

# ACTEMRA

## Products Affected

- ACTEMRA INTRAVENOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried
<b>Age Restrictions</b>	(Initial therapy only): GCA/RA-18 years and older. PJIA/SJIA-2 years and older.
<b>Prescriber Restrictions</b>	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	RA initial - approve if the patient meets one of the following (A or B): A) patient has tried ONE of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq or Xeljanz/XR (Note: if the patient does not meet this requirement, previous trial(s) with: Cimzia, Kevzara, infliximab, golimumab SC/IV, Orencia or a non-preferred adalimumab product will also count.). OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial-approve if the patient meets one of the following (A or B): A) patient has tried ONE of the following drugs in the past: Enbrel, Rinvoq, Xeljanz or a preferred adalimumab product. (Note: if the patient does not meet this requirement, a previous trial with the drug Kevzara, infliximab, Orencia or a non-preferred adalimumab product will be counted.), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Systemic-onset JIA, approve. Giant cell arteritis, initial-approve if the patient has tried or is currently taking a systemic corticosteroid or corticosteroid is contraindicated. Cont tx, RA/PJIA/SJIA/GCA - approve if the pt had a response as determined by the prescriber. Cytokine release syndrome associated with chimeric antigen receptor (CAR) T-Cell therapy-approve. Please Note: preferred adalimumab products include Hadlima, Simlandi.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ACTEMRA SQ

## Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	Interstitial lung disease-18 years and older (initial and continuation). GCA/RA-18 years and older (initial only). SJIA/PJIA-2 years and older (initial only).
<b>Prescriber Restrictions</b>	RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA) [A or B]: A) tried one of the following: Enbrel, preferred adalimumab product (see Example 1), Rinvoq or Xeljanz/XR (Note: trials with the following will also count: Cimzia, infliximab, Kevzara, golimumab SC/IV, non-preferred adalimumab product, Orencia), or B) heart failure or a previously treated lymphoproliferative disorder. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A or B]: A) tried one of the following: Enbrel, Rinvoq, Xeljanz, preferred adalimumab product. (Note: trials with Kevzara, infliximab, Orencia or a non-preferred adalimumab product will also count), or B) heart failure or a previously treated lymphoproliferative disorder. SYSTEMIC-ONSET JIA (SJIA): Approve. GIANT CELL ARTERITIS: tried or is currently taking a one systemic CS or CS is contraindicated. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) elevated acute phase reactants and B) diagnosis confirmed by high-resolution computed tomography. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Example 1: preferred adalimumab products include Hadlima, Simlandi.
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ACTIMMUNE

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## Products Affected

- ACTIMMUNE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Chronic granulomatous disease - prescribed by or in consultation with an immunologist, hematologist or infectious disease specialist. Malignant osteopetrosis- prescribed by or in consultation with an endocrinologist or hematologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Chronic granulomatous disease - approve if diagnosis has been established by a molecular genetic test identifying a gene-related pathogenic variant linked to chronic granulomatous disease. Malignant osteopetrosis, severe - approve if pt has had radiographic (X-ray) imaging demonstrating skeletal features related to osteopetrosis or pt had a molecular genetic test identifying a gene-related pathogenic variant linked to severe, malignant osteopetrosis.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ACYCLOVIR (TOPICAL)

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## Products Affected

- *acyclovir topical ointment*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ADALIMUMAB

## Products Affected

- HADLIMA
- HADLIMA PUSH TOUCH
- HADLIMA(CF)
- HADLIMA(CF) PUSH TOUCH
- SIMLANDI(CF) AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML
- SIMLANDI(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Initial therapy only: CD-6 years and older, UC-5 years and older, AS/PsA/RA/PP/ Pyoderma gangrenosum/ sarcoidosis/ scleritis/ sterile corneal ulceration/ non-radiographic axial spondyloarthritis-18 years and older, JIA/UV/Behcet's disease-2 years and older, HS-12 years and older
<b>Prescriber Restrictions</b>	Initial therapy only for all dx, prescribed by or in consultation with one of the following specialists-RA/JIA/JRA/Ankylosing spondylitis/nr-axSpA, rheumatologist. PsA, rheumatologist or dermatologist. PP, dermatologist. UC/ CD, gastroenterologist. HS/pyoderma gangrenosum - dermatologist.UV/scleritis/sterile corneal ulceration-ophthalmologist. Behcet's- rheum, dermatologist, ophthalmologist, gastro, neuro. Sarcoidosis, pulm, ophthalmologist, dermatologist.
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: CROHN'S DISEASE (CD): approve. JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA (one of A, B, C, D, or E): A) tried one other systemic therapy (e.g., MTX, sulfasalazine, leflunomide, NSAID), B) tried a biologic (e.g., etanercept, abatacept, infliximab, anakinra, tocilizumab), C) will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide, D) patient has absolute contraindication to MTX, sulfasalazine, or leflunomide, or E) patient has aggressive disease. HIDRADENITIS SUPPURATIVA (HS): tried one other therapy (e.g., intralesional or oral CS, systemic antibiotics,

