescriber Restrictions	SLE (init): Prescribed by or in consultation with a rheumatologist. Lupus Nephritis (init): Prescribed by or in consultation with a nephrologist or rheumatologist.

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PA Criteria	Criteria Details
Coverage Duration	SLE, Lupus Nephritis (init, reauth): 6 months
Other Criteria	SLE, Lupus Nephritis (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BESREMI

PRODUCTS AFFECTED

- BESREMI
- BESREMI PEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of polycythemia vera. One of the following: a) Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women or b) Hematocrit greater than 49% for men or hematocrit greater than 48% for women. One of the following: a) Presence of JAK2 V617F or JAK2 exon 12 mutation or b) Patient has subnormal serum erythropoietin level. For high-risk polycythemia vera only (patient greater than or equal to 60 years old and/or prior thrombosis history), trial and inadequate response, contraindication or intolerance to hydroxyurea.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BOSULIF

PRODUCTS AFFECTED

- BOSULIF
- *bosutinib oral tablet 400 mg*

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

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

BRAFTOVI

PRODUCTS AFFECTED

- BRAFTOVI ORAL CAPSULE 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
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. 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). Both of the following a) Used in combination with Erbitux (cetuximab) AND b) One of the following: i) Patient has received prior therapy OR ii) Used in combination with fluorouracil-based chemotherapy (e.g., mFOLFOX6, FOLFIRI). Non-Small Cell Lung Cancer (NSCLC): Diagnosis of metastatic NSCLC. Cancer is BRAF V600E 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).

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BRIVIACT

PRODUCTS AFFECTED

- *brivaracetam oral solution*
- *brivaracetam oral tablet*
- BRIVIACT ORAL

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

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BRONCHITOL

PRODUCTS AFFECTED
- BRONCHITOL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert), including additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BRUKINSA

PRODUCTS AFFECTED
- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Mantle Cell Lymphoma (MCL): Diagnosis of MCL. Patient has received at least one prior therapy for MCL [e.g., Calquence (acalabrutinib)]. Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. Disease is relapsed or refractory. Patient has received at least one prior anti-CD20-based regimen for MZL (e.g., rituximab, obinutuzumab). Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of ONE of the following: CLL or SLL. Contraindication or intolerance to Calquence (acalabrutinib). Follicular Lymphoma (FL): Diagnosis of FL. Disease is relapsed or refractory. Used in combination with Gazyva (obinutuzumab). Patient has received at least two prior lines of systemic therapy (e.g., chemotherapy).
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months.
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CABLIVI

PRODUCTS AFFECTED
- CABLIVI

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

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CABOMETYX

PRODUCTS AFFECTED

- CABOMETYX ORAL TABLET 20 MG, 40 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Trial and failure, contraindication, or intolerance to Nexavar (sorafenib tosylate). Differentiated Thyroid Cancer (DTC): Diagnosis of DTC. Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]). Disease or patient is refractory to radioactive iodine treatment or ineligible. Neuroendocrine Tumors: Diagnosis of one of the following: 1) Pancreatic neuroendocrine tumors (pNET) or 2) Extra-pancreatic neuroendocrine tumors (epNET). Disease is one of the following: 1) Unresectable, 2) Locally advanced, or 3) Metastatic. Tumors are well-differentiated. Patient has been previously treated (e.g., octreotide, lanreotide, chemotherapy).
Age Restrictions	DTC: Patient is 12 years of age or older.
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CALQUENCE

PRODUCTS AFFECTED
- CALQUENCE ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL). One of the following: A) All of the following: 1) Patient has received no prior therapy for MCL (e.g., bortezomib, rituximab), 2) Patient is ineligible for autologous hematopoietic stem cell transplantation (HSCT), and 3) Used in combination with bendamustine and rituximab, OR B) 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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CAPLYTA

PRODUCTS AFFECTED
- CAPLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Schizophrenia: Diagnosis of schizophrenia. Trial and failure, contraindication, or intolerance to two of the following oral generic formulary atypical antipsychotic agents: asenapine, aripiprazole, olanzapine, paliperidone, quetiapine (IR or ER), risperidone, ziprasidone. Bipolar disorder: Diagnosis of bipolar I or II disorder (bipolar depression). Patient has depressive episodes associated with bipolar disorder. Used as monotherapy or as adjunctive therapy with lithium or valproate. Trial and failure, contraindication, or intolerance to quetiapine (IR or ER) or olanzapine. Major depressive disorder (MDD): Diagnosis of MDD. Used as adjunctive therapy with an antidepressant (e.g., escitalopram, sertraline, venlafaxine/desvenlafaxine, etc.). Trial and failure, contraindication, or intolerance to both of the following oral generic formulary atypical antipsychotic agents: aripiprazole and quetiapine IR/ER.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CAPRELSA

PRODUCTS AFFECTED

- CAPRELSA ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Thyroid Cancer: Diagnosis of one of the following: a) metastatic medullary thyroid cancer (MTC) or b) unresectable locally advanced MTC. Patient has symptomatic disease or progressive disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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CAYSTON

PRODUCTS AFFECTED
- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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).
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CERDELGA

PRODUCTS AFFECTED
- CERDELGA

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

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CHOLBAM

PRODUCTS AFFECTED
- CHOLBAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect based on one of the following: a) an abnormal urinary bile acid analysis by mass spectrometry OR b) molecular genetic testing consistent with the diagnosis. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of a peroxisomal disorder based on one of the following: a) an abnormal urinary bile acid analysis by mass spectrometry OR b) molecular genetic testing consistent with the diagnosis, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) will be used as an adjunctive treatment.
Age Restrictions	
Prescriber Restrictions	All uses (initial): Prescribed by a hepatologist, medical geneticist, gastroenterologist, OR other specialist that treats inborn errors of metabolism.

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PA Criteria	Criteria Details
Coverage Duration	All uses: 4 months (initial), 12 months (reauth).
Other Criteria	All uses (reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement in liver function.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CIALIS

PRODUCTS AFFECTED

- *tadalafil oral tablet 2.5 mg, 5 mg*

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

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CICLOPIROX

PRODUCTS AFFECTED

- *ciclopirox external solution*

PA Criteria	Criteria Details
Exclusion Criteria	
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 target toenail, AND 5) One of the following: a) For onychomycosis of fingernails, Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine, or b) For onychomycosis of toenails, trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	48 weeks.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CINRYZE

PRODUCTS AFFECTED
- CINRYZE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks (initial): Diagnosis of HAE. One of the following: 1) Diagnosis has been confirmed by both of the following: a) C4 level below the lower limit of normal, and b) C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: i) C1-INH antigenic level below the lower limit of normal OR ii) C1-INH functional level below the lower limit of normal, OR 2) Diagnosis has been confirmed by both of the following: a) Both of the following: i) Normal C4 level AND ii) Normal C1-INH levels (HAE-nl-C1INH previously referred to as HAE Type III), and b) One of the following: i) Presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR ii) Patient has a confirmed family history of recurrent angioedema. For prophylaxis against HAE attacks. Not used in combination with other approved treatments for prophylaxis against HAE attacks.
Age Restrictions	HAE (prophylaxis) (initial): Patient is 6 years of age or older

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PA Criteria	Criteria Details
Prescriber Restrictions	HAE (prophylaxis) (initial): Prescribed by or in consultation with an immunologist or an allergist
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy. Not used in combination with other approved treatments for prophylaxis against HAE attacks.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COBENFY

PRODUCTS AFFECTED

- COBENFY
- COBENFY STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of schizophrenia. Trial and failure, contraindication, or intolerance to two of the following oral generic formulary atypical antipsychotic agents: a) aripiprazole, b) asenapine, c) olanzapine, d) paliperidone, e) quetiapine (IR or ER), f) risperidone, or g) ziprasidone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COMETRIQ

PRODUCTS AFFECTED

- COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medullary thyroid cancer (MTC): Diagnosis of Metastatic MTC.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	All uses: 12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COPIKTRA

PRODUCTS AFFECTED
- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COSENTYX

PRODUCTS AFFECTED

- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SENSOREADY PEN
- COSENTYX SUBCUTANEOUS
- COSENTYX UNOREADY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but

PA Criteria	Criteria Details
	without definitive radiographic evidence of structural damage on sacroiliac joints.) Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. nr-axSpA, ERA (Initial): Minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, naproxen) at maximally tolerated doses. Hidradenitis suppurativa (HS) (Initial): Diagnosis of moderate to severe HS.
Age Restrictions	
Prescriber Restrictions	Plaque psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS, nr-axSpA, ERA (initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	All uses (initial): 6 months. All uses (reauth): 12 months
Other Criteria	PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS, nr-axSpA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg,

PA Criteria	Criteria Details
	pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. ERA (Reauth): Patient demonstrates a positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. HS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the abscess and inflammatory nodule count from baseline, reduced formation of new sinus tracts and scarring, improvement in symptoms (eg, pain, suppuration) from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COSENTYX IV

PRODUCTS AFFECTED
- COSENTYX INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Cosentyx SC (secukinumab), Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Otezla (apremilast), Skyrizi (risankizumab-rzaa), one formulary ustekinumab product, Rinvoq/LQ (upadacitinib), or Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: a) TF/C/I to two of the following: Cosentyx SC, Enbrel, one formulary adalimumab product, Rinvoq, Xeljanz/XR, OR b) for continuation of prior 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). One of the following: a) TF/C/I to both of the following: Cosentyx SC and Rinvoq, OR b) for continuation of prior therapy.

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS, nr-axSpA (Initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	All uses (Initial): 6 months. All uses (Reauth): 12 months
Other Criteria	PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the body surface area (BSA) involvement from baseline. AS, nr-axSpA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count.
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

COTELLIC

PRODUCTS AFFECTED
- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	
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 Zelboraf (vemurafenib). Histiocytic Neoplasm: Diagnosis of histiocytic neoplasm. Used as monotherapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CRESEMBA ORAL

PRODUCTS AFFECTED
- CRESEMBA ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Fungal infection: Diagnosis of invasive aspergillosis or invasive mucormycosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

CTEXLI

PRODUCTS AFFECTED
- CTEXLI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of cerebrotendinous xanthomatosis (cholestanol storage disease). Disease is confirmed by the presence of pathogenic variant(s) in the CYP27A1 gene as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	
Prescriber Restrictions	Initial: Prescribed by or in consultation with one of the following: a) Neurologist, b) Geneticist, c) Metabolic disease specialist, or d) Endocrinologist.
Coverage Duration	Initial: 12 months. Reauth: 12 months.
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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CYCLOBENZAPRINE

PRODUCTS AFFECTED

- *cyclobenzaprine hcl oral tablet 10 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prescriber acknowledges anticholinergic risks (e.g., confusion, dry mouth, blurry vision, constipation, urinary retention) and will consider lowering the dose or discontinuing medication(s) that are no longer clinically warranted for the patient. Muscle spasm: Diagnosis of muscle spasm associated with acute, painful musculoskeletal conditions. Fibromyalgia (off-label): Used to treat fibromyalgia related symptoms (e.g., difficulty sleeping). Acute temporomandibular disorder (off-label): All of the following: a) Diagnosis of acute temporomandibular disorder, b) Patient has pain on palpitation of the lower jaw muscle, and c) Used in combination with a nonsteroidal anti-inflammatory drug (NSAID) (e.g., naproxen).
Age Restrictions	PA applies to patients 65 years or older.
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	Muscle spasm, temporomandibular disorder: 4 weeks. Fibromyalgia: 12 months.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DALIRESP

PRODUCTS AFFECTED

- *roflumilast*

PA Criteria	Criteria Details
Exclusion Criteria	
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 (e.g., Combivent, Spiriva).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	COPD (init, reauth): 12 months
Other Criteria	COPD (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DANZITEN

PRODUCTS AFFECTED
- DANZITEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

DARAPRIM

PRODUCTS AFFECTED

- *pyrimethamine oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Toxoplasmosis: 1) Patient is using pyrimethamine for the active treatment of toxoplasmosis (e.g., toxoplasmic encephalitis, ocular toxoplasmosis), secondary prophylaxis of toxoplasmosis, or treatment of congenital toxoplasmosis OR 2) Patient is using pyrimethamine for the primary prophylaxis of toxoplasmosis, 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: Requests for coverage of any pyrimethamine products for the treatment and/or prophylaxis of malaria are not authorized and will not be approved. The use of pyrimethamine for the treatment and/or prophylaxis of malaria is not recommended by the Centers for Disease Control and Prevention (CDC).
Age Restrictions	
Prescriber Restrictions	Toxoplasmosis: Prescribed by or in consultation with an infectious disease specialist

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PA Criteria	Criteria Details
Coverage Duration	Toxoplasmosis: 12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DAURISMO

PRODUCTS AFFECTED
- DAURISMO

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DEFERASIROX

PRODUCTS AFFECTED

- *deferasirox*
- *deferasirox granules*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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.
Age Restrictions	Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 mo. NTDT (initial, reauth): 6mo.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DEMSER

PRODUCTS AFFECTED

- *metyrosine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Preoperative preparation: Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: a) plasma free metanephrines OR b) urinary fractioned metanephrines. Medication is being used for preoperative preparation. Trial and failure, contraindication, or intolerance to both of the following: a) alpha-adrenergic blocker (e.g., phenoxybenzamine, doxazosin, terazosin) AND b) beta-adrenergic blocker (e.g., propranolol, metoprolol). Treatment of pheochromocytoma (initial): Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: a) plasma free metanephrines OR b) urinary fractioned metanephrines. Patient with hormonally active (catecholamine excess) pheochromocytoma. One of the following: a) patient is not a candidate for surgery OR b) chronic treatment due to malignant pheochromocytoma. Patient has not reached normotension after treatment with a selective alpha-1-adrenergic blocker (e.g., doxazosin, terazosin) and beta-adrenergic blocker (e.g., propranolol, metoprolol). Medication will not be used to control essential hypertension.
Age Restrictions	

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PA Criteria	Criteria Details
Prescriber Restrictions	Preop prep: Prescribed by or in consultation with an endocrinologist OR Endocrine surgeon. Pheochromocytoma (initial): Prescribed by or in consultation with endocrinologist OR provider who specializes in the management of pheochromocytoma.
Coverage Duration	Preop prep: 4 wks. Treatment of pheo (initial): 6 months, (reauth): 12 months.
Other Criteria	Treatment of pheochromocytoma (reauth): Patient demonstrates positive clinical response to therapy (e.g., decreased frequency and severity of hypertensive attacks).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIACOMIT

PRODUCTS AFFECTED
- DIACOMIT

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

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

DOPTELET

PRODUCTS AFFECTED

- DOPTELET ORAL TABLET 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Thrombocytopenia Prior to Planned Procedure (TPPP): Diagnosis (dx) of thrombocytopenia. Patient has chronic liver disease and is scheduled to undergo a procedure. Baseline platelet count is less than 50,000/mcL. Immune Thrombocytopenia (ITP) (initial): Diagnosis of chronic ITP, relapsed/refractory ITP, or pediatric patient with persistent ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy.
Age Restrictions	
Prescriber Restrictions	ITP (initial): Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	TPPP: 1 month. ITP (initial, reauth): 12 months

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PA Criteria	Criteria Details
Other Criteria	ITP (reauth): Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DULERA

PRODUCTS AFFECTED

- DULERA INHALATION AEROSOL 100-5 MCG/ACT, 200-5 MCG/ACT, 50-5 MCG/ACT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Asthma (initial): Diagnosis of asthma. Trial and failure, contraindication (e.g., safety concerns, not indicated for patient-+s age), or intolerance to Breo Ellipta (fluticasone furoate and vilanterol trifenatate).
Age Restrictions	Initial: Patient is 5 years or older.
Prescriber Restrictions	
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Asthma (reauthorization): Patient demonstrates positive clinical response to therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DUPIXENT

PRODUCTS AFFECTED

- DUPIXENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/1.14ML, 300 MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/1.14ML, 300 MG/2ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Eosinophilic Asthma (EA) (init): Dx of mod to severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-tx) peripheral blood eosinophil level greater than or equal to 150 cells/ml. One of the following: 1) Pt has had 2 or more asthma exacerbations requiring systemic corticosteroids (CS) (eg, prednisone) w/in the past 12 mo, 2) Prior asthma-related hospitalization w/in the past 12 mo. Corticosteroid Dependent Asthma (CDA) (init): Dx of mod to severe asthma. Pt is currently dependent on oral CS for the treatment of asthma. EA, CDA (init): One of the following: 1) Both of the following: a) Pt is at least 6 yo but less than 12 yo b) Pt is currently being treated w/ 1 of the following unless there is a contraindication or intolerance (C/I) to these meds: i) Medium-dose inhaled corticosteroid (ICS) (eg, greater than 100 200mcg fluticasone propionate equivalent/day) and Additional asthma controller med (eg, leukotriene receptor antagonist [LTRA] [eg, montelukast], long-acting beta-2 agonist [LABA] [eg, salmeterol], long-acting muscarinic antagonist [LAMA] [eg, tiotropium]) or ii) 1 medium dosed combo ICS/LABA product (eg, fluticasone propionate 100mcg/salmeterol50mcg, budesonide80mcg/formoterol4.5mcg, fluticasone furoate 50mcg/vilanterol 25mcg) OR 2) Pt is at least 12 yo and Pt is currently

PA Criteria	Criteria Details
	being treated w/ 1 of the following unless there is a C/I to these meds: a) Both of the following: i) High-dose ICS [eg, greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller med, OR b) 1 maximally-dosed combo ICS/LABA product [eg, fluticasone propionate 500mcg/salmeterol50mcg, budesonide160mcg/formoterol4.5mcg, fluticasone200mcg/vilanterol25mcg]. Chronic rhinosinusitis with nasal polyposis (CRSwNP) (init): Dx of CRSwNP. Unless contraindicated, the pt has had an inadequate response to 2 mo of tx with an intranasal CS (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP.
Age Restrictions	AD (initial): Patient is 6 months or age or older. CRSwNP, PN: no age restriction. EoE (initial): Patient is at least 1 year of age.
Prescriber Restrictions	AD, PN, CSU, BP (Init): Prescribed/consult with a dermatologist or allergist/immunologist. Asthma (init): Prescribed/consult with a pulmonologist or allergist/immunologist. CRSwNP (init, reauth): Prescribed/consult with an otolaryngologist, allergist/immunologist, or pulmonologist. EoE (init): Prescribed/consult with a gastroenterologist or allergist/immunologist. AFRS (init): Prescribed/consult with an otolaryngologist, allergist/immunologist, or pulmonologist.
Coverage Duration	AFRS, CRSwNP, EoE (Init/Reauth): 12 mo. Asthma, AD, PN, COPD, CSU, BP (Init): 6 mo, (reauth): 12 mo.
Other Criteria	Eosinophilic esophagitis (EoE) (init): Dx of EoE. Pt has symptoms of esophageal dysfunction (eg, dysphagia, food impaction, GERD/heartburn symptoms, chest pain, abdominal pain). Pt has at least 15 intraepithelial eosinophils per high