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>isotretinoin). PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of a biologic will also count) or B) contraindication to MTX. RHEUMATOID ARTHRITIS (RA): tried one conventional synthetic DMARD for at least 3 months (Note: a 3-month trial of a biologic will also count). ULCERATIVE COLITIS: approve. BEHCET'S DISEASE (A or B): A) tried one conventional therapy (e.g., systemic CS, azathioprine, MTX, CSA, chlorambucil, cyclophosphamide, interferon alfa), or B) has ophthalmic manifestations. SARCOIDOSIS (A and B): A) tried one CS, and B) tried one immunosuppressant (e.g. MTX, mycophenolate mofetil, chlorambucil, thalidomide, infliximab, chloroquine). SCLERITIS/STERILE CORNEAL ULCERATION: tried one other therapy (e.g. CS, CSA). NON RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation defined as either (A or B): A) C-reactive protein elevated beyond upper limit of normal, or B) sacroiliitis on MRI. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Behcet's disease, pyoderma gangrenosum, sarcoidosis, scleritis/sterile corneal ulceration, non-radiographic axial spondyloarthritis.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ADBRY

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## Products Affected

- ADBRY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with another monoclonal antibody therapy (examples: Dupixent, Cinqair, Ebglyss, Fasentra, Nemluvio, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical] (examples: Cibinco, Leqselvi, Rinvoq/LQ, Opzelura)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	AD-12 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
<b>Coverage Duration</b>	Initial-Atopic Dermatitis-4 months, Continuation-1 year
<b>Other Criteria</b>	Atopic Dermatitis, initial-approve. Continuation- Approve if the patient has been receiving Adbry for at least 4 months and patient has responded to therapy. Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Adbry should be considered under initial therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ADEMPAS

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## Products Affected

- ADEMPAS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ADSTILADRIN

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## Products Affected

- ADSTILADRIN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a urologist or an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Non-Muscle Invasive Bladder Cancer, approve initial therapy if the patient meets (A and B): A) patient has high-risk, Bacillus Calmette-Guerin (BCG)-unresponsive disease, and B) the patient has carcinoma in situ (CIS) OR the patient has high-grade papillary Ta/T1 tumors without CIS. Non-Muscle Invasive Bladder Cancer, continuation of therapy - approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# AIMOVIG

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## Products Affected

- AIMOVIG AUTOINJECTOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination therapy with another cGRP inhibitor for migraine headache prevention
<b>Required Medical Information</b>	Diagnosis, number of migraine headaches per month
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) If pt is currently taking Aimovig, the pt has had significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Aimovig was initiated.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# AKEEGA

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## Products Affected

- AKEEGA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Prostate cancer, metastatic castration-resistant or metastatic castration-sensitive- Approve if the patient meets the following (A, B, and C): A) Patient has a Breast Cancer (BRCA) mutation, AND B) The medication is used in combination with prednisone, AND C) Patient meets one of the following (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog, Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), and Orgovyx (relugolix tablets). OR ii. Patient has had a bilateral orchiectomy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Effective 05/01/2026

# ALDURAZYME

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## Products Affected

- ALDURAZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has a laboratory test demonstrating deficient alpha-L-iduronidase activity in leukocytes, fibroblasts, plasma, or serum OR has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic alpha-L-iduronidase gene variants.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ALECENSA

## Products Affected

- ALECENSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Pediatric diffuse high grade glioma- less than or equal to 21 years old, All others- 18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Non-small cell lung cancer-approve if the patient has both (A and B): A) either (i or ii): i) medication is used as adjuvant treatment following tumor resection (note: for tumors greater than or equal to 4 cm or node positive) or ii) advanced or metastatic disease and B) anaplastic lymphoma kinase (ALK)-positive disease as detected by an approved test. Anaplastic large cell lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease and (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor- pt has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) pt has advanced, recurrent or metastatic disease, or (ii) tumor is inoperable. Large B-Cell Lymphoma- pt has ALK-positive disease AND pt has relapsed or refractory disease. Pediatric diffuse high grade glioma- approve if (A and B): A) ALK-positive disease, and B) either (i or ii): i) medication is used as adjuvant treatment AND tumor is not diffuse midline glioma, H3 K27-altered or pontine location, or ii) medication is used for recurrent or progressive disease.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma, Pediatric Diffuse High Grade Glioma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ALOSETRON

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## Products Affected

- *alosetron*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ALPHA 1 PROTEINASE INHIBITORS

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## Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Alpha1-Antitrypsin Deficiency with Emphysema (or Chronic Obstructive Pulmonary Disease)-approve if the patient has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ALUNBRIG

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## Products Affected

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLETS,DOSE PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	ALK status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has ALK positive disease and has advanced, recurrent or metastatic disease or the tumor is inoperable. NSCLC, must be ALK-positive, as detected by an approved test, have advanced or metastatic disease and patients new to therapy must have a trial of Alecensa, Ensacove or Lorbrina prior to approval of Alunbrig. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT), Peripheral T-Cell Lymphoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ANKTIVA

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## Products Affected

- ANKTIVA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist (initial/maintenance therapy)
<b>Coverage Duration</b>	Initial-6 months, Maintenance-3 months
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. INITIAL-NON-MUSCLE INVASIVE BLADDER CANCER-all of (i, ii, iii): i) Patient has high risk Bacillus Calmette-Guerin (BCG) unresponsive disease, AND ii) Patient has carcinoma in situ, AND iii) Medication is used in combination with BCG.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ANTIBIOTICS (IV)