PA Criteria	Criteria Details
	power field. Other causes of esophageal eosinophilia have been excluded. Pt weighs at least 15 kg. Trial and failure, contraindication, or intolerance (TF/C/I) to at least an 8-wk trial of 1 of the following: proton pump inhibitors (eg, pantoprazole, omeprazole) or topical (esophageal) CS (eg, budesonide, fluticasone). PN (init): Dx of PN. Atopic dermatitis (AD) (init): Dx of mod to severe AD. 1 of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing AD (SCORAD) index value of at least 25. TF of a min 30-day supply (14-day supply for TCS), CI (eg, safety concerns, not indicated for pt's age/wt), or intol to 1 of the following: a) Medium or higher potency TCS, b) Pimecrolimus, c) Tacrolimus ointment, or d) crisaborole. Chronic Obstructive Pulmonary Disease (COPD) (init): Dx of COPD. Presence of type 2 inflammation evidenced by baseline blood eosinophils greater than or equal to 300 cells/mcL. Pt is receiving 1 of the following at maximally tolerated doses: triple therapy [ie, an ICS, a LAMA, and a LABA] OR if CI to ICS, a LAMA and a LABA. Pt has had at least 2 exacerbations where systemic CS [IM/IV/oral] were required at least once OR COPD-related hospitalization w/in the past 12 mo. Bullous Pemphigoid (BP) (init): Dx of BP as confirmed by skin biopsy or serology. Will be used in combo w/ a tapering course of oral CS until disease control has occurred. AD (reauth): Pt demonstrates positive clinical response to therapy as evidenced by a reduction in BSA involvement or SCORAD index value from baseline. AFRS, EA, CDA, PN, CRSwNP, COPD, BP (reauth): Pt demonstrates positive clinical response to therapy. CRSwNP (reauth): Used in combination with another agent for CRSwNP. EoE (reauth): Pt demonstrates positive clinical response to therapy as evidenced by improvement of 1 of the following from baseline: symptoms (eg, dysphagia, food impaction, chest pain, heartburn), histologic measures (eg, esophageal intraepithelial eosinophil count), or endoscopic measures (eg, edema, furrows, exudates, rings, strictures). COPD (reauth): Pt cont on triple therapy (ie, an ICS, a LAMA, and a LABA) OR if CI

PA Criteria	Criteria Details
	to ICS, a LAMA and a LABA. Chronic Spontaneous Urticaria (CSU) (init): Dx of CSU. Persistent symptoms (itching and hives) with a 2nd generation H1 antihistamine (H1A) (eg, cetirizine, fexofenadine), unless C/I to H1A. Used concurrently with an H1A unless C/I to H1A. CSU (reauth): Pt demonstrates positive clinical response to therapy as evidenced by a reduction from baseline in itching severity or number of hives. Allergic Fungal Rhinosinusitis (AFRS) (init): Dx of AFRS. Pt has history of sino-nasal surgery.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EBGLYSS 2

PRODUCTS AFFECTED
- EBGLYSS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of moderate to severe atopic dermatitis. Patient weighs at least 40 kg. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) crisaborole ointment.
Age Restrictions	Initial: Patient is 12 years of age or older.
Prescriber Restrictions	Initial: Prescribed by or in consultation with a dermatologist or allergist/immunologist.
Coverage Duration	Initial: 6 months. Reauth: 12 months.

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Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EMGALITY

PRODUCTS AFFECTED

- EMGALITY
- EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Episodic Migraines (EM) (120 mg/mL strength only) (initial): Diagnosis of EM. Patient has greater than or equal to 4 migraine days per month. Chronic Migraines (CM) (120 mg strength/mL only) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 8 migraine days per month. Episodic Cluster Headache (ECH) (100 mg/mL strength only) (initial): Diagnosis of episodic cluster headache. Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months. Medication will not be used in combination with another injectable CGRP inhibitor. EM, CM (120 mg/mL strength only) (initial): Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.
Age Restrictions	EM, CM, ECH (initial): 18 years of age or older.
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	EM, CM (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (reauth): 12 months.
Other Criteria	EM, CM (120 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy. Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (120 mg/mL strength only) (reauth): Patient continues to be monitored for medication overuse headache. ECH (100 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy. Medication will not be used in combination with another injectable CGRP inhibitor.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EMPAVELI

PRODUCTS AFFECTED
- EMPAVELI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Paroxysmal Nocturnal Hemoglobinuria (PNH) (initial): Diagnosis of PNH. Complement 3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN) (initial): Diagnosis of C3G or primary IC-MPGN. For primary IC-MPGN, patient has not had a kidney transplant. Used to reduce proteinuria. Patient is currently being treated with a maximally tolerated dose of one of the following for at least 12 weeks prior to initiating treatment: 1) Angiotensin-converting enzyme inhibitors (e.g., benazepril, lisinopril), 2) Angiotensin receptor blockers (e.g., losartan, valsartan), or 3) Sodium-glucose cotransporter-2 (SGLT2) inhibitors (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]).
Age Restrictions	C3G, Primary IC-MPGN (initial): Patient is 12 years of age or older.
Prescriber Restrictions	PNH (initial): Prescribed by or in consultation with a hematologist or oncologist. C3G, Primary IC-MPGN (initial): Prescribed by or in consultation with a nephrologist.

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PA Criteria	Criteria Details
Coverage Duration	PNH, C3G, Primary IC-MPGN (initial, reauth): 12 months.
Other Criteria	PNH (reauth): Patient demonstrates positive clinical response to therapy. C3G, Primary IC-MPGN (reauth): Patient demonstrates positive clinical response to therapy. For primary IC-MPGN, patient has not had a kidney transplant. Patient continues to be treated with a maximally tolerated dose of one of the following: 1) Angiotensin-converting enzyme inhibitors (e.g., benazepril, lisinopril), 2) Angiotensin receptor blockers (e.g., losartan, valsartan), or 3) Sodium-glucose cotransporter-2 (SGLT2) inhibitors (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ENBREL

PRODUCTS AFFECTED

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids),

PA Criteria	Criteria Details
	contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses.
Age Restrictions	
Prescriber Restrictions	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.
Coverage Duration	All uses (initial): 6 months. All uses (reauth): 12 months
Other Criteria	RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as

PA Criteria	Criteria Details
	evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ENDARI

PRODUCTS AFFECTED

- *l-glutamine oral packet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Sickle cell disease (initial): Diagnosis of sickle cell disease. Used to reduce acute complications of sickle cell disease. Patient has had 2 or more painful sickle cell crises within the past 12 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Sickle cell disease (initial, reauth): 12 months
Other Criteria	Sickle cell disease (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ENSACOVE

PRODUCTS AFFECTED
- ENSACOVE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: a) Locally advanced or b) Metastatic. Disease is anaplastic lymphoma kinase (ALK) rearrangement-positive as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has not previously received an ALK-inhibitor [e.g., Alecensa (alectinib), Alunbrig (brigatinib), Lorbrena (lorlatinib), Xalkori (crizotinib), Zykadia (ceritinib)].
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EPCLUSA

PRODUCTS AFFECTED

- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C. Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)].
Age Restrictions	
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, Liver transplant specialist. Prescriber requirement does not apply for patient who is Hepatitis C treatment naive without decompensation.
Coverage Duration	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EPIDIOLEX

PRODUCTS AFFECTED
- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
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	LGS, DS, TSC: Patient is 1 year of age or older.
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.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EPOETIN ALFA

PRODUCTS AFFECTED
- PROCRIT

PA Criteria	Criteria Details
Exclusion Criteria	
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 receiving 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

PA Criteria	Criteria Details
	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	
Prescriber Restrictions	
Coverage Duration	CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo.
Other Criteria	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. Patient demonstrates positive clinical response to therapy from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Patient demonstrates positive clinical response to therapy from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Patient demonstrates positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most

PA Criteria	Criteria Details
	recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates positive clinical response to therapy from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates a positive clinical response to therapy from pre-treatment level. Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Adequate iron stores confirmed by both of the following: a) Patient's ferritin level is greater than 100 mcg/L and b) Patient's transferrin saturation (TSAT) is greater than 20%.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ERIVEDGE

PRODUCTS AFFECTED
- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ERLEADA

PRODUCTS AFFECTED

- ERLEADA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of prostate cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ESBRIET

PRODUCTS AFFECTED

- *pirfenidone*

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

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PA Criteria	Criteria Details
Other Criteria	IPF (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EUCRISA

PRODUCTS AFFECTED
- EUCRISA

PA Criteria	Criteria Details
Exclusion Criteria	
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 (e.g., triamcinolone acetonide, fluocinolone acetonide), unless the affected area is sensitive (i.e., face, axillae, groin).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Reauth: Patient demonstrates a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity).
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EVRYSDI

PRODUCTS AFFECTED

- EVRYSDI ORAL SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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 Part 2 (HINE-2) (infant to early childhood), Hammersmith Functional Motor Scale Expanded (HFMSE), Revised Upper Limb Module (RULM) Test (Non ambulatory), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Motor Function Measure 32 (MFM-32) Scale, or Item 22 of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III). 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

PA Criteria	Criteria Details
	previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).
Age Restrictions	
Prescriber Restrictions	SMA (Initial, Reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	SMA (Reauth): Patient demonstrates positive clinical response to therapy. Pt is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) pt has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) pt has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months).
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FABRAZYME

PRODUCTS AFFECTED
- FABRAZYME

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Fabry Disease (init): Diagnosis of Fabry disease. One of the following: a) detection of pathogenic mutations in the GLA gene by molecular genetic testing, b) deficiency in a-galactosidase A (a-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS), or c) significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata). Will not be used in combination with other drugs used for Fabry disease.
Age Restrictions	Fabry Disease (init): Patient is 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	Fabry Disease (init, reauth): 12 months

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PA Criteria	Criteria Details
Other Criteria	Fabry Disease (reauth): Patient demonstrates positive clinical response to therapy. Will not be used in combination with other drugs used for Fabry disease.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FASENRA

PRODUCTS AFFECTED

- FASENRA PEN
- FASENRA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 10 MG/0.5ML, 30 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR 2) Prior asthma-related hospitalization within the past 12 months. One of the following: 1) Both of the following: a) Patient is 6 years of age or older but less than 12 years of age b) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: i) Medium-dose inhaled corticosteroid (e.g., greater than 100-200 mcg fluticasone propionate equivalent/day) and Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) or ii) One medium dosed combination ICS/LABA product (e.g., Wixela Inhub [fluticasone propionate 100mcg/salmeterol 50mcg], budesonide 80mcg/ formoterol 4.5mcg, Breo Ellipta [fluticasone furoate 50 mcg/vilanterol 25 mcg]) OR 2) Patient is 12 years of age or older and Patient is currently being

PA Criteria	Criteria Details
	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 [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]), OR b) One maximally-dosed combination ICS/LABA product [e.g., Wixela Inhub (fluticasone propionate 500mcg/salmeterol 50mcg), budesonide 160mcg/formoterol 4.5mcg, Breo Ellipta (fluticasone 200mcg/vilanterol 25mcg)].
Age Restrictions	
Prescriber Restrictions	Asthma (initial): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. EGPA (initial): Prescribed by or in consultation with a pulmonologist, rheumatologist, or allergist/immunologist. HES (initial): Prescribed by or in consultation with an allergist/immunologist or hematologist.
Coverage Duration	Asthma (init): 6 months. Asthma (reauth): 12 months. EGPA, HES (init/reauth): 12 months.
Other Criteria	Eosinophilic granulomatosis with polyangiitis (EGPA) (initial): Diagnosis of EGPA. Patient is currently receiving corticosteroid therapy (eg, prednisolone, prednisone) unless there is a contraindication or intolerance to corticosteroid therapy. Hypereosinophilic Syndrome (HES) (initial): Diagnosis of HES. Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-

PA Criteria	Criteria Details
	hematologic malignancy). Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative. Patient has pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter. Trial and failure, contraindication, or intolerance to corticosteroid therapy (e.g., prednisone) or cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib). Asthma, EGPA, HES (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FENTANYL

PRODUCTS AFFECTED

- *fentanyl citrate buccal lozenge on a handle*
  1600 mcg, 200 mcg, 400 mcg, 800 mcg

PA Criteria	Criteria Details
Exclusion Criteria	
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 g/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, Oral hydrocodone at a dose of greater than or equal to 60 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FINTEPLA

PRODUCTS AFFECTED
- FINTEPLA

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

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FIRAZYR

PRODUCTS AFFECTED

- *icatibant acetate subcutaneous solution prefilled syringe*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks (initial): Diagnosis of HAE. One of the following: 1) Diagnosis has been confirmed by both of the following: a) C4 level below the lower limit of normal, and b) C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: i) C1-INH antigenic level below the lower limit of normal OR ii) C1-INH functional level below the lower limit of normal, OR 2) Diagnosis has been confirmed by both of the following: a) Both of the following: i) Normal C4 level AND ii) Normal C1-INH levels (HAE-nl-C1INH previously referred to as HAE Type III), and b) One of the following: i) Presence of a factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR ii) Patient has a confirmed family history of recurrent angioedema. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	Initial: Patient is 18 years of age or older

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PA Criteria	Criteria Details
Prescriber Restrictions	HAE (initial): Prescribed by or in consultation with an immunologist or an allergist
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy. Not used in combination with other approved treatments for acute HAE attacks.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FIRMAGON

PRODUCTS AFFECTED

- FIRMAGON (240 MG DOSE)
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of advanced or metastatic prostate cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FOTIVDA

PRODUCTS AFFECTED
- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of advanced renal cell carcinoma. Disease is one of the following: relapsed or refractory. Patient has received two or more prior systemic therapies (e.g., chemotherapy).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FRUZAQLA

PRODUCTS AFFECTED
- FRUZAQLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of metastatic colorectal cancer. Patient has been previously treated with both of the following: A) Fluoropyrimidine-, oxaliplatin-, irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI), and B) Anti-VEGF biological therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-afibercept]). One of the following: A) Patient has RAS mutant tumors, OR B) Both of the following: a) Patient has RAS wild-type tumors, AND b) Patient has been previously treated with both of the following: 1) An anti-EGFR biological therapy (e.g., Vectibix [panitumumab], Erbitux [cetuximab]), and 2) One of the following: i) Lonsurf [trifluridine/tipiracil] or ii) Stivarga [regorafenib].
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GAMASTAN

PRODUCTS AFFECTED

- GAMASTAN INTRAMUSCULAR SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	14 days
Other Criteria	
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GAVRETO

PRODUCTS AFFECTED
- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.
Age Restrictions	Thyroid Cancer: Patient is 12 years of age or older.
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GILENYA

PRODUCTS AFFECTED
- *fingolimod hcl*

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

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GILOTRIF

PRODUCTS AFFECTED
- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	
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 (e.g., cisplatin, carboplatin) and b) squamous NSCLC.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GLATIRAMER ACETATE

PRODUCTS AFFECTED

- *glatiramer acetate subcutaneous solution prefilled syringe 20 mg/ml, 40 mg/ml*

PA Criteria	Criteria Details
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GLEEVEC

PRODUCTS AFFECTED

- *imatinib mesylate oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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) 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 OR G) Aggressive systemic mastocytosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	All uses: 12 months
Other Criteria	All uses: Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GLYCOPYRROLATE TABLET

PRODUCTS AFFECTED

- *glycopyrrolate oral tablet 1 mg, 2 mg*

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

PA Criteria	Criteria Details
	contraindication or intolerance to PPIs, and b) Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine). Patient experienced a reduction in peptic ulcer symptoms while on therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GOMEKLI

PRODUCTS AFFECTED
- GOMEKLI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of neurofibromatosis type 1. Patient has plexiform neurofibromas that are inoperable.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

GROWTH HORMONE

PRODUCTS AFFECTED

- GENOTROPIN MINIQUICK SUBCUTANEOUS PREFILLED SYRINGE
- GENOTROPIN SUBCUTANEOUS CARTRIDGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PGHD(initial):PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)]. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender assoc

PA Criteria	Criteria Details
	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.
Age Restrictions	
Prescriber Restrictions	PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, IGHDA, ISS: prescribed by or in consultation with an endocrinologist. GFCRI: prescribed by or in consultation with an endocrinologist or nephrologist
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT],glucagon,macimorelin) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin at or below 2.8 ng/mL 30, 45, 60 and 90 mins after admin]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IGF-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. IGHDA(initial):doc GHD after 2 GH stim

PA Criteria	Criteria Details
	tests(ITT,glucagon,macimorelin), w/ 2 corresponding peak GH values [ITT at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin at or below 2.8 ng/mL 30,45,60,90 mins after admin].
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HERNEXEOS

PRODUCTS AFFECTED
- HERNEXEOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of non-squamous non-small cell lung cancer (NSCLC). Disease is one of the following: a) unresectable, b) metastatic. Presence of HER2 (ERBB2) tyrosine kinase domain activating mutations as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months.
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HUMIRA

PRODUCTS AFFECTED

- HUMIRA (2 PEN) SUBCUTANEOUS AUTO-INJECTOR KIT 40 MG/0.4ML, 40 MG/0.8ML, 80 MG/0.8ML
- HUMIRA (2 SYRINGE) SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML
- HUMIRA-CD/UC/HS STARTER SUBCUTANEOUS AUTO-INJECTOR KIT 80 MG/0.8ML
- HUMIRA-PED>/=40KG UC STARTER SUBCUTANEOUS AUTO-INJECTOR KIT
- HUMIRA-PSORIASIS/UVEIT STARTER SUBCUTANEOUS AUTO-INJECTOR KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque Psoriasis (PsO) (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms,

PA Criteria	Criteria Details
	soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis.
Age Restrictions	
Prescriber Restrictions	RA, AS, PJIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. PsO, 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.
Coverage Duration	UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo.

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PA Criteria	Criteria Details
Other Criteria	Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. Hidradenitis Suppurativa (HS) (Initial): Diagnosis of moderate to severe HS (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. HS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the abscess and inflammatory nodule count from baseline, reduced formation of new sinus tracts and scarring, improvement in symptoms (eg, pain, suppuration) from baseline. Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. PsO (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing,

PA Criteria	Criteria Details
	improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HYRNUO

PRODUCTS AFFECTED
- HYRNUO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of non-squamous non-small cell lung cancer (NSCLC). Disease is locally advanced or metastatic. Presence of HER2 (ERBB2) tyrosine kinase domain activating mutations as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received prior systemic therapy (e.g., chemotherapy).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IBRANCE

PRODUCTS AFFECTED
- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of breast cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

IBTROZI

PRODUCTS AFFECTED
- IBTROZI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: 1) Locally advanced or 2) Metastatic. Presence of ROS1 rearrangement-positive tumor as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ICLUSIG

PRODUCTS AFFECTED

- ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic myelogenous leukemia: Diagnosis of chronic myelogenous leukemia. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL). One of the following: a) Used in combination with chemotherapy up to 20 cycles OR b) Used as monotherapy in patients where one of the following applies: i) No other kinase inhibitors are indicated OR ii) Disease is T315I-positive Ph+ ALL.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	All uses: 12 months
Other Criteria	All uses: Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IDHIFA

PRODUCTS AFFECTED
- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IGALMI

PRODUCTS AFFECTED
- IGALMI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	One of the following diagnoses: Schizophrenia or Bipolar I or II disorder. For the treatment of acute agitation. Trial and failure, contraindication or intolerance to at least two products used in acute agitation (e.g., olanzapine, ziprasidone). Patient is currently being managed with maintenance medication for their underlying disorder (e.g., aripiprazole, olanzapine, quetiapine, lithium, valproic acid).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	14 days
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IMBRUVICA

PRODUCTS AFFECTED

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG
- IMBRUVICA ORAL SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Waldenstrom's macroglobulinemia: Diagnosis of Waldenstrom-+s macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD AND trial and failure of one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate).
Age Restrictions	(cGVHD): Patient is 1 year of age or older.
Prescriber Restrictions	
Coverage Duration	All Uses: 12 months

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PA Criteria	Criteria Details
Other Criteria	All Uses: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IMKELDI

PRODUCTS AFFECTED
- *imkeldi*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Myelogenous/Myeloid Leukemia (CML): Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) CML. Acute Lymphoblastic Leukemia/Acute Lymphoblastic Lymphoma (ALL): Diagnosis of Ph+/BCR ABL+ ALL. Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD): Diagnosis of MDS/MPD. Aggressive Systemic Mastocytosis (ASM): Diagnosis of ASM. Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL): Diagnosis of at least one of the following: a) HES or b) CEL. Dermatofibrosarcoma Protuberans (DFSP): Diagnosis of unresectable, recurrent, or metastatic DFSP. Gastrointestinal Stromal Tumors (GIST): Diagnosis of GIST. All indications: Patient is unable to swallow generic imatinib tablet due to one of the following: a) Age, b) Physical impairment (e.g., difficulties with motor or oral coordination), c) Dysphagia, or d) Patient is using a feeding tube or nasal gastric tube.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INBRIJA

PRODUCTS AFFECTED
- INBRIJA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Parkinson's disease (PD) (initial): Diagnosis of PD. Patient is experiencing intermittent OFF episodes. Patient is currently being treated with carbidopa/levodopa. Trial and failure, contraindication or intolerance to two of the following: MAO-B inhibitor (e.g., rasagiline, selegiline), dopamine agonist (e.g., pramipexole, ropinirole), or COMT Inhibitor (e.g., entacapone).
Age Restrictions	
Prescriber Restrictions	PD (initial): Prescribed by or in consultation with a neurologist
Coverage Duration	PD (initial, reauth): 12 months
Other Criteria	PD (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INCRELEX

PRODUCTS AFFECTED
- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	(Reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INFLECTRA

PRODUCTS AFFECTED
- INFLECTRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Diagnosis (Dx) of moderately to severely active CD or FCD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (eg, prednisone), methotrexate. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, 6-mercaptopurine. Rheumatoid arthritis (RA) (initial): Dx of moderately to severely active RA. Used in combination with methotrexate. Psoriatic arthritis (PsA) (initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp

PA Criteria	Criteria Details
	psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus).
Age Restrictions	
Prescriber Restrictions	RA, AS: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. CD, FCD, UC: Prescribed by or in consultation with a gastroenterologist. Plaque Psoriasis: Prescribed by or in consultation with a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.
Coverage Duration	All uses (initial): 6 months, (reauth): 12 months
Other Criteria	Ankylosing spondylitis (AS) (initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Sarcoidosis (initial): Dx of sarcoidosis. TF/C/I to one of the following: corticosteroid (eg, prednisone) OR immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine). All indications (initial): Trial and failure or intolerance to Remicade or Infliximab. Plaque psoriasis (reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC

PA Criteria	Criteria Details
	(reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

INGREZZA

PRODUCTS AFFECTED

- INGREZZA ORAL CAPSULE 40 MG, 60 MG, 80 MG
- INGREZZA ORAL CAPSULE SPRINKLE 40 MG, 60 MG, 80 MG
- INGREZZA ORAL CAPSULE THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Tardive Dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: a) patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication OR b) patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Chorea associated with Huntington's disease (initial): Diagnosis of chorea in patients with Huntington's disease.
Age Restrictions	
Prescriber Restrictions	Tardive Dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist. Chorea associated with Huntington's disease (initial): Prescribed by or in consultation with a neurologist.

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PA Criteria	Criteria Details
Coverage Duration	initial, reauth: 12 months
Other Criteria	All Uses (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INLURIYO

PRODUCTS AFFECTED
- INLURIYO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of breast cancer. Disease is advanced or metastatic. Disease is estrogen receptor (ER)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Presence of estrogen receptor-1 (ESR1) mutation(s) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)].
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INLYTA

PRODUCTS AFFECTED
- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: (1) used as first-line treatment in combination with avelumab or pembrolizumab or (2) used after failure of one prior systemic therapy (e.g., chemotherapy).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INQOVI

PRODUCTS AFFECTED
- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome. Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS). Acute Myeloid Leukemia (AML): Diagnosis of newly-diagnosed AML. Used in combination with venetoclax. One of the following: a) Patient is 75 years of age or older or b) Patient has comorbidities that preclude the use of intensive induction chemotherapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INREBIC

PRODUCTS AFFECTED
- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Myelofibrosis: Diagnosis of one of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IRESSA

PRODUCTS AFFECTED

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ISTURISA

PRODUCTS AFFECTED

- ISTURISA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cushing's Syndrome (initial): Diagnosis of Cushing's syndrome. Used for treatment of endogenous hypercortisolemia. One of the following: a) Patient is not a candidate for surgery (e.g., adrenalectomy, transsphenoidal surgery), OR b) Surgery has not been curative for the patient.
Age Restrictions	
Prescriber Restrictions	Cushing's Syndrome (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Cushing's Syndrome (initial, reauth): 12 months
Other Criteria	Cushing's Syndrome (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ITOVEBI

PRODUCTS AFFECTED
- ITOVEBI ORAL TABLET 3 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of breast cancer. Disease is one of the following: a) Locally advanced, or b) Metastatic. Disease is all of the following (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]): a) PIK3CA-mutated, b) Hormone receptor (HR)-positive, c) Human epidermal growth-factor receptor 2 (HER2)-negative. Used following recurrence on or after completing adjuvant endocrine therapy (e.g. Zoladex [goserelin], Arimidex [anastrozole], Nolvadex [tamoxifen]). Used in combination with both of the following: a) Ibrance (Palbociclib), and b) Fulvestrant.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ITRACONAZOLE CAPSULE

PRODUCTS AFFECTED

- *itraconazole oral capsule*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Systemic Fungal Infection (SFI): Diagnosis of a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis). Fingernail Onychomycosis: Diagnosis of fingernail onychomycosis as confirmed by one of the following: i) positive potassium hydroxide (KOH) preparation, ii) fungal culture, OR iii) nail biopsy. Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine. Toenail Onychomycosis: Diagnosis of toenail onychomycosis as confirmed by one of the following: i) positive potassium hydroxide (KOH) preparation, ii) fungal culture, OR iii) nail biopsy. Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	SFI:6mo.Fingernail Onychomycosis:5wks.Toenail Onychomycosis:3mo.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IVERMECTIN

PRODUCTS AFFECTED

- *ivermectin oral*

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

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IVIG

PRODUCTS AFFECTED

- BIVIGAM
- PRIVIGEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG -+ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient-+s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/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.

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PA Criteria	Criteria Details
	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/mm3. Continued in Other Criteria Section.
Age Restrictions	
Prescriber Restrictions	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).
Coverage Duration	4 months: Solid organ transplant. 12 months: all other diagnoses.
Other Criteria	[D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barr-+ 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. 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises. 7) Stiff person syndrome AND Patient had a TF/C/I to at least one standard therapy (i.e., baclofen, corticosteroid). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., 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

PA Criteria	Criteria Details
	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. Patient does not meet criteria for Part B or patient is in a long-term care facility. 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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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IWILFIN

PRODUCTS AFFECTED
- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of high-risk neuroblastoma (HRNB). Patient has shown at least a partial response to prior multiagent, multimodality therapy. Prior therapy included anti-GD2 immunotherapy (e.g., Danyelza [naxitamab-gqgk], Unituxin [dinutuximab]).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

JAKAFI

PRODUCTS AFFECTED

- JAKAFI ORAL TABLET 10 MG, 15 MG, 20 MG, 25 MG, 5 MG
- JAKAFI XR

PA Criteria	Criteria Details
Exclusion Criteria	
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. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD. Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months.
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

JAYPIRCA

PRODUCTS AFFECTED

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Mantle Cell Lymphoma (MCL): Diagnosis of MCL. Disease is one of the following: a) relapsed, or b) refractory. Patient has received at least two prior therapies for MCL, one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Calquence (acalabrutinib), Imbruvica (ibrutinib)]. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of one of the following: a) CLL, or b) SLL. Disease is one of the following: a) Relapsed, or b) Refractory. Patient has previously been treated with a covalent BTK inhibitor [e.g., Calquence (acalabrutinib), Imbruvica (ibrutinib)].
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

JIDEYTRO

PRODUCTS AFFECTED

- JIDEYTRO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert), including additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

JYLAMVO

PRODUCTS AFFECTED
- JYLAMVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Neoplastic diseases: Diagnosis of one of the following: A) acute lymphoblastic leukemia (ALL), B) mycosis fungoides (cutaneous T-cell lymphoma), or C) relapsed or refractory non-hodgkin lymphomas. Rheumatoid arthritis (RA): Diagnosis of RA. Psoriasis: Diagnosis of severe psoriasis. Polyarticular juvenile idiopathic arthritis (pJIA): Diagnosis of polyarticular juvenile idiopathic arthritis.
Age Restrictions	
Prescriber Restrictions	RA: Prescribed by or in consultation with a rheumatologist. Psoriasis: Prescribed by or in consultation with a dermatologist. pJIA: Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Neoplastic diseases, RA, Psoriasis, pJIA: 12 months.
Other Criteria	Subject to Part B vs D review. Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

JYNARQUE

PRODUCTS AFFECTED

- JYNARQUE ORAL TABLET
- *tolvaptan oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Autosomal dominant polycystic kidney disease (ADPKD) (initial): Diagnosis of rapidly progressing ADPKD. One of the following: 1) Both of the following: Patient has received Jynarque for less than or equal to 18 months AND Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy OR 2) Both of the following: Patient has received Jynarque for longer than 18 months AND ALT, AST, and bilirubin will be measured at least every 3 months. Patient does not have a history of significant liver impairment or injury, not including uncomplicated polycystic liver disease.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	ADPKD (reauth): Patient demonstrates positive clinical response to therapy. One of the following: 1) Patient does not have signs or symptoms consistent with hepatic injury or 2) Patient has uncomplicated polycystic liver disease. One of the following: 1) Both of the following: Patient has received Jynarque for less than or equal to 18 months AND Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy OR 2) Both of the following: Patient has received Jynarque for longer than 18 months AND ALT, AST, and bilirubin will be measured at least every 3 months.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KALYDECO

PRODUCTS AFFECTED

- KALYDECO ORAL PACKET
- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	CF (initial): Patient is 1 month 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

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PA Criteria	Criteria Details
Other Criteria	CF (Reauth): Patient demonstrates positive clinical response (i.e. improvement in lung function [percent predicted forced expiratory volume in one second (PPFEV1)], decreased number of pulmonary exacerbations) while on therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KERENDIA

PRODUCTS AFFECTED
- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic kidney disease (CKD) associated with type 2 diabetes (T2D) (Initial): Diagnosis of CKD associated with T2D. Patient has a urine albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g. Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m2. Patient has a serum potassium level less than or equal to 5.0 mEq/L prior to initiating treatment. One of the following: 1) Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following: a) generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril), or b) generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs. Heart failure (HF) with Left Ventricular Ejection Fraction (LVEF) greater than or equal to 40% (Initial): Diagnosis of HF. Patient has LVEF greater than or equal to 40%. Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms. Patient has an eGFR greater than or equal to 25 mL/min/1.73 m2. Patient has a serum potassium level less than or equal to 5.0 mEq/L prior to initiating treatment. Both of the following: 1) Patient is on diuretic treatment (e.g., bumetanide, furosemide) for the management of symptoms of heart failure for at least 30 days prior to initiating treatment, AND 2) Patient is not receiving drug in combination with spironolactone or

PA Criteria	Criteria Details
	eplerenone. One of the following: 1) Patient is receiving drug in combination with a sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin]), OR 2) Patient has a contraindication or intolerance to an SGLT2 inhibitor.
Age Restrictions	
Prescriber Restrictions	HF with LVEF greater than or equal to 40% (Initial): Prescribed by or in consultation with a cardiologist.
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	CKD associated with T2D (Reauth): Patient demonstrates positive clinical response to therapy. One of the following: 1) Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB, OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs. HF with LVEF greater than or equal to 40% (Reauth): Patient demonstrates positive clinical response to therapy. One of the following: 1) Patient continues to be on an SGLT2 inhibitor, OR 2) Patient has a contraindication or intolerance to an SGLT2 inhibitor.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

KESIMPTA

PRODUCTS AFFECTED
- KESIMPTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple Sclerosis (MS) (Initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS [e.g., Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Gilenya fingolimod)], OR 2) For continuation of prior therapy. Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]).
Age Restrictions	
Prescriber Restrictions	MS (Initial, Reauth): Prescribed by or in consultation with a neurologist

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PA Criteria	Criteria Details
Coverage Duration	MS (Initial, Reauth): 12 months
Other Criteria	MS (Reauth): Patient demonstrates positive clinical response to 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]).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KINERET

PRODUCTS AFFECTED

- KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been confirmed by one of the following: 1) NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3) gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation OR 2) Both of the following: a) two of the following clinical symptoms: urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia), chronic aseptic meningitis, or skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing) AND b) elevated acute phase reactants (eg, erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid

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PA Criteria	Criteria Details
	A [SAA]). Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA.
Age Restrictions	
Prescriber Restrictions	RA (initial): Prescribed by or in consultation with a rheumatologist. NOMID (initial): Prescribed by or in consultation with allergist/immunologist or rheumatologist or pediatrician.
Coverage Duration	RA, NOMID (initial): 6 months, (reauth): 12 months. DIRA: 12 months.
Other Criteria	RA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. NOMID (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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KISQALI

PRODUCTS AFFECTED

- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast cancer: Diagnosis of breast cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KISQALI-FEMARA PACK

PRODUCTS AFFECTED

- KISQALI FEMARA (200 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast cancer: Diagnosis of breast cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

KOMZIFTI

PRODUCTS AFFECTED
- KOMZIFTI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of acute myeloid leukemia (AML). Disease is relapsed or refractory. Presence of a susceptible nucleophosmin 1 (NPM1) mutation as detected by a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KORLYM

PRODUCTS AFFECTED

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial, reauth: 6 months
Other Criteria	Reauth: Patient demonstrates one of the following: patient has improved glucose tolerance while on therapy or patient has stable glucose tolerance while on therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KOSELUGO

PRODUCTS AFFECTED
- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	
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).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KRAZATI

PRODUCTS AFFECTED
- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: locally advanced or metastatic. Disease is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy). Colorectal Cancer (CRC): Diagnosis of CRC. Disease is one of the following: locally advanced or metastatic. Tumor is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Erbitux (cetuximab). Patient has received prior treatment with ALL of the following: a) fluoropyrimidine-based chemotherapy, b) oxaliplatin-based chemotherapy, and c) irinotecan-based chemotherapy.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KUVAN

PRODUCTS AFFECTED

- *sapropterin dihydrochloride oral packet*
- *sapropterin dihydrochloride oral tablet*
- ZELVYSIA

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	PKU (Init): 2 months (Reauth): 12 months
Other Criteria	PKU (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KYGEVVI

PRODUCTS AFFECTED
- KYGEVVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of thymidine kinase 2 deficiency (TK2d). Diagnosis confirmed by the presence of a mutation in the TK2 gene. Patient experienced symptom onset on or before 12 years of age.
Age Restrictions	
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a clinical specialist knowledgeable in the treatment of TK2d (e.g., geneticist, neurologist).
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Provider attests the patient would benefit from continued therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LAZCLUZE

PRODUCTS AFFECTED

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of non-small cell lung cancer (NSCLC). Disease is locally advanced or metastatic. Used as first line treatment of NSCLC. Used in combination with Rybrevant (amivantamab). Presence of 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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LENVIMA

PRODUCTS AFFECTED

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Differentiated thyroid cancer (DTC): Diagnosis of DTC. Renal Cell Carcinoma (RCC): Diagnosis of RCC. One of the following: 1) Both of the following: a) Used as first-line treatment and b) Used in combination with Keytruda (pembrolizumab), or 2) Both of the following: a) Treatment follows one prior anti-angiogenic therapy and b) Used in combination with everolimus. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Endometrial Carcinoma (EC): Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR) [i.e. disease is mismatch repair proficient (pMMR)], 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 disease progression following systemic therapy. Used in combination with Keytruda (pembrolizumab) therapy. Patient is not a candidate for curative surgery or radiation.

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LETAIRIS

PRODUCTS AFFECTED

- *ambrisentan*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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LIDOCAINE TOPICAL

PRODUCTS AFFECTED

- *lidocaine external ointment 5 %*
- *lidocaine-prilocaine external cream*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIDODERM

PRODUCTS AFFECTED

- *lidocaine external patch 5 %*
- TRIDACAINE II
- TRIDACAINE III

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

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIFYORLI

PRODUCTS AFFECTED

- LIFYORLI (125 MG DOSE) ORAL CAPSULE THERAPY PACK 1 X 25 MG & 1 X 100 MG
- LIFYORLI (150 MG DOSE) ORAL CAPSULE THERAPY PACK 2 X 25 MG & 1 X 100 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Disease is platinum resistant. Used in combination with nab-paclitaxel. Patient has received one prior bevacizumab-containing systemic treatment regimen. Patient has not received more than three prior systemic treatment regimens (e.g., chemotherapy).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIVMARLI

PRODUCTS AFFECTED

- LIVMARLI ORAL SOLUTION 19 MG/ML, 9.5 MG/ML
- LIVMARLI ORAL TABLET 10 MG, 15 MG, 20 MG, 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Alagille syndrome (ALGS) (initial): Both of the following: a) Diagnosis of ALGS, and b) Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene. Progressive Familial Intrahepatic Cholestasis (PFIC) (initial): Both of the following: a) Diagnosis of PFIC, and b) Molecular genetic testing confirms mutations in the ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, or MYO5B gene.
Age Restrictions	ALGS (initial): Patient is 3 months of age or older. PFIC (initial): Patient is 12 months of age or older.
Prescriber Restrictions	All indications (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist.
Coverage Duration	ALGS (initial, reauth): 12 months. PFIC (initial): 6 months, (reauth): 12 months.