## Products Affected

- *amikacin injection solution 1,000 mg/4 ml, 500 mg/2 ml*
- *ampicillin sodium injection recon soln 1 gram, 10 gram, 2 gram, 250 mg, 500 mg*
- *ampicillin sodium intravenous*
- *ampicillin-sulbactam*
- *azithromycin intravenous*
- *aztreonam*
- **BICILLIN L-A**
- *cefoxitin*
- *cefoxitin in dextrose, iso-osm*
- *ceftazidime*
- *cefuroxime sodium injection recon soln 750 mg*
- *cefuroxime sodium intravenous*
- *ciprofloxacin in 5 % dextrose*
- *clindamycin in 5 % dextrose*
- *clindamycin phosphate injection*
- *colistin (colistimethate na)*
- *doxy-100*
- *doxycycline hyclate intravenous*
- *ertapenem*
- *gentamicin in nacl (iso-osm) intravenous piggyback 100 mg/100 ml, 60 mg/50 ml, 80 mg/100 ml, 80 mg/50 ml*
- *gentamicin injection*
- *gentamicin sulfate (ped) (pf)*
- *imipenem-cilastatin*
- *levofloxacin in d5w*
- *levofloxacin intravenous*
- *lincomycin*
- *linezolid in dextrose 5%*
- *linezolid-0.9% sodium chloride*
- *meropenem intravenous recon soln 1 gram, 2 gram, 500 mg*
- *metro i.v.*
- *metronidazole in nacl (iso-os)*
- *moxifloxacin-sod.chloride(iso)*
- *nafcillin in dextrose iso-osm intravenous piggyback 2 gram/100 ml*
- *nafcillin injection*
- *oxacillin*
- *oxacillin in dextrose(iso-osm) intravenous piggyback 2 gram/50 ml*
- **PENICILLIN G POT IN DEXTROSE INTRAVENOUS PIGGYBACK 2 MILLION UNIT/50 ML, 3 MILLION UNIT/50 ML**
- *penicillin g potassium*
- *penicillin g sodium*
- *pfizerpen-g*
- **STREPTOMYCIN**
- *sulfamethoxazole-trimethoprim intravenous*
- *tazicef*
- **TEFLARO**
- *tigecycline*
- *tobramycin sulfate injection recon soln*
- *tobramycin sulfate injection solution*
- **VIBATIV INTRAVENOUS RECON SOLN 750 MG**

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ANTIFUNGALS (IV)

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## Products Affected

- *fluconazole in nacl (iso-osm) intravenous piggyback 200 mg/100 ml, 400 mg/200 ml*
- *voriconazole*
- *voriconazole-hpbc*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# ARCALYST

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## Products Affected

- ARCALYST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent biologic therapy
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age.
<b>Prescriber Restrictions</b>	Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA initial-rheum, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum
<b>Coverage Duration</b>	CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont
<b>Other Criteria</b>	INITIAL THERAPY: DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) [ all of A, B, and C]: A) weighs at least 10 kg, B) genetic test has confirmed bi-allelic pathogenic variants in the IL1RN gene, and C) had clinical benefit with anakinra subcutaneous injection. PERICARDITIS: pericarditis is recurrent. CONTINUATION THERAPY: ALL INDICATIONS: patient had a positive response to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ARIKAYCE

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## Products Affected

- ARIKAYCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous medication history (as described in Other Criteria field)
<b>Age Restrictions</b>	MAC-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>INITIAL THERAPY: MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE (all of A, B, and C): A) positive sputum culture for MAC [Note: any positive sputum culture taken after completion of a background multidrug regimen (throughout, see Example 1 below) fulfills this criterion], B) MAC isolate is susceptible to amikacin, and C) Arikayce will be used in combination with a background multidrug regimen.</p> <p>CONTINUATION THERAPY: MAC LUNG DISEASE (A and B): A) Arikayce prescribed in combination with a background multidrug regimen and B) patient meets one of the following (a or b): a) patient has not achieved negative sputum cultures for MAC or b) patient has achieved negative sputum cultures for MAC for less than 12 months. Example 1: background multidrug regimen example - a macrolide (azithromycin or clarithromycin), ethambutol, and a rifamycin (rifampin or rifabutin).</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# ASPARLAS

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## Products Affected

- ASPARLAS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	1 month to 21 years
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# AUBAGIO

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## Products Affected

- *teriflunomide*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use of teriflunomide with other disease-modifying agents used for multiple sclerosis (MS)
<b>Required Medical Information</b>	Relapsing form of MS, to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# AUGTYRO

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## Products Affected

- AUGTYRO ORAL CAPSULE 160 MG, 40 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	NSCLC - 18 and older, Solid tumors - 12 and older, Pediatric Diffuse High-Grade Glioma-less than 18
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Non-Small Cell Lung Cancer-approve if the patient has locally advanced or metastatic disease, patient has ROS1-positive non-small cell lung cancer and the mutation was detected by an approved test. Note: If the patient has non-small cell lung cancer with neurotrophic receptor tyrosine kinase (NTRK) gene fusion, see Solid Tumors indication. Solid tumors - approve if tumor is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND tumor is locally advanced or metastatic or surgical resection will likely result in severe morbidity. Pediatric Diffuse High-Grade Gliomas - approve if tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used as adjuvant therapy or for recurrent or progressive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pediatric Diffuse High-Grade Gliomas
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# AUSTEDO

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## Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR
- AUSTEDO XR TITRATION KT(WK1-4) ORAL TABLET, EXT REL 24HR DOSE PACK 12-18-24-30 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	TD - Prescribed by or in consultation with a neurologist or psychiatrist. Chorea HD - prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing. Tardive dyskinesia-approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# AVMAPKI-FAKZYNJA

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## Products Affected

- AVMAPKI-FAKZYNJA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER- ALL of the following (A, B and C): A) Patient has recurrent low-grade serous cancer, AND B) The cancer has a KRAS mutation, AND C) Patient has tried at least one systemic therapy. Note: Examples of systemic therapy include one or more of the following medications: paclitaxel, carboplatin, bevacizumab, letrozole, anastrozole, or exemestane.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Fallopian Tube or Primary Peritoneal Cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# AVONEX