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PA Criteria	Criteria Details
Other Criteria	All indications (reauth): Patient demonstrates positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LONSURF

PRODUCTS AFFECTED
- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Colorectal Cancer: Diagnosis of metastatic colorectal cancer AND One of the following: Used as a single agent or Used in combination with bevacizumab AND Patient has been previously treated with both of the following: A) fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND B) anti-VEGF therapy (e.g., Avastin [bevacizumab]) AND One of the following: A) patient has RAS wild-type tumors and patient has been previously treated with one anti-EGFR therapy (e.g., Vectibix [panitumumab], Erbitux [cetuximab]) OR Patient has RAS mutant tumors. Gastric/Gastroesophageal Junction Adenocarcinoma: Diagnosis of metastatic gastric cancer or diagnosis of metastatic gastroesophageal junction adenocarcinoma. Patient has been previously treated with two of the following: fluropyrimidine-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).
Age Restrictions	

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PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LORBRENA

PRODUCTS AFFECTED
- LORBRENA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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LOTRONEX

PRODUCTS AFFECTED

- *alosetron hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Coverage Duration	IBS (initial): 12 weeks. IBS (reauth): 6 mo.
Other Criteria	IBS (reauth): Symptoms of IBS continue to persist. Patient demonstrates positive clinical response to therapy (e.g., relief of IBS abdominal pain and discomfort, improvement in stool consistency and frequency, improvement as measured by the Global Improvement Scale).

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LUMAKRAS

PRODUCTS AFFECTED
- LUMAKRAS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: a) locally advanced or b) metastatic. Presence of KRAS G12C-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 received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy). Metastatic Colorectal Cancer (mCRC): Diagnosis of mCRC. Presence of KRAS G12C-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 received prior therapy with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy. Used in combination with Vectibix (panitumumab).
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LUPRON

PRODUCTS AFFECTED

- *leuprolide acetate injection*

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

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

LUPRON DEPOT

PRODUCTS AFFECTED

- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	
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): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl estradiol, estradiol and norethindrone). Uterine Leiomyomata (UL) (3.75 mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all of the following: treatment of anemia, anemia is caused by uterine leiomyomata (fibroids), and for use prior to surgery.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	Prostate CA: 12 mo. Endomet:6mo. UL (anemia):3 mo (fibroids):4 mo
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LUPRON DEPOT PED

PRODUCTS AFFECTED

- LUPRON DEPOT-PED (1-MONTH)
- LUPRON DEPOT-PED (3-MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	CPP (initial, reauth): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	CPP (initial, reauth): 12 months
Other Criteria	CPP (reauth): Patient demonstrates positive clinical response to therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LYNPARZA TABLET

PRODUCTS AFFECTED
- LYNPARZA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Breast cancer: Diagnosis of breast cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Pancreatic adenocarcinoma: Diagnosis of pancreatic adenocarcinoma. Prostate cancer: Diagnosis of castration-resistant prostate cancer. All indications: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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LYTGOBI

PRODUCTS AFFECTED

- LYTGOBI (12 MG DAILY DOSE)
- LYTGOBI (16 MG DAILY DOSE)
- LYTGOBI (20 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of intrahepatic cholangiocarcinoma. Disease is one of the following: a) unresectable, b) locally advanced, or c) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements. Patient has been previously treated (e.g., chemotherapy).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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MARINOL

PRODUCTS AFFECTED

- *dronabinol oral capsule*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	CINV: 6 months. AIDS anorexia: 12 months.

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PA Criteria	Criteria Details
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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MAVYRET

PRODUCTS AFFECTED

- MAVYRET ORAL PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: 1) One of the following: a) Diagnosis of hepatitis C, or b) Patient was not infected with hepatitis C virus prior to receiving an organ transplant, and patient received a liver or non-liver organ transplant from a donor with a diagnosis of hepatitis C, 2) patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and 3) not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
Age Restrictions	
Prescriber Restrictions	One of the following: 1) Non-transplant patient who is treatment-na ve without decompensation, or 2) 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, Liver transplant specialist.

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PA Criteria	Criteria Details
Coverage Duration	8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MAYZENT

PRODUCTS AFFECTED

- MAYZENT ORAL TABLET 0.25 MG, 1 MG, 2 MG
- MAYZENT STARTER PACK ORAL TABLET THERAPY PACK 12 X 0.25 MG, 7 X 0.25 MG

PA Criteria	Criteria Details
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Patient demonstrates positive clinical response to therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEKINIST

PRODUCTS AFFECTED
- MEKINIST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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 Tafinlar (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 Tafinlar (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

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PA Criteria	Criteria Details
	Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Tafinlar (dabrafenib).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. 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). Medication is used in combination with Tafinlar (dabrafenib). Low-grade glioma: Diagnosis of low-grade glioma. Patient requires systemic therapy. 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). Medication is used in combination with Tafinlar (dabrafenib).
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEKTOVI

PRODUCTS AFFECTED
- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	
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). Non-Small Cell Lung Cancer (NSCLC): Diagnosis of metastatic NSCLC. Cancer is BRAF V600E 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	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MIGRANAL

PRODUCTS AFFECTED

- *dihydroergotamine mesylate nasal*

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

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MODEYSO

PRODUCTS AFFECTED
- MODEYSO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of diffuse midline glioma. Disease is confirmed by the presence of H3 K27M mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed following prior therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MOUNJARO

PRODUCTS AFFECTED

- MOUNJARO SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MS INTERFERONS (NON-PREFERRED)

PRODUCTS AFFECTED

- REBIF REBIDOSE SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- REBIF REBIDOSE TITRATION PACK SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- REBIF SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- REBIF TITRATION PACK SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one of the following: Avonex (interferon beta-1a) or Betaseron (interferon beta-1b), or 2) for continuation of prior therapy.
Age Restrictions	
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist

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PA Criteria	Criteria Details
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MS INTERFERONS (PREFERRED)

PRODUCTS AFFECTED

- AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT
- AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT
- BETASERON SUBCUTANEOUS KIT

PA Criteria	Criteria Details
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Patient demonstrates positive clinical response to therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NERLYNX

PRODUCTS AFFECTED
- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Early Stage Breast cancer: Diagnosis (dx) of early stage breast cancer. Advanced or Metastatic Breast Cancer: Dx of advanced or metastatic breast cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

NEULASTA

PRODUCTS AFFECTED

- NEULASTA ONPRO SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- NEULASTA SUBCUTANEOUS SOLUTION 4 MG/0.4ML
- NEULASTA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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

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PA Criteria	Criteria Details
	anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications.
Age Restrictions	
Prescriber Restrictions	All uses: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NEXAVAR

PRODUCTS AFFECTED

- *sorafenib tosylate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of advanced RCC. Hepatocellular carcinoma (HCC): Diagnosis of HCC. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC. One of the following: locally recurrent disease, or metastatic disease. Patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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NEXLETOL

PRODUCTS AFFECTED
- NEXLETOL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Heterozygous familial hypercholesterolemia (HeFH), Hypercholesterolemia, or Prevention of Cardiovascular (CV) Events in patients at increased risk for major adverse cardiovascular events (Initial): One of the following diagnoses: A) HeFH, B) Hypercholesterolemia, C) At increased risk for a major adverse CV event. One of the following LDL-C values within the last 120 days: (1) LDL-C greater than or equal to 55 mg/dL with ASCVD or (2) LDL-C greater than or equal to 70 mg/dL without ASCVD. One of the following: 1) Used as adjunct to statin therapy, 2) Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase), OR 3) Patient has a contraindication to all statins.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy (eg reduction in LDL-C levels). Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) or pt has a documented inability to take other lipid-lowering therapy (eg statins, ezetimibe).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NEXLIZET

PRODUCTS AFFECTED
- NEXLIZET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Heterozygous familial hypercholesterolemia (HeFH), Hypercholesterolemia, or Prevention of Cardiovascular (CV) Events in patients at increased risk for major adverse cardiovascular events (Initial): One of the following diagnoses: A) HeFH, B) Hypercholesterolemia, C) At increased risk for a major adverse CV event (e.g., cardiovascular death, myocardial infarction, stroke, or coronary revascularization). One of the following LDL-C values within the last 120 days: (1) LDL-C greater than or equal to 55 mg/dL with ASCVD or (2) LDL-C greater than or equal to 70 mg/dL without ASCVD. One of the following: 1) Used as adjunct to statin therapy, 2) Pt is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase), OR 3) Patient has a contraindication to all statins.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy (eg reduction in LDL-C levels). Patient continues to receive other lipid-lowering tx (eg statins, ezetimibe) or patient has a documented inability to take other lipid-lowering therapy (eg statins, ezetimibe).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NINLARO

PRODUCTS AFFECTED
- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple myeloma: Diagnosis of multiple myeloma.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

NORTHERA

PRODUCTS AFFECTED

- *droxidopa*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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): Patient demonstrates positive clinical response to therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NOXAFIL SUSPENSION

PRODUCTS AFFECTED

- *posaconazole oral*

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

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PA Criteria	Criteria Details
Coverage Duration	Prophylaxis of SFI: 6 months. OPC: 1 month.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUBEQA

PRODUCTS AFFECTED
- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Castration-resistant prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) prostate cancer. Metastatic Castration-sensitive prostate cancer (mCSPC): Diagnosis of metastatic castration-sensitive prostate cancer (mCSPC) [also known as metastatic hormone-sensitive prostate cancer (mHSPC)].
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	CRPC, mCSPC: 12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUCALA

PRODUCTS AFFECTED

- NUCALA SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 40 MG/0.4ML
- NUCALA SUBCUTANEOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Asthma (init): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by one of the following: baseline(pre-tx) peripheral blood eosinophil level is greater than or equal to 150cells/ml or peripheral blood eosinophil levels were greater than or equal to 300cells/ml within the past 12 mo. Patient has had two or more asthma exacerbations requiring systemic corticosteroids(eg, prednisone) within the past 12 mo or Patient has had a prior asthma-related hospitalization within the past 12 mo. One of the following: 1)Both of the following: a)Patient is 6 years of age or older but less than 12 years of age b)Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: i)Medium-dose inhaled corticosteroid[ICS](eg, greater than 100-200 mcg fluticasone propionate equivalent/day) and Additional asthma controller medication(eg, leukotriene receptor antagonist[LTRA][eg, montelukast], long-acting beta-2 agonist[LABA][eg, salmeterol], long-acting muscarinic antagonist[LAMA][eg, tiotropium]) or ii)One medium dosed combination ICS/LABA product (eg,

PA Criteria	Criteria Details
	Wixela Inhub[fluticasone propionate 100mcg/salmeterol 50mcg], budesonide 80mcg/formoterol 4.5mcg, Breo Ellipta[fluticasone furoate 50 mcg/vilanterol 25 mcg]) OR Patient is 12 years of age or older and 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 ICS(eg, greater than 500 mcg fluticasone propionate equivalent/day) and ii)additional asthma controller medication(eg, leukotriene receptor antagonist[LTRA][eg, montelukast], long-acting beta-2 agonist[LABA][eg, salmeterol], long-acting muscarinic antagonist[LAMA][eg, tiotropium]), OR b)One maximally-dosed combination ICS/LABA product(eg, Wixela Inhub[fluticasone propionate 500mcg/salmeterol 50mcg], budesonide 160mcg/formoterol 4.5mcg, Breo Ellipta[fluticasone 200mcg/vilanterol 25mcg])
Age Restrictions	
Prescriber Restrictions	Asthma (init): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (init, reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist. HES (init): Prescribed by or in consultation with an allergist/immunologist or hematologist.
Coverage Duration	Asthma, COPD (init): 6 mo, (reauth): 12 months. CRSwNP, EGPA, HES (init, reauth): 12 months
Other Criteria	Hypereosinophilic Syndrome (HES) (init): Diagnosis (dx) of HES. Patient (Pt) has been diagnosed for at least 6 months. Verification that other non-hematologic

PA Criteria	Criteria Details
	secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy). Pt is FIP1L1-PDGFRA-negative. Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter. Trial and failure, contraindication (CI), or intolerance to corticosteroid (CS) therapy (tx) (e.g., prednisone) or cytotoxic/immunosuppressive tx (e.g., hydroxyurea, cyclosporine, imatinib). Asthma (reauth): Pt demonstrates positive clinical response to tx. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (init): Dx of CRSwNP. Unless CI, the pt has had an inadequate response to 2 months of treatment with an intranasal CS (e.g., fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Dx of EGPA. Pt's disease has relapsed or is refractory to standard of care tx (i.e., CS treatment with or without immunosuppressive tx). Pt is currently receiving CS tx (e.g., prednisolone, prednisone) unless there is a CI or intolerance to CS tx. CRSwNP (reauth): Pt demonstrates positive clinical response to tx. Used in combination with another agent for CRSwNP. EGPA, HES (reauth): Pt demonstrates positive clinical response to tx. Chronic Obstructive Pulmonary Disease (COPD) (init): Dx of COPD. Presence of Type 2 inflammation evidenced by 1 of the following: a) Blood eosinophils greater than or equal to 150 cells/microliter at baseline, or b) Blood eosinophils greater than or equal to 300 cells/microliter in the last 12 months. Pt is receiving 1 of the following: a) Triple tx (i.e., ICS, LAMA, and a LABA), or b) If CI to ICS, a LAMA and a LABA. Pt has had 1 of the following within the past 12 months: a) At least 2 exacerbations where systemic CS [intramuscular, intravenous, or oral (e.g., prednisone)] were required at least once, or b) COPD-related hospitalization. COPD (reauth): Pt demonstrates positive clinical response to tx. Pt continues to

PA Criteria	Criteria Details
	receive 1 of the following tx: a) Triple tx (i.e., ICS, LAMA, and LABA, or b) If CI to ICS, a LAMA and a LABA.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUEDEXTA

PRODUCTS AFFECTED
- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome, c) Known hypersensitivity to dextromethorphan (e.g., rash, hives), d) Taking monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, selegiline, tranylcypromine) or have taken MAOIs within the preceding 14 days, e) Has prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or has heart failure, f) Receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), g) Has complete atrioventricular (AV) block without implanted pacemakers, or at high risk of complete AV block.
Age Restrictions	
Prescriber Restrictions	PBA (initial): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist.

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PA Criteria	Criteria Details
Coverage Duration	PBA (initial/reauth): 12 months
Other Criteria	PBA (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUPLAZID

PRODUCTS AFFECTED

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

NURTEC

PRODUCTS AFFECTED
- NURTEC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acute Treatment of Migraine (initial): Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines.
Age Restrictions	All Indications (initial): 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Acute Treatment (init): 12mo. Preventive Treatment (init): 6mo. All Indications (reauth): 12mo.
Other Criteria	Preventive Treatment of Episodic Migraine (EM) (initial): Both of the following: 1) Diagnosis of EM and 2) Patient has greater than or equal to 4 migraine days per month. Acute Treatment of Migraine (reauth): Patient has experienced a positive response to therapy. Medication will not be used in combination with

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PA Criteria	Criteria Details
	another CGRP inhibitor for the acute treatment of migraines. Preventive Treatment of EM (reauth): Patient has experienced a positive response to therapy. Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUVIGIL

PRODUCTS AFFECTED

- *armodafinil oral tablet 150 mg, 200 mg, 250 mg, 50 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: a) 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or b) both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), AND 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial):Dx of SWD confirmed by one of the following: 1) symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of

PA Criteria	Criteria Details
	narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not feasible).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	OSA, SWD: Initial, Reauth: 6 mo. Narcolepsy: Initial, Reauth: 12 mo
Other Criteria	OSA, Narcolepsy (Reauth): Patient demonstrates positive clinical response to armodafinil therapy. SWD (Reauth): Patient demonstrates positive clinical response to armodafinil therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ODACTRA

PRODUCTS AFFECTED
- ODACTRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Allergic rhinitis (AR) (Initial): Diagnosis of house dust mite (HDM)-induced allergic rhinitis. One of the following: 1) positive in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, OR 2) skin testing to licensed house dust mite allergen extracts. Trial and failure, contraindication, or intolerance to an intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, flunisolide nasal spray) AND an antihistamine (e.g., cetirizine, loratadine, azelastine nasal spray, olapatadine nasal spray).
Age Restrictions	AR (Initial): Patient is 5 to 65 years of age
Prescriber Restrictions	AR (Initial): Prescribed by or in consultation with an allergist or immunologist
Coverage Duration	AR (initial, reauth): 12 months

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PA Criteria	Criteria Details
Other Criteria	AR (Reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ODOMZO

PRODUCTS AFFECTED
- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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OFEV

PRODUCTS AFFECTED

- *nintedanib esylate*
- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (initial): Diagnosis of SSc-ILD as documented by all of the following: a) exclusion of other known causes of ILD (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on HRCT revealing SSc-ILD or probable SSc-ILD, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD. Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype (initial), Progressive Pulmonary Fibrosis (PPF): 1)

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PA Criteria	Criteria Details
	diagnosis of chronic fibrosing interstitial lung disease or progressive pulmonary fibrosis (PPF), AND 2) patient has a high-resolution computed tomography (HRCT) showing 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.
Age Restrictions	
Prescriber Restrictions	All Indications (initial): Prescribed by or in consultation with a pulmonologist or a rheumatologist.
Coverage Duration	Initial, reauth: 12 months
Other Criteria	All Indications (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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OGSIVEO

PRODUCTS AFFECTED

- OGSIVEO ORAL TABLET 100 MG, 150 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of desmoid tumor. Patient requires systemic treatment. Disease is progressive.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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OJEMDA

PRODUCTS AFFECTED

- OJEMDA ORAL SUSPENSION RECONSTITUTED
- OJEMDA ORAL TABLET 100 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of pediatric low-grade glioma. Disease is relapsed or refractory. Disease has a BRAF fusion or rearrangement, or BRAF V600 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).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJJAARA

PRODUCTS AFFECTED

- OJJAARA ORAL TABLET 100 MG, 150 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Patient has anemia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ONPATTRO

PRODUCTS AFFECTED
- ONPATTRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) (initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Presence of a transthyretin (TTR) mutation (e.g., V30M) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb, a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2, or a baseline neuropathy impairment score (NIS) between 5 and 130. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy). Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Vyndaqel).
Age Restrictions	
Prescriber Restrictions	hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist

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PA Criteria	Criteria Details
Coverage Duration	hATTR amyloidosis (initial, reauth): 12 months
Other Criteria	Subject to Part B vs D review. hATTR amyloidosis (reauth): Patient demonstrates postive clinical response to therapy. Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Vyndaqel).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ONUREG

PRODUCTS AFFECTED
- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML). Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin, etc.). Patient has achieved one of the following: a) first complete remission (CR) or b) complete remission with incomplete blood count recovery (CRi). Patient is not able to complete intensive curative therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPIPZA

PRODUCTS AFFECTED
- OPIPZA ORAL FILM 10 MG, 2 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Schizophrenia: Diagnosis of Schizophrenia. Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: a) aripiprazole (failure or contraindication are not required), b) olanzapine, c) quetiapine IR/ER, d) risperidone, e) clozapine, f) ziprasidone, g) paliperidone, or h) asenapine. Major Depressive Disorder (MDD): Diagnosis of MDD. Both of the following: a) TF/C/I to quetiapine IR/ER and b) Trial of or intolerance to aripiprazole. Autism: Diagnosis of irritability associated with autistic disorder. Both of the following: a) Trial and failure, contraindication (e.g., age), or intolerance to risperidone and b) Trial of or intolerance to aripiprazole. Tourette's Syndrome: Diagnosis of Tourette's Syndrome. Trial of or intolerance to aripiprazole.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OPSUMIT

PRODUCTS AFFECTED

- *macitentan*
- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORENCIA IV

PRODUCTS AFFECTED
- ORENCIA INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Acute graft versus host disease (aGVHD): Used for prophylaxis of aGVHD. Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor. Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT. Used in combination with both of the following: calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate.