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## Products Affected

- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use of other disease-modifying agent used for multiple sclerosis
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or after consultation with a neurologist or an MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# AYVAKIT

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## Products Affected

- AYVAKIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation or if the patient has tried two of the following: Gleevec (imatinib), Sutent (sunitinib), Sprycel (dasatinib), Stivarga (regorafenib) or Qinlock (ripretinib). Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for PDGFRA D842V mutation. Systemic mastocytosis-Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has either indolent systemic mastocytosis or one of the following subtypes of advanced systemic mastocytosis-aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm or mast cell leukemia.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myeloid/Lymphoid neoplasms with Eosinophilia
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# BALVERSA

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## Products Affected

- BALVERSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy, other chemotherapy or checkpoint inhibitor therapy.</p> <p>Pancreatic adenocarcinoma- approve if (A, B, C and D): A) patient has a fibroblast growth factor receptor (FGFR) genetic alterations, and B) locally advanced, recurrent or metastatic disease, and C) medication is used for subsequent therapy and D) medication is used as a single agent. NSCLC- approve if patient has metastatic disease and FGFR alterations.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pancreatic adenocarcinoma, non-small cell lung cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# BENLYSTA

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## Products Affected

- BENLYSTA

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or Lupkynis
Required Medical Information	Diagnosis
Age Restrictions	5 years and older (initial).
Prescriber Restrictions	SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)
Coverage Duration	1 year
Other Criteria	Lupus Nephritis Initial-approve if the patient has a diagnosis of lupus nephritis confirmed on biopsy (For example, World Health Organization class III, IV, or V lupus nephritis), AND the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid). Cont-approve if the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid) AND the patient has responded to Benlysta subcutaneous or intravenous. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA [anti-dsDNA] antibody AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity. Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to

<b>PA Criteria</b>	<b>Criteria Details</b>
	be intolerant due to a significant toxicity AND The patient has responded to Benlysta subcutaneous or intravenous.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# BENLYSTA IV

## Products Affected

- BENLYSTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	5 years and older (initial).
<b>Prescriber Restrictions</b>	SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)
<b>Coverage Duration</b>	SLE-Initial-4 months, cont-1 year, Lupus Nephritis-6 mo initial, 1 year cont
<b>Other Criteria</b>	Lupus Nephritis Initial-approve if the patient has a diagnosis of lupus nephritis confirmed on biopsy (For example, World Health Organization class III, IV, or V lupus nephritis), AND the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid). Cont-approve if the medication is being used concurrently with an immunosuppressive regimen (ex: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil and/or a systemic corticosteroid) AND the patient has responded to Benlysta subcutaneous or intravenous. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA [anti-dsDNA] antibody AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity. Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to

<b>PA Criteria</b>	<b>Criteria Details</b>
	be intolerant due to a significant toxicity AND The patient has responded to Benlysta subcutaneous or intravenous.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# BESREMI

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## Products Affected

- BESREMI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with other interferon products
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# BETASERON/EXTAVIA

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## Products Affected

- BETASERON SUBCUTANEOUS KIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agent used for multiple sclerosis
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or after consultation with a neurologist or an MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# BEXAROTENE (ORAL)

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## Products Affected

- *bexarotene*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# BEXAROTENE (TOPICAL)

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## Products Affected

- *bexarotene*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Cutaneous T-Cell lymphoma-approve if pt has cutaneous manifestations/lesions. Adult T-Cell Leukemia/Lymphoma- approve if the patient has smoldering symptomatic subtype and this medication is used as first-line therapy. Primary cutaneous B-Cell lymphoma-approve if used as skin-directed therapy for either (a or b): a) primary cutaneous marginal zone lymphoma or b) follicle center lymphoma.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Adult T-Cell Leukemia/Lymphoma, Primary Cutaneous B-Cell Lymphoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# BIZENGRI

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## Products Affected

- BIZENGRI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>NON-SMALL CELL LUNG CANCER-All of (A, B and C): A) Patient has advanced, unresectable, or metastatic disease, AND B) The disease is neuregulin 1 (NRG1) gene fusion positive, AND C) Patient has tried at least one systemic regimen. Note: Examples of a systemic regimen include one or more of the following drugs: carboplatin, cisplatin, or programmed cell death protein 1 (PD)-1 or PD-ligand 1 (PD-L1) blockers.</p> <p>PANCREATIC ADENOCARCINOMA-All of (A, B and C): A) Patient has advanced, unresectable, or metastatic disease, AND B) The disease is neuregulin 1 (NRG1) gene fusion positive, AND C) Patient has tried at least one systemic regimen. Note: Examples of systemic regimen include one or more of the following drugs: fluorouracil, leucovorin, irinotecan, oxaliplatin, gemcitabine, paclitaxel, capecitabine.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# BLNREP

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## Products Affected

- BLNREP

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Approve if (A, B and C): A) the patient has tried at least two prior systemic lines of therapy and B) has received at least one drug from each of the following drug classes- proteasome inhibitor, [ex: bortezomib, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules)] and immunomodulatory drug [ex: lenalidomide, Pomalyst (pomalidomide capsules), and Thalomid (thalidomide capsules], and C) will be used in combination with bortezomib and dexamethasone.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# BONIVA INJECTION

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## Products Affected

- *ibandronate intravenous*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other medications for Osteoporosis
<b>Required Medical Information</b>	Diagnosis, test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Treatment of postmenopausal osteoporosis, must meet ONE of the following 1. T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, or total hip, 2. has had osteoporotic fracture or fragility fracture, 3. had a T-score (current or at any time in the past) between 1.0 and -2.5 at the lumbar spine, femoral neck, or total hip and the physician determines the patient is at high risk for fracture AND has had an inadequate response to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescribing physician (e.g., ongoing and significant loss of bone mineral density (BMD), lack of BMD increase), had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy, or experienced intolerability to an oral bisphosphonate (e.g., severe GI-related adverse effects) OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid) OR the patient has had an osteoporotic fracture or a fragility fracture.
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# BOSENTAN/AMBRISENTAN

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## Products Affected

- *ambrisentan*
- *bosentan oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For treatment of pulmonary arterial hypertension, ambrisentan or bosentan must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH - prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan)
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# BOSULIF

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## Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	ALL - 15 years and older. Myeloid/lymphoid neoplasms w eosinophilia- 18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	CML-approve if the patient has Ph-positive or BCR::ABL1-positive CML. For Ph-positive ALL-approve if pt has tried at least one other tyrosine kinase inhibitor for Ph+ ALL. Myeloid/lymphoid neoplasms with eosinophilia - approve if tumor has an ABL1 rearrangement.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia, myeloid/lymphoid neoplasms with eosinophilia
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# BRAFTOVI

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## Products Affected

- BRAFTOVI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. Colon or Rectal cancer-approve if the patient meets the following (A and B): A) The patient has BRAF V600E mutation-positive disease AND B) meets (i or ii): i) will be used as first-line systemic therapy for metastatic disease in combination with (a and b) a) Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion) and b) FOLFOX (5-FU, leucovorin, and oxaliplatin) or ii) patient has previously received a chemotherapy regimen for colon or rectal cancer and this is prescribed in combination with Erbitux or Vectibix (panitumumab intravenous infusion). NSCLC-approve if pt has BRAF V600E mutation-positive recurrent, advanced or metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets). Appendiceal adenocarcinoma-approve if (A, B and C): A) BRAF V600E mutation-positive, and B) pt has advanced or metastatic disease, and C) used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Appendiceal adenocarcinoma
Part B Prerequisite	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# BRIUMVI

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## Products Affected

- BRIUMVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
<b>Required Medical Information</b>	Relapsing form of MS, to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# BRUKINSA

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## Products Affected

- BRUKINSA ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Follicular Lymphoma - approve if pt tried at least two other systemic regimens and will use this in combination with Gazyva (obinutuzumab intravenous infusion). CLL/SLL - approve. Mantle Cell Lymphoma-approve if patient meets one of (A, B, C or D): A) tried at least one systemic regimen, or B) is not a candidate for a chemotherapy regimen, or C) will use this medication in combination with rituximab, or D) patient has TP53 mutation and this medication is used as induction therapy in combination with Venclexta (venetoclax tablets) and Gazyva (obinutuzumab intravenous infusion). Marginal zone lymphoma-approve if the patient has tried at least one systemic regimen. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma-approve. Hairy Cell Leukemia - approve if pt has received therapy for relapsed or refractory disease AND pt has progressive disease. Primary Central Nervous System Lymphoma - approve if pt has tried at least one systemic regimen and the medication is used in combination with autologous stem cell reinfusion.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Hairy Cell Leukemia, Primary Central Nervous System Lymphoma
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# BYOOVIZ

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## Products Affected

- BYOOVIZ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Administered by or under the supervision of an ophthalmologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Retinopathy of prematurity, diabetic retinopathy, diabetic macular edema
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# C1 ESTERASE INHIBITORS

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## Products Affected

- CINRYZE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II], Prophylaxis, Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50 percent of normal) at baseline and lower than normal serum C4 levels at baseline. Patient is currently taking Cinryze for prophylaxis - approve if the patient meets the following criteria (i and ii): i) patient has a diagnosis of HAE type I or II, and ii) according to the prescriber, the patient has had a favorable clinical response since initiating Cinryze as prophylactic therapy compared with baseline. HAE with Normal (C1-INH) [Type III], Prophylaxis: Approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CABLIVI

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## Products Affected

- CABLIVI INJECTION KIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, concurrent medications
<b>Age Restrictions</b>	12 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist
<b>Coverage Duration</b>	Approve for 12 months
<b>Other Criteria</b>	aTTP-approve if the requested medication was initiated in the inpatient setting in combination with plasma exchange therapy AND patient is currently receiving at least one immunosuppressive therapy AND if the patient has previously received Cablivi, he/she has not had more than two recurrences of aTTP while on Cablivi.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CABOMETYX

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## Products Affected

- CABOMETYX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, histology, RET gene rearrangement status for NSCLC
<b>Age Restrictions</b>	Neuroendocrine tumor/Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried Lenvima or sorafenib. Endometrial carcinoma-approve if the patient has tried one systemic regimen. GIST-approve if the patient has tried two of the following-imatinib, Ayvakit, sunitinib, dasatinib, Stivarga or Qinlock. NSCLC-approve if the patient has RET rearrangement positive tumor and has progressed on one of the first-line therapies, Gavreto (pralsetinib capsules) or Retevmo (selpercatinib capsules or tablets). Neuroendocrine tumors- approve if (A, B, C and D): A) pt has locally advanced, unresectable, or metastatic disease, and B) patient has well-differentiated neuroendocrine tumors, and C) patient has pancreatic or extra-pancreatic neuroendocrine tumors and D) the medication will be used as subsequent therapy. Adrenal gland tumor- approve if pt has locoregional unresectable or metastatic adrenocortical carcinoma. Pheochromocytoma/paraganglioma- approve if pt has locally unresectable disease.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Non-Small Cell Lung Cancer, Gastrointestinal stromal tumors (GIST), Bone cancer, Endometrial carcinoma, Adrenal gland tumor, Pheochromocytoma/paraganglioma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# CALQUENCE