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PA Criteria	Criteria Details
Age Restrictions	aGVHD: Patient is 2 years of age or older
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	RA, JIA, PsA (initial): 6 months, (reauth): 12 months. aGVHD: 2 months
Other Criteria	RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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ORENCIA SC

PRODUCTS AFFECTED

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 125 MG/ML, 50 MG/0.4ML, 87.5 MG/0.7ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement.
Age Restrictions	
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.

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PA Criteria	Criteria Details
Coverage Duration	All uses (initial): 6 months, (reauth): 12 months
Other Criteria	RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORENITRAM

PRODUCTS AFFECTED

- ORENITRAM
- ORENITRAM MONTH 1
- ORENITRAM MONTH 2
- ORENITRAM MONTH 3

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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): Patient demonstrates positive clinical response to therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORGOVYX

PRODUCTS AFFECTED
- ORGOVYX

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

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORKAMBI

PRODUCTS AFFECTED
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
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).

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORSERDU

PRODUCTS AFFECTED
- ORSERDU

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of breast cancer. Disease is advanced or metastatic. Disease is estrogen receptor (ER)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Presence of estrogen receptor (ESR1) mutation(s) 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). Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)].
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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OSENVELT

PRODUCTS AFFECTED
- OSENVELT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Skeletal prevention in Multiple Myeloma (MM)/Bone Metastasis from Solid Tumors (BMST): One of the following: 1) Both of the following: a) Diagnosis of multiple myeloma and b) Trial and failure, contraindication (e.g., renal insufficiency), or intolerance to one bisphosphonate therapy, OR 2) Both of the following: a) Diagnosis of solid tumors (e.g., breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and b) Documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Diagnosis of giant cell tumor of bone. One of the following: 1) One of the following: a) tumor is unresectable or b) surgical resection is likely to result in severe morbidity, OR 2) Approve for continuation of prior therapy. Hypercalcemia of malignancy (HCM): Diagnosis of hypercalcemia of malignancy. Trial and failure, contraindication, or intolerance to one bisphosphonate therapy.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	MM/BMST, GCTB, HCM: 12 months.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OSPHENA

PRODUCTS AFFECTED
- OSPHENA

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	All uses (Initial, reauth): 12 months
Other Criteria	Dyspareunia, Vaginal dryness (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OTEZLA

PRODUCTS AFFECTED

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Psoriatic arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Diagnosis of plaque psoriasis. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, OR calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Patient weighs at least 20 kg. Oral ulcers associated with Behcet-+s Disease (Initial): Diagnosis of Behcet-+s Disease. Patient has active oral ulcers.
Age Restrictions	Plaque psoriasis (initial): Patient is 6 years of age or older.
Prescriber Restrictions	PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.

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PA Criteria	Criteria Details
Coverage Duration	All uses (initial): 6 months. All uses (reauth): 12 months.
Other Criteria	PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (reauth): Patient demonstrates positive clinical response to therapy. Oral ulcers associated with Behcet-+s Disease (reauth): Patient demonstrates positive clinical response to therapy (eg, reduction in pain from oral ulcers or reduction in number of oral ulcers).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OZEMPIC

PRODUCTS AFFECTED

- OZEMPIC (0.25 OR 0.5 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/3ML
- OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 4 MG/3ML
- OZEMPIC (2 MG/DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diabetes Mellitus (DM) Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test). Metabolic dysfunction-associated steatohepatitis (MASH) Initial: Diagnosis of MASH, formerly known as nonalcoholic steatohepatitis (NASH). Patient does not have cirrhosis (e.g., decompensated cirrhosis). Submission of medical records (e.g., chart notes) confirming diagnosis has been confirmed by one of the following: FibroScan-aspartate aminotransferase (FAST), MRI-aspartate aminotransferase (MAST), or liver biopsy. Submission of medical records (e.g., chart notes) confirming disease is

PA Criteria	Criteria Details
	fibrosis stage F2 or F3 as confirmed by one of the following: FibroScan, Fibrosis-4 index (FIB-4), or Magnetic Resonance Elastography (MRE).
Age Restrictions	
Prescriber Restrictions	MASH (Initial): Prescribed by or in consultation with one of the following: gastroenterologist, endocrinologist, or hepatologist.
Coverage Duration	12 months
Other Criteria	DM (Reauth): Patient demonstrates positive clinical response to therapy. MASH (Reauth): Patient demonstrates positive response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OZEMPIC TABLETS

PRODUCTS AFFECTED

- OZEMPIC ORAL TABLET 1.5 MG, 4 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial, Reauth: 12 months.

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PA Criteria	Criteria Details
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PEGASYS

PRODUCTS AFFECTED

- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic hepatitis B: Diagnosis of chronic hepatitis B infection. Chronic Hepatitis C: Diagnosis of chronic hepatitis C infection. Patient has compensated liver disease. One of the following: a) Used in combination with one other hepatitis C virus (HCV) antiviral drug (e.g., Mavyret [glecaprevir-pibrentasvir], ribavirin) OR b) Both of the following: Used as monotherapy AND contraindication or intolerance to all other HCV antiviral drugs (e.g., Mavyret [glecaprevir-pibrentasvir], ribavirin).
Age Restrictions	
Prescriber Restrictions	Chronic Hepatitis C: 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	HepB, HepC: 48 wks.

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PA Criteria	Criteria Details
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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PEMAZYRE

PRODUCTS AFFECTED
- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is one of the following: unresectable locally advanced or metastatic. Disease is confirmed by the presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior line of therapy (e.g., chemotherapy). Myeloid/lymphoid neoplasms: Diagnosis of myeloid/lymphoid neoplasms (MLNs). Disease is relapsed or refractory. Disease is confirmed by the presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PENNSAID

PRODUCTS AFFECTED

- *diclofenac sodium external solution 1.5 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees. Patient meets one of the following: 1) Trial and failure, contraindication or intolerance to at least two prescription strength topical or oral non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., diclofenac, ibuprofen, meloxicam, naproxen) OR 2) History of peptic ulcer disease/gastrointestinal bleed OR 3) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial, reauth: 12 months

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PA Criteria	Criteria Details
Other Criteria	Osteoarthritis of the knees (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PHESGO

PRODUCTS AFFECTED
- PHESGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert), including additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PIQRAY

PRODUCTS AFFECTED

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

PA Criteria	Criteria Details
Exclusion Criteria	
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). Used in combination with fulvestrant. Disease has progressed on or after an endocrine-based regimen.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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POMALYST

PRODUCTS AFFECTED

- *pomalidomide oral capsule 1 mg, 2 mg, 3 mg, 4 mg*
- POMALYST ORAL CAPSULE 1 MG, 2 MG, 3 MG, 4 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple Myeloma (MM): Diagnosis of MM. Kaposi sarcoma (KS): One of the following: 1) Diagnosis of AIDS-related KS, OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV-negative.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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POSACONAZOLE TABLET

PRODUCTS AFFECTED

- *posaconazole oral*

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

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PA Criteria	Criteria Details
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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PRALUENT

PRODUCTS AFFECTED

- PRALUENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse cardiovascular event (init): One of the following diagnoses: A) HeFH, B) ASCVD, OR C) Primary hyperlipidemia (HLD) or hypercholesterolemia, OR D) At increased risk for a major adverse CV event. One of the following: 1) Patient has been receiving highest tolerable dose of statin therapy, 2) Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (eg, creatine kinase), OR 3) Patient has an FDA labeled contraindication to all statins. HoFH (init): Diagnosis of HoFH as confirmed by one of the following: 1) Genetic confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2) untreated LDL greater than 400, AND either xanthoma before 20 yo or evidence of HeFH in both parents. One of the following: 1) Patient is receiving other lipid-lowering therapy (eg, statin, ezetimibe) or 2) Patient has a documented inability to take other lipid-lowering therapy (eg, statin, ezetimibe).

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PA Criteria	Criteria Details
Age Restrictions	HeFH (Initial): Patient is 8 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse cardiovascular event (reauth): Patient continues to receive other lipid-lowering therapy (eg, statins, ezetimibe) at max tolerated dose (unless patient has documented inability to take these medications). HoFH (reauth): One of the following: 1) Patient continues to receive other lipid-lowering therapy (eg, statin, ezetimibe) or 2) Patient has a documented inability to take other lipid-lowering therapy (eg, statin, ezetimibe). HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse cardiovascular event/HoFH (reauth): Patient demonstrates positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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PROMACTA

PRODUCTS AFFECTED
- *eltrombopag olamine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: relapsed/refractory ITP, persistent ITP, or chronic ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, intolerance, contraindication to corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytopenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) currently receiving interferon-based treatment. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy). Used in combination with standard immunosuppressive therapy (e.g., horse antithymocyte globulin, cyclosporine). Patient meets at least two of the following: 1) absolute neutrophil count less than 500/mcL, 2) platelet count less than 20,000/mcL, 3) absolute reticulocyte count less than 60,000/mcL. Refractory SAA (initial): Diagnosis of refractory SAA. Patient has one of the following: a) neutrophils less than 0.5 x 10^9/L, b) platelet count less than 30,000/mcL, or c) reticulocytes less than 60 x 10^9/L. Insufficient response to immunosuppressive therapy.

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	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).1stline SAA:6mo.RefractSAA:16wk-init,12mo-reauth
Other Criteria	ITP (reauth): Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. Hepatitis C (reauth): Patient currently on antiviral interferon therapy for treatment of chronic hepatitis C. Refractory SAA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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PROVIGIL

PRODUCTS AFFECTED

- *modafinil oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial):Dx of SWD confirmed by one of the following: 1) Symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). MS Fatigue (initial): Dx of multiple sclerosis (MS). Patient is experiencing fatigue. Depression (initial): Treatment-

PA Criteria	Criteria Details
	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).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Narcolepsy, MS Fatigue: Init, Reauth: 12 mo. All other indications: Init, Reauth: 6 mo.
Other Criteria	OSA, SWD, MS Fatigue, Narcolepsy, Idiopathic Hypersomnia (Reauth): Patient demonstrates positive clinical response to therapy. Depression (reauth): Patient demonstrates positive clinical response to modafinil therapy. Used as adjunctive therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

PULMOZYME

PRODUCTS AFFECTED

- PULMOZYME INHALATION SOLUTION 2.5 MG/2.5ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF) (Initial, Reauth): Diagnosis of CF.
Age Restrictions	
Prescriber Restrictions	
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).
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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PYRUKYND

PRODUCTS AFFECTED

- PYRUKYND ORAL TABLET 20 MG, 5 MG, 50 MG
- PYRUKYND TAPER PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count). Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene: a) Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant AND b) Patients is not homozygous for the c.1436G to A (p.R479H) variant AND c) Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene. Hemoglobin is less than or equal to 10g/dL. Patient has symptomatic anemia or is transfusion dependent. Exclusion of other causes of hemolytic anemias (e. g., infections, toxins, drugs).
Age Restrictions	
Prescriber Restrictions	Initial: Prescribed by or in consultation with a hematologist.

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PA Criteria	Criteria Details
Coverage Duration	Initial: 6 months. Reauth: 12 months.
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

QINLOCK

PRODUCTS AFFECTED
- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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QUALAQUIN

PRODUCTS AFFECTED

- *quinine sulfate oral*

PA Criteria	Criteria Details
Exclusion Criteria	Excluded if used solely for the treatment or prevention of nocturnal leg cramps.
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.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	7 days
Other Criteria	
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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QULIPTA

PRODUCTS AFFECTED
- QULIPTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Episodic Migraine (EM) (initial): Diagnosis of EM. Patient has greater than or equal to 4 migraine 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 8 migraine days per month. All Indications (initial): Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines.
Age Restrictions	EM, CM (initial): 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	EM, CM (init): 6mo. EM, CM (reauth): 12mo.
Other Criteria	EM, CM (reauth): Patient has experienced a positive response to therapy. Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs

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PA Criteria	Criteria Details
	(NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (reauth): Patient continues to be monitored for medication overuse headache.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REMICADE

PRODUCTS AFFECTED
- *infliximab*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (Initial): Diagnosis (Dx) of moderately to severely active CD or FCD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Ulcerative colitis (UC) (Initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine). Rheumatoid arthritis (RA) (Initial): Dx of moderately to severely active RA. Used in combination with methotrexate. Psoriatic arthritis (PsA) (Initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (Initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp

PA Criteria	Criteria Details
	psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus).
Age Restrictions	
Prescriber Restrictions	CD, FCD, UC (initial): Prescribed by or in consultation with a gastroenterologist. RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.
Coverage Duration	All uses (initial): 6 months, (reauth): 12 months
Other Criteria	Ankylosing spondylitis (AS) (Initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Sarcoidosis (Initial): Dx of sarcoidosis. TF/C/I to both of the following: one immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine) AND one corticosteroid (eg, prednisone). Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced

PA Criteria	Criteria Details
	by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (Reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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RENFLEXIS

PRODUCTS AFFECTED
- RENFLEXIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Diagnosis (Dx) of moderately to severely active CD or FCD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroids (eg, prednisone), methotrexate. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone), aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, 6-mercaptopurine. Rheumatoid arthritis (RA) (initial): Dx of moderately to severely active RA. Used in combination with methotrexate. Psoriatic arthritis (PsA) (initial): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp

PA Criteria	Criteria Details
	psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus).
Age Restrictions	
Prescriber Restrictions	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. Sarcoidosis (initial): Prescribed by or in consultation with a pulmonologist, dermatologist, or ophthalmologist.
Coverage Duration	All indications (initial): 6 months, (reauth): 12 months
Other Criteria	Ankylosing spondylitis (AS) (initial): Dx of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Sarcoidosis (initial): Dx of sarcoidosis. TF/C/I to one of the following: corticosteroid (eg, prednisone) OR immunosuppressant (eg, methotrexate, cyclophosphamide, azathioprine). All indications (initial): Trial and failure or intolerance to Remicade or Infliximab. Plaque psoriasis (reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the BSA involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC

PA Criteria	Criteria Details
	(reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. RA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. Sarcoidosis (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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REPATHA

PRODUCTS AFFECTED

- REPATHA
- REPATHA SURECLICK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse CV event (init): One of the following diagnoses: A) HeFH, B) ASCVD, C) Primary hyperlipidemia (HLD) or hypercholesterolemia, OR D) At increased risk for a major adverse CV event. One of the following: a) Patient has been receiving the highest tolerable dose of statin therapy, OR b) Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (eg, creatine kinase), OR c) Patient has an FDA labeled contraindication to all statins. HoFH (init): Diagnosis of HoFH as confirmed by one of the following: 1) Genetic confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2) untreated LDL greater than 400, AND either xanthoma before 20 yo or evidence of HeFH in both parents. One of the following: 1) Patient is receiving other lipid-lowering therapy (eg, statin, ezetimibe) or 2) Patient has a documented inability to take other lipid-lowering therapy (eg, statin, ezetimibe).
Age Restrictions	(Initial) HeFH/HoFH: 10 years or older.

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PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse CV event (reauth): Patient continues to receive other lipid-lowering therapy (eg, statins, ezetimibe) at max tolerated dose (unless patient has documented inability to take these medications). HoFH (reauth): One of the following: 1) Patient continues to receive other lipid-lowering therapy (eg, statin, ezetimibe) or 2) Patient has a documented inability to take other lipid-lowering therapy (eg, statin, ezetimibe). HeFH/ASCVD/Primary HLD/Hypercholesterolemia/Prevention of Cardiovascular (CV) Events in patients at increased risk for a major adverse CV event/HoFH (reauth): Patient demonstrates positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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RETACRIT

PRODUCTS AFFECTED

- RETACRIT INJECTION SOLUTION 10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 40000 UNIT/ML

PA Criteria	Criteria Details
Exclusion Criteria	
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 receiving 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

PA Criteria	Criteria Details
	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	
Prescriber Restrictions	
Coverage Duration	CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo.
Other Criteria	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. Patient demonstrates positive clinical response to therapy from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Patient demonstrates positive clinical response to therapy from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Patient demonstrates positive clinical response to therapy from pre-treatment level. Patient is receiving chemo.

PA Criteria	Criteria Details
	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. Patient demonstrates positive clinical response to therapy from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates positive clinical response to therapy from pre-treatment level. Other Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Adequate iron stores confirmed by both of the following: a) Patient's ferritin level is greater than 100 mcg/L and b) Patient's transferrin saturation (TSAT) is greater than 20%.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RETEVMO

PRODUCTS AFFECTED

- RETEVMO ORAL CAPSULE
- RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-Small Cell Lung Cancer: Diagnosis of non-small cell lung cancer (NSCLC). Disease is locally advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s) 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). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation tumor(s) 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 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) 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 requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. Solid Tumors: Diagnosis of solid tumors. Disease is locally advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s) as detected by a U.S. Food and Drug

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PA Criteria	Criteria Details
	Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). ONE of the following: a) Disease has progressed on or following prior systemic treatment (e.g., chemotherapy), OR b) There are no satisfactory alternative treatment options.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Non-Small Cell Lung Cancer, MTC, Thyroid Cancer, Solid Tumors: 12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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REVATIO

PRODUCTS AFFECTED

- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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REVCOVI

PRODUCTS AFFECTED
- REVCOVI

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

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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REVLIMID

PRODUCTS AFFECTED

- *lenalidomide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple myeloma (MM): Diagnosis of MM. 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. Follicular Lymphoma (FL): Diagnosis of FL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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REVUFORJ

PRODUCTS AFFECTED
- REVUFORJ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acute leukemia: Diagnosis of acute leukemia. Disease is relapsed or refractory. Presence of lysine methyltransferase 2A gene (KMT2A) translocation. Acute myeloid leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. One of the following: 1) Presence of a lysine methyltransferase 2A gene (KMT2A) translocation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR 2) Presence of a susceptible nucleophosmin 1 (NPM1) mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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REZDIFFRA

PRODUCTS AFFECTED
- REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH). Patient does not have cirrhosis (e.g., decompensated cirrhosis). Disease is fibrosis stage F2 or F3 as confirmed by one of the following: 1) Both of the following: A) Serum biomarker [e.g., enhanced liver fibrosis (ELF) test, fibrosis-4 index (FIB-4)], and B) Imaging biomarker [e.g., FibroScan, magnetic resonance imaging-proton density fat fraction (MRI-PDFF)], or 2) One of the following: A) FibroScan aspartate aminotransferase (FAST), B) MRI-aspartate aminotransferase (MAST), C) Magnetic Resonance Elastography combined with fibrosis-4 index (MEFIB), or D) Liver biopsy within the past 12 months.
Age Restrictions	
Prescriber Restrictions	Initial: Prescribed by or in consultation with one of the following: gastroenterologist, endocrinologist, or hepatologist.