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## Products Affected

- CALQUENCE (ACALABRUTINIB MAL)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	CLL and SLL-approve. Mantle Cell Lymphoma- approve if the patient meets (A or B): A) has tried at least one systemic regimen or is not a candidate for a systemic regimen (e.g., rituximab, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, bortezomib, or lenalidomide) or B) this medication is used in combination with rituximab. Marginal Zone Lymphoma-approve if patient has tried at least one systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, lenalidomide, or chlorambucil). Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen (e.g., Brukinsa [zanubrutinib capsules], Imbruvica [ibrutinib tablets and capsules], rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, fludarabine, or cladribine)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma.
Part B Prerequisite	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# CAMZYOS

## Products Affected

- CAMZYOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial and continuation)
<b>Prescriber Restrictions</b>	Prescribed by a cardiologist (initial and continuation)
<b>Coverage Duration</b>	Initial-8 months, continuation- 1 year
<b>Other Criteria</b>	<p>Obstructive hypertrophic cardiomyopathy, initial-Approve if the pt meets the following criteria (i, ii and iii): i.Pt meets both of the following (a and b): a)Pt has at least 1 symptom associated w/obstructive hypertrophic cardiomyopathy (Note: examples include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise), AND b)Pt has New York Heart Association Class II or III symptoms of heart failure (Note:Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest), AND ii.Pt has left ventricular hypertrophy and meets 1 of the following (a or b): a)Pt has maximal left ventricular wall thickness greater than or equal to 15 mm, OR b)Pt has familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness greater than or equal to 13 mm, AND iii.Pt has a peak left ventricular outflow tract gradient greater than or equal to 50 mmHg (at rest or after provocation [Valsalva maneuver or post exercise]). Cont-Approve if pt meets ALL of the following criteria (i, ii, iii and iv): i.Pt has been established on therapy for at least 8 months (Note: pt who has received less than 8 months of therapy or who is restarting therapy is reviewed under initial therapy), AND ii.Pt meets both of the following (a and b): a)Currently or prior to starting therapy, pt has or has experienced at least 1 symptom associated with obstructive hypertrophic cardiomyopathy, AND</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>b)Currently or prior to starting therapy, pt is in or was in New York Heart Association Class II or III heart failure, AND iii.Pt has a current left ventricular ejection fraction of greater than or equal to 50 percent, AND iv.Pt meets at least 1 of the following (a or b): a)Pt experienced a beneficial clinical response when assessed by at least 1 objective measure (Note:Examples include improved peak oxygen consumption/mixed venous oxygen tension, decreases in left ventricular outflow tract gradient, reductions in N-terminal pro-B-type natriuretic peptide levels, decreased high-sensitivity cardiac troponin I levels, reduced ventricular mass index, and/or a reduction in maximum left atrial volume index), OR b)Pt experienced stabilization or improvement in at least 1 symptom related to obstructive hypertrophic cardiomyopathy (Note:Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, ability to perform physical exercise, and/or favorable changes in the Kansas City Cardiomyopathy Questionnaire-23 (KCCQ-23) Clinical Summary Score (CSS) or Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ) Shortness of Breath domain scores.)</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CAPRELSA

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## Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	MTC - approve. DTC - approve if refractory to radioactive iodine therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CARGLUMIC ACID

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## Products Affected

- *carglumic acid*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases
<b>Coverage Duration</b>	NAGS-Pt meets criteria no genetic test - 3mo. Pt had genetic test - 12mo, other-approve 7 days
<b>Other Criteria</b>	N-Acetylglutamate synthase deficiency with hyperammonemia-Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency or if the patient has hyperammonemia. Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia, Acute Treatment-approve if the patient's plasma ammonia level is greater then or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (generic carglumic acid)
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CAYSTON

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## Products Affected

- CAYSTON

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist, infectious diseases specialist or a physician who specializes in the treatment of cystic fibrosis.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has <i>Pseudomonas aeruginosa</i> in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CEPROTIN

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## Products Affected

- CEPROTIN (BLUE BAR)
- CEPROTIN (GREEN BAR)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Protein C Deficiency, Severe-approve if the patient meets the following criteria A, B and C: A) The diagnosis of protein C deficiency is confirmed by at least one of the following (i, ii, or iii): i. Plasma protein C activity below the lower limit of normal based on the age-specific reference range for the reporting laboratory OR ii. Plasma protein C antigen below the lower limit of normal based on the age-specific reference range for the reporting laboratory OR iii. Genetic testing demonstrating biallelic pathogenic variants in the PROC gene AND B) Acquired causes of protein C deficiency have been excluded AND C) Patient has a current or prior history of symptoms associated with severe protein C deficiency (e.g., purpura fulminans, thromboembolism).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# CHEMET

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## Products Affected

- CHEMET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Blood lead level
<b>Age Restrictions</b>	Approve in patients between the age of 12 months and 18 years
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a professional experienced in the use of chelation therapy (eg, a medical toxicologist or a poison control center specialist)
<b>Coverage Duration</b>	Approve for 2 months
<b>Other Criteria</b>	Approve if Chemet is being used to treat acute lead poisoning (not as prophylaxis) and prior to starting Chemet therapy the patient's blood lead level was greater than 45 mcg/dL.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CIMZIA

## Products Affected

- CIMZIA
- CIMZIA POWDER FOR RECONST
- CIMZIA STARTER KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried
<b>Age Restrictions</b>	18 years and older for AS, nr-axSpA, PsA, RA, CD and PP (initial therapy). 2 years and older for JIA (initial therapy).
<b>Prescriber Restrictions</b>	All dx initial therapy only. RA, AS, JIA, prescribed by or in consultation with a rheumatologist. Crohn's disease, prescribed by or in consultation with a gastroenterologist. PsA prescribed by or in consultation with a rheumatologist or dermatologist. PP, prescribed by or in consultation with a dermatologist. nr-axSpA-prescribed by or in consultation with a rheumatologist
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	AS initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Xeljanz/XR, Cosentyx. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. PsA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Cosentyx, Tremfya, a preferred ustekinumab product, Otezla, Rinvoq, Skyrizi or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab/ustekinumab product will also count. RA initial tx, approve if the patient has tried two of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of another non-preferred adalimumab product will also count. CD initial tx, approve if patient has previously tried ONE of the following drugs in the past: a preferred adalimumab product, a preferred infliximab product, a preferred ustekinumab product, Skyrizi, Rinvoq, or Tremfya. Note: if the patient does not meet this requirement, a previous trial of another non-preferred

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>adalimumab/infliximab/ustekinumab product will also count. Plaque Psoriasis (PP), initial tx-approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product, Otezla, Cosentyx, Tremfya. A trial of a non-preferred adalimumab/ustekinumab also counts. JIA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, Rinvoq/LQ, Xeljanz, a preferred adalimumab product. Note pt does not meet this requirement, a trial with a non-preferred adalimumab, Simponi Aria, tocilizumab, Kevzara, or inflixmab will also count. Cont tx, AS/PsA/RA/CD/PP/JIA - approve if the pt had a response as determined by the prescriber. Non-radiographic axial spondylitis (nr-axSpA), initial tx-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroilitis reported on MRI. nr-axSpA continuation tx-approve if the patient has had a response as determined by the prescriber. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Otulfi, Pyzchiva, Selarsdi, Yesintek.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# CINACALCET

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## Products Affected

- *cinacalcet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Hypercalcemia d/t parathyroid CA-prescr/consult w/onco or endo. Hypercalcemia w/primary hyperparathyroidism-prescr/consult w/nephro or endo. Hyperparathyroidism in post-renal transplant-prescr/consult w/transplant physician/nephro/endo.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Hypercalcemia due to parathyroid carcinoma-approve. Hypercalcemia in patients with primary hyperparathyroidism-approve if the patient has failed or is unable to undergo a parathyroidectomy due to a contraindication. Secondary Hyperparathyroidism in patients with chronic kidney disease on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundles payment benefit). Hyperparathyroidism in Post-Renal Transplant Patients-approve if the baseline (prior to starting cinacalcet therapy) calcium and intact parathyroid hormone (iPTH) levels are above the normal range, as defined by the laboratory reference values.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	hyperparathyroidism in post-renal transplant patients
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CLOBAZAM

## Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*
- SYMPAZAN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other medications tried
<b>Age Restrictions</b>	2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist (initial therapy)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Lennox-Gastaut Syndrome, initial therapy-patient has tried and/or is concomitantly receiving one of the following: lamotrigine, topiramate, rufinamide, felbamate, Fintepla, Epidiolex or valproic acid. Treatment refractory seizures/epilepsy, initial therapy-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Continuation-prescriber confirms patient is responding to therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Dravet Syndrome and treatment-refractory seizures/epilepsy
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# CLOMIPHENE

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## Products Affected

- *clomid*
- *clomiphene citrate*
- *milophene*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Use in patients for infertility
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Woman (a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Male hypogonadism
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# COLUMVI

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## Products Affected

- COLUMVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-cell lymphoma-approve if the patient has received one or more lines of systemic therapy and the patient has or will receive pretreatment with obinutuzmab intravenous infusion before the first dose of Columvi. Note: Examples of diffuse large B-cell lymphoma (DLBCL) include DLBCL not otherwise specified, high-grade B-cell lymphoma, and DLBCL arising from indolent lymphoma. Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and DHA (dexamethasone, cytarabine) plus platinum (carboplatin, cisplatin, or oxaliplatin) plus/minus rituximab. Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma-approve if the patient has received one or more lines of systemic therapy and the patient has or will receive pretreatment with obinutuzmab intravenous infusion before the first dose of Columvi. Note: HIV-related B-cell lymphomas includes HIV-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus-8 (HHV8) positive DLBCL or for HIV-related plasmablastic lymphoma. Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and R-EPOCH (rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin). Post-transplant lymphoproliferative disorders- approve if the patient has received one or more lines of systemic</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	therapy and the patient has or will receive pretreatment with obinutuzmab intravenous infusion before the first dose of Columvi. Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma. Post-transplant lymphoproliferative disorders.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# COMETRIQ

## Products Affected

- COMETRIQ ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY(80 MG X1-20 MG X1), 140 MG/DAY (20 MG X 3/DAY)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	MTC - approve. Non-Small Cell Lung Cancer-approve if patient meets (A, B and C): A) recurrent, advanced, or metastatic disease, B) has RET gene rearrangement-positive tumor, and C) has progressed on one of the first-line therapies, Gavreto (pralsetinib capsules) or Retevmo (selpercatinib capsules or tablets). Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy and patient has tried Lenvima (lenvatinib capsules) or sorafenib tablets.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# COPIKTRA