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PA Criteria	Criteria Details
Coverage Duration	Initial, Reauth: 12 months.
Other Criteria	Reauth: Patient demonstrates positive response to therapy. Patient has not progressed to cirrhosis.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZLIDHIA

PRODUCTS AFFECTED
- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of acute myeloid leukemia (AML). Disease is relapsed or refractory. Presence of a susceptible 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).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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REZUROCK

PRODUCTS AFFECTED
- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic graft versus host disease (cGVHD) (initial): Diagnosis of cGVHD. Trial and failure of two or more lines of systemic therapy [e.g., corticosteroids (e.g., prednisone, methylprednisolone), mycophenolate, chemotherapy].
Age Restrictions	Initial: Patient is 12 years of age or older.
Prescriber Restrictions	
Coverage Duration	cGVHD (initial, reauth): 12 months
Other Criteria	cGVHD (reauth): Patient does not show evidence of progressive disease while on therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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RINVOQ

PRODUCTS AFFECTED
- RINVOQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid arthritis (RA)(init): Diagnosis (Dx) of moderately to severely active RA. RA,PJIA(init): Minimum (min) duration of a 3-mo(RA)/6-wk(PJIA) trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, (RA only) sulfasalazine. Psoriatic arthritis (PsA)(init): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS)(init): Dx of active AS. Non-radiographic axial spondyloarthritis(NRAS, init): Dx of active NRAS. Pt has signs of inflammation. Pt has had an inadequate response or intolerance to one TNF inhibitors (TNF-I) (eg, certolizumab pegol). AS, NRAS(init): Min duration of a 1-mo TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PJIA, PsA, AS(init): Pt has had an inadequate response or intolerance to one or more TNF-I (eg, adalimumab, etanercept). RA, PJIA, PsA, AS, NRAS(init, reauth): Not used in combo with other JAK inhibitors (JAK-I), biologic DMARDs, or potent immunosuppressants (eg, azathioprine [AZA], cyclosporine [CYC]). Atopic dermatitis(AD)(init): Dx of moderate to severe AD. One of the following: Involvement of at least 10% body surface area (BSA), or SCORing Atopic Dermatitis (SCORAD) index value of at least 25. TF of a min 30-day supply (14-day supply for topical

PA Criteria	Criteria Details
	corticosteroids), C/I to one of the following: Medium or higher potency topical corticosteroid, Pimecrolimus, Tacrolimus oint, or Eucrisa. One of the following: 1) TF of a min 12-wk supply of at least one systemic drug product for the treatment of AD (examples include, but are not limited to, Adbry, Dupixent), OR 2) Pt has a C/I, or treatment is inadvisable with both of the following FDA-approved AD therapies: Adbry and Dupixent. Not used in combo with other JAK-I, biologic immunomodulators, or other immunosuppressants (eg, AZA, CYC).
Age Restrictions	AD (initial): Patient is 12 years of age or older
Prescriber Restrictions	RA, PJIA, AS, NRAS, GCA (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (init): Prescribed by or in consultation with a dermatologist or allergist/immunologist. CD, UC (init): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	RA, PJIA, PsA, AS, NRAS, CD, UC, AD, GCA (init): 6 months, (reauth): 12 months.
Other Criteria	Polyarticular juvenile idiopathic arthritis (PJIA) (init): Dx of active PJIA. Crohn's disease (CD) (init): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Ulcerative colitis (UC) (init): Dx of moderately to severely active UC. One of the following: greater than 6 stools/day, frequent blood in the stools, frequent urgency, presence of ulcers,

PA Criteria	Criteria Details
	abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. CD, UC (init): Pt has had an inadequate response or intolerance to one or more TNF-I (eg, adalimumab), OR if treatment is inadvisable (ie, CI) with a TNF-I, pt has had a trial of a systemic therapy approved for CD/UC (eg, risankizumab, ustekinumab). Not used in combination with other JAK-I, biological therapies for CD/UC, or potent immunosuppressants (eg, AZA, CYC). Giant cell arteritis (GCA) (init): Dx of GCA. GCA (reauth): Pt demonstrates positive clinical response to therapy. GCA (init, reauth): Not used in combo with other JAK-I, biologic DMARDs, or potent immunosuppressants (eg, AZA, CYC). RA, PJIA (reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS, NRAS (Reauth): Pt demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (ESR, CRP), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. AD (reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. Not used in combination with other JAK-I, biologic immunomodulators, or other immunosuppressants (eg, AZA, CYC). CD/UC (Reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal

PA Criteria	Criteria Details
	healing, improvement of lab values [platelet counts, ESR, CRP]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK-I, biological therapies for CD/UC, or potent immunosuppressants (eg, AZA, CYC).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RINVOQ LQ

PRODUCTS AFFECTED
- RINVOQ LQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Polyarticular juvenile idiopathic arthritis (PJIA) (init): Diagnosis of active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide. Psoriatic arthritis (PsA) (init): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PJIA, PsA (init): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). PJIA, PsA (init, reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine).
Age Restrictions	
Prescriber Restrictions	PJIA (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist.

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PA Criteria	Criteria Details
Coverage Duration	PJIA, PsA (init): 6 months, (reauth): 12 months.
Other Criteria	PJIA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RIVFLOZA

PRODUCTS AFFECTED

- RIVFLOZA SUBCUTANEOUS SOLUTION
- RIVFLOZA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 128 MG/0.8ML, 160 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of primary hyperoxaluria type 1 (PH1). Disease has been confirmed by both of the following: a) One of the following: i) Elevated urinary oxalate excretion, ii) Elevated plasma oxalate concentration, or iii) Spot urinary oxalate to creatinine molar ratio greater than normal for age, and b) One of the following: i) Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene, or ii) Liver biopsy demonstrating absence or reduced alanine:glyoxylate aminotransferase (AGT) activity. Patient has preserved kidney function (e.g., eGFR greater than or equal to 30mL/min/1.73m^2).
Age Restrictions	Initial: Patient is 2 years of age or older.
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with one of the following: hepatologist, nephrologist, urologist, geneticist, or specialist with expertise in the treatment of PH1.

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PA Criteria	Criteria Details
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ROMVIMZA

PRODUCTS AFFECTED
- ROMVIMZA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of tenosynovial giant cell tumor (TGCT). Patient is symptomatic. Surgical resection will potentially cause worsening functional limitation or severe morbidity.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ROZLYTREK

PRODUCTS AFFECTED
- ROZLYTREK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer (NSCLC). Presence of ROS1 rearrangement positive tumor(s). Solid Tumors: Diagnosis of solid tumors. Presence of neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.) 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). No 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	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RUBRACA

PRODUCTS AFFECTED

- RUBRACA ORAL TABLET 200 MG, 250 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Ovarian cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Prostate cancer: Diagnosis of castration-resistant prostate cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RYBELSUS

PRODUCTS AFFECTED

- RYBELSUS ORAL TABLET 14 MG, 3 MG, 7 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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RYDAPT

PRODUCTS AFFECTED
- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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).
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SABRIL

PRODUCTS AFFECTED

- *vigabatrin*
- VIGADRONE

PA Criteria	Criteria Details
Exclusion Criteria	
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	IS: 1 month to 2 years of age. CPS: 2 years or older.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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SANDOSTATIN

PRODUCTS AFFECTED

- *octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml*

PA Criteria	Criteria Details
Exclusion Criteria	
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.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	Acromegaly (reauth): Patient demonstrates positive clinical response to therapy. 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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SCEMBLIX

PRODUCTS AFFECTED

- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of chronic myelogenous/myeloid leukemia (CML). Disease is Philadelphia chromosome-positive (Ph+). Disease is in chronic phase.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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SCIG

PRODUCTS AFFECTED

- HIZENTRA SUBCUTANEOUS SOLUTION 1 GM/5ML, 10 GM/50ML, 2 GM/10ML, 4 GM/20ML
- HIZENTRA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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 patients 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).
Age Restrictions	Primary immunodeficiency (Hyqvia only) (initial): Patient is 2 years of age or older.

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PA Criteria	Criteria Details
Prescriber Restrictions	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).
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Subject to Part B vs. Part D review. Patient does not meet criteria for Part B or patient is in a long-term care facility. 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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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SIGNIFOR

PRODUCTS AFFECTED
- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	
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	
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): Patient demonstrates 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).
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SKYCLARYS

PRODUCTS AFFECTED
- SKYCLARYS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of Friedreich's ataxia confirmed via genetic testing demonstrating mutation in the FXN gene. Patient has a B-type natriuretic peptide value less than or equal to 200 pg/mL.
Age Restrictions	Initial: Patient is 16 years of age or older.
Prescriber Restrictions	Initial: Prescribed by or in consultation with one of the following: Neurologist, Neurogeneticist, or Physiatrist (Physical Medicine and Rehabilitation Specialist).
Coverage Duration	Initial, Reauth: 12 months.
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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SKYRIZI

PRODUCTS AFFECTED

- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS SOLUTION CARTRIDGE 180 MG/1.2ML, 360 MG/2.4ML
- SKYRIZI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 150 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active CD. Will be used as a maintenance dose following the intravenous induction doses. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction doses.

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PA Criteria	Criteria Details
Age Restrictions	
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. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	All uses (initial): 6 months, (reauth): 12 months
Other Criteria	Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SKYRIZI IV

PRODUCTS AFFECTED
- SKYRIZI INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Crohn's disease (CD): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Will be administered as an intravenous induction dose. Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. Will be administered as an intravenous induction dose.
Age Restrictions	
Prescriber Restrictions	UC, CD: Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	UC, CD: 3 months

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PA Criteria	Criteria Details
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SOMAVERT

PRODUCTS AFFECTED
- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acromegaly (initial): Diagnosis of acromegaly. One of the following: 1) failure to one of the following: surgery, radiation therapy, or other medical therapies (such as dopamine agonists [e.g., bromocriptine, cabergoline]) or 2) not a candidate for one of the following: surgery, radiation therapy, or dopamine agonist (e.g., bromocriptine, cabergoline) therapy. One of the following: 1) inadequate response, contraindication, or intolerance to a somatostatin analog (e.g., octreotide, lanreotide) or 2) clinical rationale provided for preferred treatment with pegvisomant (e.g., comorbid diabetes mellitus is present with acromegaly).
Age Restrictions	
Prescriber Restrictions	Acromegaly (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial and reauth: 12 months

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PA Criteria	Criteria Details
Other Criteria	Acromegaly (reauth): Patient has experienced a positive clinical response to therapy (biochemical control, decrease or normalization of IGF-1 levels).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SPEVIGO

PRODUCTS AFFECTED
- SPEVIGO SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of generalized pustular psoriasis (GPP) as defined by primary, sterile, macroscopically visible pustules (excluding cases where pustulation is restricted to psoriatic plaques). Subcutaneous formulation will not be used to treat GPP flare. Patient weighs at least 40kg.
Age Restrictions	Initial: Patient is 12 years of age or older.
Prescriber Restrictions	Initial: Prescribed by or in consultation with a dermatologist.
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SPRAVATO

PRODUCTS AFFECTED

- SPRAVATO (56 MG DOSE)
- SPRAVATO (84 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	One of the following: A) Both of the following: 1) Diagnosis of major depressive disorder and 2) Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode OR B) All of the following: 1) Diagnosis of major depressive disorder, 2) Patient has both of the following: a) depressive symptoms and b) acute suicidal ideation or behavior, and 3) Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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SPRYCEL

PRODUCTS AFFECTED

- *dasatinib*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	All Uses: 12 months
Other Criteria	All Uses: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

STELARA (IV)

PRODUCTS AFFECTED
- STELARA INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Crohn's Disease (CD): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	One time

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PA Criteria	Criteria Details
Other Criteria	Stelara is to be administered as an intravenous induction dose. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

STELARA

PRODUCTS AFFECTED

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial): One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn-+s disease. Will be used as a maintenance dose following

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PA Criteria	Criteria Details
	the intravenous induction dose. All indications (initial): Trial of either Steqeyma or Wezlana.
Age Restrictions	Plaque psoriasis, PsA (Initial): Patient is 6 years of age or older.
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. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	All uses (Initial): 6 months. All uses (reauth): 12 months
Other Criteria	Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD (Reauth), UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts,

PA Criteria	Criteria Details
	erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

STEQEYMA

PRODUCTS AFFECTED
- STEQEYMA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial): One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn-+s disease. Will be used as a maintenance dose following the intravenous induction dose. Ulcerative colitis (UC) (Initial): Diagnosis of

PA Criteria	Criteria Details
	moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose.
Age Restrictions	Plaque psoriasis, PsA (Initial): Patient is 6 years of age or older.
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. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	All uses (Initial): 6 months. All uses (Reauth): 12 months.
Other Criteria	PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

STEQEYMA IV

PRODUCTS AFFECTED
- STEQEYMA INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Crohn's Disease (CD): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	One time

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PA Criteria	Criteria Details
Other Criteria	Will be administered as an intravenous induction dose. Induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

STIVARGA

PRODUCTS AFFECTED
- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Metastatic colorectal cancer (mCRC): Diagnosis of mCRC. Gastrointestinal stromal tumor (GIST): Diagnosis of locally advanced, unresectable or metastatic GIST. Hepatocellular Carcinoma (HCC): Diagnosis of HCC.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

STRENSIQ

PRODUCTS AFFECTED
- STRENSIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Both of the following: Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) AND Additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SUCRAID

PRODUCTS AFFECTED
- SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Congenital Sucrase-Isomaltase Deficiency (CSID) (initial): Diagnosis of sucrase deficiency (which is part of congenital sucrose-isomaltase deficiency [CSID]).
Age Restrictions	CSID (initial): Patient is 5 months of age or older.
Prescriber Restrictions	CSID (initial): Prescribed by or in consultation with a gastroenterologist or geneticist.
Coverage Duration	CSID (initial, reauth): 12 months.
Other Criteria	CSID (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

SUTENT

PRODUCTS AFFECTED

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	All uses: 12 months

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PA Criteria	Criteria Details
Other Criteria	All Indications: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SYPRINE

PRODUCTS AFFECTED

- *trientine hcl oral capsule 250 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TABRECTA

PRODUCTS AFFECTED
- TABRECTA

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

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TAFAMIDIS

PRODUCTS AFFECTED
- VYNDAMAX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) (initial): Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM). One of the following: 1) Presence of a transthyretin (TTR) mutation (e.g., V122I) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), 2) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, OR 3) Both of the following: i) echocardiogram or cardiac magnetic resonance imaging or scintigraphy scan suggestive of amyloidosis, and ii) absence of light-chain amyloidosis. Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure. Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Diflunisal).
Age Restrictions	
Prescriber Restrictions	ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist

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PA Criteria	Criteria Details
Coverage Duration	ATTR-CM (initial, reauth): 12 months
Other Criteria	ATTR-CM (reauth): Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure. Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Diflunisal).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAFINLAR

PRODUCTS AFFECTED
- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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

PA Criteria	Criteria Details
	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) .
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. 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). Medication is used in combination with Mekinist (trametinib). Low-grade Glioma: Diagnosis of low-grade glioma. Patient requires systemic therapy. 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). Medication is used in combination with Mekinist (trametinib).

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAGRISSO

PRODUCTS AFFECTED

- TAGRISSO ORAL TABLET 40 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): One of the following: A) All of the following: Diagnosis of metastatic NSCLC. One of the following: 1) Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), OR 2) Both of the following: a) Patient has known active EGFR T790M mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), or Vizimpro (dacomitinib). OR B) All of the following: Diagnosis of NSCLC. Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Both of the following: 1) Patient is receiving as adjuvant therapy, and 2) Patient has had a complete surgical resection of the primary NSCLC tumor. OR C) All of the following: Diagnosis of NSCLC. Disease is locally advanced. Patient has

PA Criteria	Criteria Details
	known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. FDA-approved test or a test performed at a facility approved by CLIA. Used in combination with both of the following: a) Pemetrexed, and b) Platinum-based chemotherapy (e.g., cisplatin, carboplatin). Or D) Refer to Other Criteria element for additional indication and criteria.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	NSCLC cont: OR D) All of the following: Diagnosis of NSCLC. Disease is Locally advanced, Unresectable (Stage III). Presence of known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an 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 not progressed during or following concurrent or sequential platinum-based chemoradiation therapy. All indications: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TALZENNA

PRODUCTS AFFECTED
- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast cancer: Diagnosis of breast cancer. Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer (mCRPC). Disease is homologous recombination repair (HRR) gene-mutated. Taken in combination with Xtandi (enzalutamide).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TARCEVA

PRODUCTS AFFECTED

- *erlotinib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	All uses: 12 months

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PA Criteria	Criteria Details
Other Criteria	All Indications: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TARGRETIN

PRODUCTS AFFECTED

- *bexarotene*

PA Criteria	Criteria Details
Exclusion Criteria	
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, brentuximab vedotin, methotrexate]).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TASIGNA

PRODUCTS AFFECTED

- *nilotinib d-tartrate*
- *nilotinib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TAVNEOS

PRODUCTS AFFECTED
- TAVNEOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: a) Granulomatosis with polyangiitis (GPA) OR b) Microscopic polyangiitis (MPA). Diagnosis is confirmed by one of the following: a) ANCA test positive for proteinase 3 (PR3) antigen, b) ANCA test positive for myeloperoxidase (MPO) antigen, OR c) Tissue biopsy. Patient is receiving concurrent immunosuppressant therapy with one of the following: a) cyclophosphamide OR b) rituximab. One of the following: a) Patient is concurrently on glucocorticoids (e.g., prednisone) OR b) History of contraindication or intolerance to glucocorticoids (e.g., prednisone).
Age Restrictions	
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with one of the following, with shared decision-making regarding treatment risks: 1) nephrologist, 2) pulmonologist, or 3) rheumatologist.

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PA Criteria	Criteria Details
Coverage Duration	Initial, Reauth: 12 months.
Other Criteria	Reauth: Patient does not show evidence of progressive disease while on therapy. Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAZVERIK

PRODUCTS AFFECTED
- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TECFIDERA

PRODUCTS AFFECTED

- *dimethyl fumarate oral*
- *dimethyl fumarate starter pack oral capsule delayed release therapy pack*

PA Criteria	Criteria Details
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions).
Age Restrictions	
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months
Other Criteria	MS (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TEPMETKO

PRODUCTS AFFECTED
- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TERIPARATIDE

PRODUCTS AFFECTED

- BONSITY
- FORTEO SUBCUTANEOUS SOLUTION PEN-INJECTOR 560 MCG/2.24ML
- *teriparatide subcutaneous solution pen-injector 560 mcg/2.24ml*

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

PA Criteria	Criteria Details
	or more in the U.S., or the country-specific threshold in other countries or regions, or Set III) History of fragility fracture (e.g., hip or spine), regardless of BMD. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	All uses (initial): 24 months. All uses (reauth): 12 months.
Other Criteria	Glucocorticoid-Induced Osteoporosis (initial): Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: 1) BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site), or 2) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions, 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, or 4) One of the following: a) glucocorticoid dosing of at least 30 mg per day, or b) cumulative glucocorticoid dosing of at least 5 grams per year. TF/C/I to one bisphosphonate (e.g., alendronate). All uses (initial, reauth): One of the following: 1) Treatment duration of parathyroid hormones

PA Criteria	Criteria Details
	[e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime, or 2) Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)].
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TESTOSTERONE

PRODUCTS AFFECTED

- DEPO-TESTOSTERONE INTRAMUSCULAR SOLUTION
- *testosterone cypionate intramuscular solution 100 mg/ml, 200 mg/ml*
- *testosterone transdermal gel 1.62 %, 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)*

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

PA Criteria	Criteria Details
	Incongruence. Using hormones to change characteristics to align with gender expression.
Age Restrictions	Testosterone cypionate only: HG (init): 12 years of age or older. All other testosterone: HG (init): Patient is 18 years of age or older.
Prescriber Restrictions	
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.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TESTOSTERONE ENANTHATE

PRODUCTS AFFECTED

- *testosterone enanthate intramuscular solution*

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

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PA Criteria	Criteria Details
	GD/Gender Incongruence. Using hormones to change characteristics to align with gender expression.
Age Restrictions	HG (init): Patient is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC, GD: 12 mo. DP: 6 mo.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off Label Uses	

PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TEVIMBRA

PRODUCTS AFFECTED

- TEVIMBRA INTRAVENOUS SOLUTION
  100 MG/10ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Esophageal Squamous Cell Carcinoma: Diagnosis of esophageal squamous cell carcinoma. Disease is unresectable or metastatic. One of the following: 1) Both of the following: a) Patient has received prior systemic chemotherapy and b) Patient has not previously been treated with a PD-(L)1 inhibitor (e.g., Keytruda, Opdivo) OR 2) Used in combination with platinum-containing chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin). Gastric or Gastroesophageal Junction Adenocarcinoma: Diagnosis of gastric or gastroesophageal junction adenocarcinoma. Disease is unresectable or metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Tumor(s) express PD-L1 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with platinum (e.g., carboplatin, cisplatin, oxaliplatin) and fluoropyrimidine (e.g., fluorouracil)-based chemotherapy.
Age Restrictions	

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PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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THALOMID

PRODUCTS AFFECTED
- THALOMID

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TIBSOVO

PRODUCTS AFFECTED
- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Relapsed or refractory Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. One of the following: 1) patient is greater than or equal to 75 years old OR 2) patient has comorbidities that preclude use of intensive induction chemotherapy. Locally Advanced or Metastatic Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is locally advanced or metastatic. Patient has been previously treated. Relapsed or Refractory Myelodysplastic Syndromes: Diagnosis of myelodysplastic syndromes (MDS). Disease is relapsed or refractory. All indications: Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOPICAL RETINOID

PRODUCTS AFFECTED

- *tretinoin external cream 0.025 %, 0.05 %*

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TORPENZ

PRODUCTS AFFECTED
- TORPENZ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. Renal cell carcinoma: Diagnosis of advanced 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. Breast Cancer: Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole). 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	SEGA associated with TSC: Patient is 1 year of age or older.
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	All uses: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRELSTAR

PRODUCTS AFFECTED

- TRELSTAR MIXJECT INTRAMUSCULAR SUSPENSION RECONSTITUTED 11.25 MG, 22.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TREMFYA IV

PRODUCTS AFFECTED
- TREMFYA INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Both of the following: Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) AND Additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TREMFYA SC

PRODUCTS AFFECTED

- TREMFYA ONE-PRESS SUBCUTANEOUS SOLUTION PEN-INJECTOR
- TREMFYA PEN SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML, 200 MG/2ML
- TREMFYA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 200 MG/2ML
- TREMFYA-CD/UC INDUCTION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, OR palmoplantar (ie, palms, soles), facial, scalp, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (initial): Diagnosis of moderately to severely active CD. One of the following: a) Will be used as a maintenance dose following the intravenous induction doses, OR b) Both of the following: 1) Will be used as induction dosing, and 2) One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, C-reactive

PA Criteria	Criteria Details
	protein [CRP]), OR CD Activity Index (CDAI) greater than 220. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: a) Will be used as a maintenance dose following the intravenous induction doses, OR b) Both of the following: 1) Will be used as induction dosing, and 2) One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids.
Age Restrictions	
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. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	All Indications (Initial): 6 months, (reauth): 12 months
Other Criteria	Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced

PA Criteria	Criteria Details
	by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRIKAFTA

PRODUCTS AFFECTED

- TRIKAFTA ORAL TABLET THERAPY PACK 100-50-75 & 150 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis (CF) (initial): Diagnosis of CF. Presence of at least one 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 facility approved by Clinical Laboratory Improvement Amendments (CLIA). CFTR mutation is responsive based on clinical and/or in vitro data OR CFTR mutation results in the production of CFTR protein.
Age Restrictions	CF (initial): For granule packets: patient is at least 2 to less than 6 years of age. For tablets: patient is 6 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

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PA Criteria	Criteria Details
Other Criteria	CF (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRULICITY

PRODUCTS AFFECTED

- TRULICITY SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRUQAP

PRODUCTS AFFECTED
- TRUQAP

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of breast cancer. Disease is one of the following: locally advanced or metastatic. Will be taken in combination with fulvestrant. Disease is hormone receptor (HR)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Patient has one or more PIK3CA/AKT1/PTEN-alterations 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). One of the following: A) Following progression on at least one endocrine-based regimen in the metastatic setting (e.g., anastrozole, letrozole, exemestane, tamoxifen, etc.) OR B) Recurrence on or within 12 months of completing adjuvant therapy (e.g., chemotherapy).
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRYNGOLZA

PRODUCTS AFFECTED

- TRYNGOLZA SUBCUTANEOUS SOLUTION AUTO-INJECTOR 80 MG/0.8ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Familial Chylomicronemia syndrome (FCS) (Initial): Diagnosis of FCS (type 1 hyperlipoproteinemia). One of the following: a) Genetic confirmation of biallelic pathogenic variants in FCS-causing genes (i.e., LPL, GPIHBP1, APOA5, APOC2, or LMF1), b) A North American FCS (NAFCS) Score of greater than or equal to 45, or c) A Moulin score greater than 10. Both of the following: a) One of the following: i) Patient has tried or will receive treatment with standard of care triglyceride lowering therapy (i.e., prescription omega-3 fatty acid and a fibrate), or ii) Patient has an intolerance to standard of care triglyceride lowering therapy (i.e., prescription omega-3 fatty acid and a fibrate), and b) Baseline fasting triglyceride levels are greater than or equal to 880 mg/dL prior to treatment with requested drug. Severe hypertriglyceridemia (Initial): Diagnosis of severe hypertriglyceridemia. One of the following baseline fasting triglyceride levels prior to treatment with requested drug: a) Greater than or equal to 500 mg/dL and at high risk for acute pancreatitis not related to alcohol use, biliary disease, or uncontrolled diabetes or b) Greater than or equal to 1000 mg/dL. One of the following: a) Both of the following: i) Patient has tried at least a 30-day trial of one of the following standard of care triglyceride lowering therapies:

PA Criteria	Criteria Details
	Prescription omega-3 fatty acid [e.g., icosapent ethyl] or fibrate [e.g., fenofibrate, gemfibrozil] AND ii) Patient has been unable to achieve treatment goals (i.e., triglyceride levels less than 500 mg/dL) OR b) Patient has an intolerance to standard of care triglyceride lowering therapy (i.e., prescription omega-3 fatty acid [e.g., icosapent ethyl] and a fibrate [e.g., gemfibrozil)]. One of the following: a) Patient is receiving other lipid lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose or b) Patient has a documented inability to take other lipid lowering therapy.
Age Restrictions	
Prescriber Restrictions	All uses (Initial): Prescribed by or in consultation with a cardiologist, endocrinologist, gastroenterologist, or lipid specialist (lipidologist).
Coverage Duration	All uses (Initial, Reauth): 12 months.
Other Criteria	All uses (Reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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TUKYSA

PRODUCTS AFFECTED
- TUKYSA

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TURALIO

PRODUCTS AFFECTED

- TURALIO ORAL CAPSULE 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TYENNE SC

PRODUCTS AFFECTED
- TYENNE SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib) or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Giant Cell Arteritis (GCA) (Initial): Diagnosis of GCA. Systemic Juvenile Idiopathic Arthritis (SJIA) (Initial): Diagnosis of active SJIA. TF/C/I to one of the following conventional therapies at maximally tolerated doses: minimum duration of a one month trial of a nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen), minimum duration of a 3-month trial of methotrexate, or minimum duration of a 2-week trial of a systemic glucocorticoid (eg, prednisone). Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: a) TF/C/I to two of the following, or attestation demonstrating a trial may be inappropriate: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq/LQ, or Xeljanz (tofacitinib), OR b) for continuation of prior therapy. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (Initial): Diagnosis of SSc-ILD as documented by the following: a) Exclusion of other known causes of ILD AND b) One of the

PA Criteria	Criteria Details
	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 high-resolution computed tomography (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.
Age Restrictions	
Prescriber Restrictions	RA, GC, SJIA, PJIA (initial): Prescribed by or in consultation with a rheumatologist. SSc-ILD (initial): Prescribed by or in consultation with a pulmonologist or rheumatologist.
Coverage Duration	RA, GC, SJIA, PJIA, SSc-ILD (initial): 6 months, (reauth): 12 months
Other Criteria	RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. SJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in clinical features or symptoms (eg, pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline. GC, SSc-ILD (Reauth): Patient demonstrates positive clinical response to therapy.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TYKERB

PRODUCTS AFFECTED
- *lapatinib ditosylate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast Cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer. Disease is one of the following: advanced, metastatic, or recurrent. Used in combination with one of the following: Trastuzumab, Xeloda (capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)].
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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TYMLOS

PRODUCTS AFFECTED
- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	One of the following diagnoses: 1) postmenopausal osteoporosis or osteopenia, OR 2) 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 (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, or Set III) History of fragility fracture (e.g., hip or spine) regardless of BMD. Treatment duration of parathyroid hormones (e.g.,

PA Criteria	Criteria Details
	teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	24 months (max 24 months of therapy per lifetime)
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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UBRELVY

PRODUCTS AFFECTED
- UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines.
Age Restrictions	Initial: 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial, Reauth: 12 months.
Other Criteria	Reauth: Patient has experienced a positive response to therapy. Will not be used for preventive treatment of migraine. Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

UDENYCA

PRODUCTS AFFECTED
- UDENYCA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	All uses: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

UDENYCA ONBODY

PRODUCTS AFFECTED
- UDENYCA ONBODY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institutes 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.
Age Restrictions	

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PA Criteria	Criteria Details
Prescriber Restrictions	All uses: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	FN (prophylaxis, treatment): 3 mo or duration of tx.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

USTEKINUMAB (IV)

PRODUCTS AFFECTED

- *ustekinumab intravenous*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Crohn's Disease (CD): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	One time

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PA Criteria	Criteria Details
Other Criteria	Will be administered as an intravenous induction dose. Induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

USTEKINUMAB

PRODUCTS AFFECTED

- *ustekinumab subcutaneous*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial): One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn-+s disease. Will be used as a maintenance dose following the intravenous induction dose. Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following

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PA Criteria	Criteria Details
	the intravenous induction dose. All indications (initial): Trial of either Steqeyma or Wezlana.
Age Restrictions	Plaque psoriasis, PsA (Initial): Patient is 6 years of age or older.
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. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	All uses (Initial): 6 months. All uses (Reauth): 12 months.
Other Criteria	PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VALCHLOR

PRODUCTS AFFECTED
- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	
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 [e.g., clobetasol, fluocinonide], bexarotene topical gel [Targretin topical gel], etc.).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VANFLYTA

PRODUCTS AFFECTED
- VANFLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acute Myeloid Leukemia (AML): Diagnosis of AML. Patient has a FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (FLT3-ITD) mutation 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). Both of the following: a) Used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) induction and cytarabine consolidation, and b) Used as maintenance monotherapy following consolidation chemotherapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VENCLEXTA

PRODUCTS AFFECTED

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VEOPOZ

PRODUCTS AFFECTED
- VEOPOZ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of active CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease. Patient has a confirmed genotype of biallelic CD55 loss-of-function mutation. Patient has hypoalbuminemia (serum albumin concentration of less than or equal to 3.2 g/dL). Patient has at least one of the following signs or symptoms within the last six months: abdominal pain, diarrhea, peripheral edema, or facial edema.
Age Restrictions	Initial: Patient is 1 year of age or older.
Prescriber Restrictions	Initial: Prescribed by or in consultation with an immunologist, geneticist, hematologist, or gastroenterologist.
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VEOZAH

PRODUCTS AFFECTED
- VEOZAH

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of moderate to severe vasomotor symptoms due to menopause. Prescriber attests that baseline serum alanine aminotransferase (ALT), serum aspartate aminotransferase (AST) and total bilirubin levels are less than 2 times the upper limit of normal (ULN) prior to initiating Veozah.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial, Reauth: 6 months
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy. One of the following: 1) If patient has been on therapy for less than 9 months, provider attests to one of the following within the past 3 months: a) For patients with total bilirubin levels less than or equal to 2 times the ULN, transaminase elevations do not exceed 5 times the ULN, or b) For patients with total bilirubin levels greater

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PA Criteria	Criteria Details
	than 2 times the ULN, transaminase elevations do not exceed 3 times the ULN, or 2) If patient has been on therapy for greater than or equal to 9 months, provider attests to both of the following: a) No hepatic issues arose during the first 9 months of therapy, and b) Patient does not currently have any hepatic related issues (e.g., signs or symptoms of hepatic strain).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VERQUVO

PRODUCTS AFFECTED
- VERQUVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic Heart Failure (CHF) (initial): Diagnosis of CHF. Patient has an ejection fraction less than 45 percent. Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms. One of the following: A) Patient was hospitalized for heart failure within the last 6 months, or B) Patient used outpatient intravenous diuretics (e.g., bumetanide, furosemide) for heart failure within the last 3 months. Trial and failure, contraindication, or intolerance to two of the following at a maximally tolerated dose: A) One of the following: 1) Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), 2) Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan), or 3) Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)], B) One of the following: 1) bisoprolol, 2) carvedilol, or 3) metoprolol succinate extended release, C) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)], or D) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone].
Age Restrictions	

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PA Criteria	Criteria Details
Prescriber Restrictions	CHF (initial): Prescribed by or in consultation with a cardiologist.
Coverage Duration	CHF (initial, reauth): 12 months
Other Criteria	CHF (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VERZENIO

PRODUCTS AFFECTED
- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast Cancer: Diagnosis of breast cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VIGAFYDE

PRODUCTS AFFECTED
- VIGAFYDE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of infantile spasms. Trial or intolerance to generic vigabatrin.
Age Restrictions	Patient is 1 month to 2 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

VITRAKVI

PRODUCTS AFFECTED
- VITRAKVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Presence of solid tumors. One of the following: 1) Diagnosis of secretory breast cancer, mammary analogue secretory cancer (MASC), congenital mesoblastic nephroma (CMN), or infantile fibrosarcoma, or 2) Both of the following: i) Disease is confirmed by the presence of neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and ii) 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	

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PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VIZIMPRO

PRODUCTS AFFECTED
- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	
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 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): exon 19 deletion or exon 21 L858R substitution.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VONJO

PRODUCTS AFFECTED
- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Pre-treatment platelet count below 50 x 10^9/L.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VOQUEZNA

PRODUCTS AFFECTED

- VOQUEZNA DUAL PAK
- VOQUEZNA ORAL TABLET 10 MG, 20 MG
- VOQUEZNA TRIPLE PAK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Helicobacter pylori (H. pylori) (Voquezna Dual Pak, Voquezna Triple Pak): Diagnosis of H. pylori infection. Trial and failure, contraindication, or intolerance to bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI]). H. pylori (Voquezna): Diagnosis of H. pylori infection. One of the following: a) Used in combination with amoxicillin and clarithromycin for the treatment of H. pylori infection, or b) Used in combination with amoxicillin for the treatment of H. pylori infecion. Trial and failure, contraindication, or intolerance to bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI]). Healing and Relief of Heartburn associated with Erosive Esophagitis (HRH) (Voquezna): Diagnosis of erosive esophagitis. Used for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis. Trial and inadequate response, contraindication, or intolerance to TWO of the following generic PPIs: a) omeprazole, b) esomeprazole, c) pantoprazole, d) lansoprazole, e) rabeprazole, or f) dexlansoprazole. Maintenance of Healing and Relief of Heartburn associated with Erosive Esophagitis (MHRH) (Voquezna): Used to maintain healing and relief of

PA Criteria	Criteria Details
	heartburn associated with erosive esophagitis. Trial and inadequate response, contraindication, or intolerance to TWO of the following generic PPIs: a) omeprazole, b) esomeprazole, c) pantoprazole, d) lansoprazole, e) rabeprazole, or f) dexlansoprazole.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	H. pylori, NERD: 1 mo. HRH: 2 months. MHRH: 6 mos.
Other Criteria	Relief of Heartburn associated with Non-Erosive Gastroesophageal Reflux Disease (NERD): Diagnosis of non-erosive Gastroesophageal Reflux Disease. Both of the following: a) Patient has history of heartburn for at least 6 months and b) Heartburn symptoms are present for at least 4 days during any consecutive 7-day period. Trial and inadequate response, contraindication, or intolerance to TWO of the following generic PPIs: a) omeprazole, b) esomeprazole, c) pantoprazole, d) lansoprazole, e) rabeprazole, or f) dexlansoprazole.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VORANIGO

PRODUCTS AFFECTED

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of astrocytoma or oligodendroglioma. Presence of a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation. History of one of the following: a) Biopsy, b) Sub-total resection, or c) Gross total resection.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VORICONAZOLE INJECTION

PRODUCTS AFFECTED

- *voriconazole intravenous solution reconstituted*

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

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PA Criteria	Criteria Details
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VOSEVI

PRODUCTS AFFECTED
- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	
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 not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
Age Restrictions	
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, Liver transplant specialist.
Coverage Duration	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VOTRIENT

PRODUCTS AFFECTED

- *pazopanib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of advanced/metastatic RCC. Soft tissue sarcoma: Diagnosis of advanced soft tissue sarcoma.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VOWST

PRODUCTS AFFECTED
- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following: 1) Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for two consecutive days, and 2) A positive stool test for C.difficile toxin or toxigenic C.difficile. Patient has a history of two or more recurrent episodes of CDI within 12 months. All of the following: 1) Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst: oral vancomycin or Dificid (fidaxomicin), 2) Patient has completed or is planning to complete the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst, and 3) Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days).
Age Restrictions	Patient is 18 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist or infectious disease specialist.

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PA Criteria	Criteria Details
Coverage Duration	14 days
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VUMERITY

PRODUCTS AFFECTED
- VUMERITY

PA Criteria	Criteria Details
Exclusion Criteria	Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS.
Required Medical Information	MS (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Teriflunomide, 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy.
Age Restrictions	
Prescriber Restrictions	MS (initial, reauth): Prescribed by or in consultation with a neurologist
Coverage Duration	MS (initial, reauth): 12 months

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PA Criteria	Criteria Details
Other Criteria	MS (reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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VYJUVEK

PRODUCTS AFFECTED
- VYJUVEK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of dystrophic epidermolysis bullosa (DEB). Patient has mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. Medication is being used for the treatment of wounds that require healing. Medication will be applied by a healthcare professional. Wound(s) being treated meet all of the following criteria: a) adequate granulation tissue, b) excellent vascularization, c) no evidence of active wound infection in the wound being treated, and d) no evidence or history of squamous cell carcinoma in the wound being treated. Medication is not being used concurrently with other FDA approved therapies (e.g., Filsuvez) for the treatment of epidermolysis bullosa.
Age Restrictions	Initial: Patient is 6 months of age or older.
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with a specialist with expertise in wound care.
Coverage Duration	Initial: 6 months. Reauth: 12 months.

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PA Criteria	Criteria Details
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy. Wound(s) being treated meet all of the following criteria: a) adequate granulation tissue, b) excellent vascularization, c) no evidence of active wound infection in the wound being treated, and d) no evidence or history of squamous cell carcinoma in the wound being treated. Medication is not being used concurrently with other FDA approved therapies (e.g., Filsuvez) for the treatment of epidermolysis bullosa.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VYVGART

PRODUCTS AFFECTED

- VYVGART HYTRULO SUBCUTANEOUS SOLUTION
- VYVGART HYTRULO SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Generalized myasthenia gravis (gMG) (Initial): Diagnosis of gMG. 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). Chronic inflammatory demyelinating polyneuropathy (CIDP) (Only applies for Vyvgart Hytrulo) (Initial): Diagnosis of CIDP as confirmed by all of the following: 1) Progressive symptoms present for at least 2 months, 2) Symptomatic polyradiculoneuropathy as indicated by one of the following: a) Progressive or relapsing motor impairment of more than one limb OR b) Progressive or relapsing sensory impairment of more than one limb. Trial and failure, contraindication, or intolerance to one of the following standard of care treatments: corticosteroids (minimum 3 month trial duration), immunoglobulin, or plasma exchange.

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PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	gMG (Initial): Prescribed by or in consultation with a neurologist. CIDP (Initial, Reauth): Prescribed by or in consultation with an immunologist, neurologist, or hematologist.
Coverage Duration	gMG (Initial, Reauth): 12 months. CIDP (Initial): 6 months, (Reauth): 12 months.
Other Criteria	gMG, CIDP (Reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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WELIREG

PRODUCTS AFFECTED
- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	von Hippel-Lindau (VHL) disease: Diagnosis of VHL disease. Patient requires therapy for one of the following: a) renal cell carcinoma (RCC), b) central nervous system (CNS) hemangioblastoma, or c) pancreatic neuroendocrine tumor (pNET). Patient does not require immediate surgery. Advanced Renal Cell Carcinoma: Diagnosis of advanced renal cell carcinoma. Disease has progressed after treatment with both of the following: a) One of the following: i) Programmed death receptor-1 (PD-1) inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)], or ii) Programmed death-ligand 1 (PD-L1) inhibitor [e.g., Bavencio (avelumab), Imfinzi (durvalumab)], and b) Vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) [e.g., Votrient (pazopanib), Inlyta (axitinib)]. Pheochromocytoma or Paraganglioma (PPGL): Diagnosis of Pheochromocytoma or Paraganglioma (PPGL). Disease is one of the following: a) locally advanced, b) unresectable, or c) metastatic.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

WEZLANA

PRODUCTS AFFECTED
- WEZLANA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial): One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to one of the following topical therapies: corticosteroids (eg, betamethasone, clobetasol), vitamin D analogs (eg, calcitriol, calcipotriene), tazarotene, or calcineurin inhibitors (eg, tacrolimus, pimecrolimus). Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn-+s disease. Will be used as a maintenance dose following the intravenous induction dose.

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PA Criteria	Criteria Details
Age Restrictions	Plaque psoriasis, PsA (Initial): Patient is 6 years of age or older.
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. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	All uses (Initial): 6 months. All uses (Reauth): 12 months.
Other Criteria	PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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WEZLANA IV

PRODUCTS AFFECTED
- WEZLANA INTRAVENOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Crohn's Disease (CD): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	One time

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PA Criteria	Criteria Details
Other Criteria	Will be administered as an intravenous induction dose. Induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

WINREVAIR

PRODUCTS AFFECTED
- WINREVAIR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. Patient is currently on at least two therapies indicated for the treatment of PAH from the following different mechanisms of action, unless there is a contraindication or intolerance: a) Endopthelin receptor antagonists (ie, Bosentan, ambrisentan or macitentan) and b) Phosphodiesterase 5 inhibitors (ie, Tadalafil or sildenafil).
Age Restrictions	
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): Patient demonstrates positive clinical response to therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

WYOST

PRODUCTS AFFECTED
- WYOST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Skeletal prevention in Multiple Myeloma (MM)/Bone Metastasis from Solid Tumors (BMST): One of the following: 1) Both of the following: a) Diagnosis of multiple myeloma and b) Trial and failure, contraindication (e.g., renal insufficiency), or intolerance to one bisphosphonate therapy, OR 2) Both of the following: a) Diagnosis of solid tumors (e.g., breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and b) Documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Diagnosis of giant cell tumor of bone. One of the following: 1) One of the following: a) tumor is unresectable or b) surgical resection is likely to result in severe morbidity, OR 2) Approve for continuation of prior therapy. Hypercalcemia of malignancy (HCM): Diagnosis of hypercalcemia of malignancy. Trial and failure, contraindication, or intolerance to one bisphosphonate therapy.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	MM/BMST, GCTB, HCM: 12 months.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XALKORI

PRODUCTS AFFECTED
- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of 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 ROS1 rearrangement-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Inflammatory Myofibroblastic Tumor (IMT): Diagnosis of IMT. Disease is one of the following: a) unresectable, b) recurrent, or c) refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

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PA Criteria	Criteria Details
Age Restrictions	IMT, ALCL: Patient is 1 year of age or older.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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XATMEP

PRODUCTS AFFECTED
- XATMEP

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acute lymphoblastic leukemia (ALL): Diagnosis of acute lymphoblastic leukemia (ALL). Polyarticular juvenile idiopathic arthritis (pJIA): Diagnosis of polyarticular juvenile idiopathic arthritis.
Age Restrictions	
Prescriber Restrictions	pJIA: Prescribed by or in consultation with a rheumatologist.
Coverage Duration	ALL, pJIA: 12 months.
Other Criteria	Subject to Part B vs D review. Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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XCOPRI

PRODUCTS AFFECTED

- XCOPRI
- XCOPRI (250 MG DAILY DOSE) ORAL TABLET THERAPY PACK 100 & 150 MG
- XCOPRI (350 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of partial onset seizures.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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XELJANZ

PRODUCTS AFFECTED

- *tofacitinib citrate er oral tablet extended release 24 hour 11 mg*
- *tofacitinib citrate oral tablet*
- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET
- XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Xeljanz tab/Xeljanz XR tab: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Xeljanz tab and solution/Xeljanz XR tab: Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Xeljanz tab/Xeljanz XR tab: Ankylosing spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PsA, AS (Initial): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). Xeljanz tab/Xeljanz XR tab: Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids.

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PA Criteria	Criteria Details
	Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab). Not used in combination with other Janus kinase (JAK) inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine).
Age Restrictions	
Prescriber Restrictions	RA, PJIA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	RA/PJIA/PsA/AS (initial): 6 mo, (reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.
Other Criteria	Xeljanz: Polyarticular course juvenile idiopathic arthritis (PJIA) (Initial): Diagnosis of active polyarticular course juvenile idiopathic arthritis. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). RA, PsA, AS, PJIA (Initial): Not used in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates

PA Criteria	Criteria Details
	positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. RA, PsA, AS, PJIA (reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine).
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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XENAZINE

PRODUCTS AFFECTED

- *tetrabenazine*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chorea associated with Huntington's Disease (HD) (Initial): Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia (Initial): Diagnosis of tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication, OR 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Tourette's syndrome (Initial): Patient has tics associated with Tourette's syndrome. Trial and failure, contraindication, or intolerance to Haldol (haloperidol).
Age Restrictions	
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	Initial, Reauth: 12 months.

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PA Criteria	Criteria Details
Other Criteria	All indications (Reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XERMELO

PRODUCTS AFFECTED
- XERMELO

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

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XIFAXAN

PRODUCTS AFFECTED
- XIFAXAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Travelers' diarrhea (TD): Diagnosis of travelers' diarrhea. 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 (ppx) of hepatic encephalopathy (HE) recurrence (initial): Used for the prophylaxis of hepatic encephalopathy recurrence, AND One of the following: 1) Trial and failure, contraindication or intolerance to lactulose or 2) Add-on treatment to lactulose. Treatment (tx) of HE: Used for the treatment of HE. One of the following: 1) Trial and failure, contraindication, or intolerance to lactulose or 2) Add-on treatment to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide].
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	TD: 14 days. HE (tx): 12 months. HE (ppx) (init, reauth): 12 months. IBS-D (init, reauth): 2 weeks.
Other Criteria	Prophylaxis of HE recurrence (reauth): Patient demonstrates positive clinical response to therapy. IBS-D (reauth): Symptoms of IBS continue to persist. Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XOLAIR

PRODUCTS AFFECTED

- XOLAIR SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML, 300 MG/2ML, 75 MG/0.5ML
- XOLAIR SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 150 MG/ML, 300 MG/2ML, 75 MG/0.5ML
- XOLAIR SUBCUTANEOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Asthma (init): Diagnosis of moderate to severe persistent allergic asthma. Positive skin test or in vitro reactivity to a perennial aeroallergen. One of the following: A) All of the following: a) Patient is 6 years of age or older but less than 12 years of age, b) Pretreatment serum immunoglobulin (Ig)E level between 30 to 1300 IU/mL, c) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: i) Both of the following: 1) Medium-dose inhaled corticosteroid [ICS] (eg, greater than 100-200 mcg fluticasone propionate equivalent/day), and 2) Additional asthma controller medication (eg, leukotriene receptor antagonist [LTRA] [eg, montelukast], long-acting beta-2 agonist [LABA] [eg, salmeterol], long-acting muscarinic antagonist [LAMA] [eg, tiotropium]), OR ii) One medium dosed combination ICS/LABA product (eg, Wixela Inhub [fluticasone propionate 100mcg/salmeterol 50mcg], budesonide 80mcg/formoterol 4.5mcg, Breo Ellipta [fluticasone furoate 50 mcg/vilanterol 25 mcg]), OR B) All of the following: a)

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PA Criteria	Criteria Details
	Patient is 12 years of age or older, b) Treatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL, c) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: i) Both of the following: 1) High-dose ICS [eg, greater than 500 mcg fluticasone propionate equivalent/day], and 2) Additional asthma controller medication (eg, LTRA [eg, montelukast], LABA [eg, salmeterol], LAMA [eg, tiotropium]), OR ii) One maximally-dosed combination ICS/LABA product [eg, Wixela Inhub (fluticasone propionate 500mcg/salmeterol 50mcg), budesonide 160mcg/ formoterol 4.5mcg, Breo Ellipta (fluticasone 200mcg/vilanterol 25mcg)].
Age Restrictions	IgE-Mediated Food Allergy (init): Patient is 1 year of age or older.
Prescriber Restrictions	Asthma (init): Prescribed by or in consultation with an allergist/immunologist, or pulmonologist. CSU (init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist. CRSwNP (init/reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. IgE-Mediated Food Allergy (Init/Reauth): Prescribed by or in consultation with an allergist/immunologist.
Coverage Duration	Asthma, CSU, Allergy (init, reauth): 12 months. CRSwNP: 12 months.
Other Criteria	Asthma (reauth): Patient demonstrates positive clinical response to therapy. Chronic Spontaneous Urticaria (CSU) (init): Diagnosis of CSU. Persistent symptoms (itching and hives) with a second generation H1 antihistamine (eg, cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1

PA Criteria	Criteria Details
	antihistamines. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines. CSU (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. Chronic Rhinosinusitis with Nasal polyps (CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for chronic rhinosinusitis with nasal polyps. CRSwNP (reauth): Patient demonstrates positive clinical response to therapy. Used in combination with another agent for chronic rhinosinusitis with nasal polyps. IgE-Mediated Food Allergy (Initial): One of the following: A) Both of the following: 1) Diagnosis of IgE Mediated Food Allergy as evidenced by one of the following: a) Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food, b) Positive food specific IgE (greater than or equal to 6 kUA/L), c) Positive oral food challenge, defined as experiencing dose-limiting symptoms at a single dose of less than or equal to 300 mg of food protein, AND 2) Clinical history of IgE Mediated Food Allergy, OR B) Provider attestation that patient has a history of severe allergic response, including anaphylaxis, following exposure to one or more foods. Used in conjunction with food allergen avoidance. Baseline (pre-Xolair tx) serum total IgE level is greater than or equal to 30 IU/mL and less than or equal to 1850 IU/mL. Dosing is according to serum total IgE levels and body weight. IgE-Mediated Food Allergy (Reauth): Patient demonstrates positive clinical response to therapy. Used in conjunction with food allergen avoidance. Dosing will continue to be based on body weight and pretreatment total IgE serum levels.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XOLREMDI

PRODUCTS AFFECTED
- XOLREMDI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome. Patient has genotype confirmed variant of CXCR4 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has an absolute neutrophil count (ANC) less than 500 cells/-+L.
Age Restrictions	Initial: Patient is 12 years of age or older.
Prescriber Restrictions	Initial: Prescribed by or in consultation with one of the following: immunologist, hematologist, geneticist, dermatologist, or allergist.
Coverage Duration	Initial: 6 months, Reauth: 12 months
Other Criteria	Reauth: Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XOSPATA

PRODUCTS AFFECTED
- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XPOVIO

PRODUCTS AFFECTED

- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 10 MG, 40 MG
- XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 60 MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG, 80 MG
- XPOVIO (80 MG TWICE WEEKLY)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of Multiple Myeloma.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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XTANDI

PRODUCTS AFFECTED
- XTANDI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Castration-resistant prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) prostate cancer. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic castration-sensitive prostate cancer. Non-metastatic castrion-sensitive prostate cancer (nm-CSPC): Diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC). Patient has high-risk biochemical recurrence (BCR) defined by a PSA doubling time less than or equal to 9 months and one of the following: A) PSA values greater than or equal to 1 ng/mL if the patient had prior prostatectomy (with or without radiotherapy) OR B) PSA values at least 2 ng/mL above the nadir if the patient had prior radiotherapy only.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XYREM

PRODUCTS AFFECTED

- *sodium oxybate*

PA Criteria	Criteria Details
Exclusion Criteria	
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 One of the following: a) patient is under 18 years of age or b) 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	All Indications (initial): Patient is 7 years of age or older.
Prescriber Restrictions	All uses (initial): Prescribed by or in consultation with one of the following: neurologist, psychiatrist, or sleep medicine specialist.

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PA Criteria	Criteria Details
Coverage Duration	All uses (initial): 6 months. All uses (reauth): 12 months
Other Criteria	All uses (Reauth): Patient demonstrates positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

YONSA

PRODUCTS AFFECTED
- YONSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prostate Cancer: Diagnosis of castration-resistant (chemical or surgical) prostate cancer. Trial and failure or intolerance to Xtandi (enzalutamide).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

YULITHIRA

PRODUCTS AFFECTED
- YULITHIRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Both of the following: Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) AND Additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ZAVESCA

PRODUCTS AFFECTED

- *miglustat*
- YARGESA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease. Niemann-Pick disease type C (NPC) (off-label) (initial): Diagnosis of NPC. Requested drug will be used in combination with Miplyffa (arimoclomol).
Age Restrictions	Gaucher disease: Patient is 18 years of age or older.
Prescriber Restrictions	NPC (initial): Prescribed by or in consultation with a specialist knowledgeable in the treatment of Niemann-Pick disease type C.
Coverage Duration	Gaucher disease: 12 months. NPC (initial): 6 months, (reauth): 12 months.
Other Criteria	NPC (reauth): Patient demonstrates positive clinical response to therapy. Requested drug will be used in combination with Miplyffa (arimoclomol).
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ZEJULA

PRODUCTS AFFECTED

- ZEJULA ORAL TABLET 100 MG, 200 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ZELBORAF

PRODUCTS AFFECTED
- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	All indications: Approve for continuation of therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZOKINVY

PRODUCTS AFFECTED
- ZOKINVY

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

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZOLINZA

PRODUCTS AFFECTED
- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ZTALMY

PRODUCTS AFFECTED

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). Patient has a mutation in the CDKL5 gene.
Age Restrictions	Patient is 2 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ZURZUVAE

PRODUCTS AFFECTED

- ZURZUVAE ORAL CAPSULE 20 MG, 25 MG, 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Postpartum Depression (PPD): Diagnosis of PPD. Onset of symptoms in the third trimester or within 4 weeks of delivery. Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 12 hours after taking each dose of Zurzuvae for the duration of the 14-day treatment course and that patients are informed that they may not be able to assess their own driving competence or the degree of driving impairment caused by Zurzuvae.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	14 days

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PA Criteria	Criteria Details
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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ZYDELIG

PRODUCTS AFFECTED
- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	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]).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZYKADIA

PRODUCTS AFFECTED
- ZYKADIA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
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	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZYTIGA

PRODUCTS AFFECTED

- *abiraterone acetate*
- ABIRTEGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Castration-Resistant Prostate Cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Castration-Sensitive Prostate Cancer (CSPC): Diagnosis of castration-sensitive prostate cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	CRPC, CSPC: 12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.

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PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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