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## Products Affected

- COPIKTRA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma - approve if the patient has tried at least one Bruton tyrosine kinase inhibitor (examples: ibrutinib, zanubrutinib, acalabrutinib, pirtobrutinib) and at least one Venclexta (venetoclax)- based regimen. T-cell lymphoma- For peripheral T-cell lymphoma, approve. For breast implant-associated anaplastic large cell lymphoma, or hepatosplenic T-cell lymphoma, approve if the patient has relapsed or refractory disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	T-cell Lymphoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# COSENTYX

## Products Affected

- COSENTYX (2 SYRINGES)
- COSENTYX PEN
- COSENTYX PEN (2 PENS)
- COSENTYX SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.5 ML
- COSENTYX UNOREADY PEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis and previous medications use
<b>Age Restrictions</b>	PP-6 yr and older.AS/Spondy/HS initial - 18 years of age and older. PsA-2 years and older. Enthesitis-4 years and older
<b>Prescriber Restrictions</b>	PP initial-presc/consult derm. PsA initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS/spondylo/enthesitis initial- by or in consultation with rheumatologist. HS initial - by or in consult w/ dermatologist
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: HIDRADENITIS SUPPURATIVA (HS): tried at least one other therapy (e.g. systemic antibiotics, isotretinoin). NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation and meets a or b: a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI. PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of at least one biologic that is not Cosentyx or a Cosentyx biosimilar also counts) or B) contraindication to MTX. CONTINUATION THERAPY: ALL INDICATIONS: patient has experienced benefit from the medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# COSENTYX IV

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## Products Affected

- COSENTYX INTRAVENOUS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	PsA initial - Prescribed by or in consultation with a dermatologist or rheumatologist. AS/Non-radio Axial Spondy-Prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	Non-Radiographic Axial Spondyloarthritis, initial therapy- approve if pt has objective signs of inflammation defined as (a or b): a) C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or b) sacroiliitis reported on magnetic resonance imaging. For continuation of therapy for all covered indications - approve if the pt has benefit from the medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# COTELLIC

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## Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf AND patient has BRAF V600 mutation positive disease. CNS Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) circumscribed ganglioglioma/neuroglioma/glioneuronal tumor OR ii. Recurrent or progressive disease for one of the following conditions (a, b or c): a) high grade glioma, b) circumscribed glioma OR c) Glioblastoma, OR iii. Melanoma with brain metastases AND medication with be taken in combination with Zelboraf (vemurafenib tablets). Histiocytic Neoplasm-approve if the patient meets one of the following (i, ii, or iii): i. Patient has Langerhans cell histiocytosis OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Central Nervous System Cancer
Part B Prerequisite	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# CRESEMBA (ORAL)

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## Products Affected

- CRESEMBA ORAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CRYSVITA

## Products Affected

- CRYSVITA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Chronic Kidney Disease (CKD), Severe Renal Impairment or End Stage Renal Disease
<b>Required Medical Information</b>	Diagnosis, lab values
<b>Age Restrictions</b>	TIO-2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or nephrologist (initial therapy)
<b>Coverage Duration</b>	XLH-1 year (initial/cont), TIO-initial-6 months, cont-1 year
<b>Other Criteria</b>	<p>XLH-Initial therapy-Approve if the patient has had a baseline (prior to any XLH treatment serum phosphorus level that was below the normal range for age and patient meets ONE of the following (a or b): a) The patient has had a baseline (i.e., prior to any XLH treatment tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender OR b) The patient has had a genetic test confirming the diagnosis of X-linked hypophosphatemia via identification of a PHEX pathogenic variant AND if the patient is greater than or equal to 18 years of age, the patient is currently exhibiting one or more signs or symptoms of XLH. Continuation-approve if the patient is continuing to derive benefit as determined by the prescribing physician.</p> <p>TIO-approve if the patient has a mesenchymal tumor that cannot be curatively resected or identified/localized AND the patient is currently exhibiting one or more signs or symptoms of TIO AND patient has had a baseline (prior to any TIO treatment) serum phosphorus level that was below the normal range for age AND patient has had a baseline (prior to any TIO treatment) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender. Cont-approve if the patient is continuing to derive benefit as determined by the prescribing physician.</p>
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CYSTEAMINE (OPHTHALMIC)

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## Products Affected

- CYSTARAN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# CYSTEAMINE (ORAL)

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## Products Affected

- CYSTAGON

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use of Cystagon and Procysbi
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Cystinosis, nephropathic-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming biallelic pathogenic or likely pathogenic variants in the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# DALFAMPRIDINE

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## Products Affected

- *dalfampridine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older (initial and continuation therapy)
<b>Prescriber Restrictions</b>	MS. If prescribed by, or in consultation with, a neurologist or MS specialist (initial and continuation).
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has impaired ambulation as evaluated by an objective measure (e.g., timed 25 foot walk and multiple sclerosis walking scale-12). Continuation-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has responded to or is benefiting from therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# DATROWAY

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## Products Affected

- DATROWAY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. BREAST CANCER - All of (A, B, C, D and E): A) Unresectable or metastatic disease, AND B) Hormone receptor (HR)-positive disease, AND C) Human epidermal growth factor receptor 2 (HER2)- negative (immunohistochemistry [IHC] 0, IHC 1+, or IHC 2+/in situ hybridization [ISH]-negative) disease, AND D) Patient has received prior endocrine-based therapy, Note: Examples of endocrine therapy are tamoxifen, anastrozole, letrozole, exemestane, AND E) Patient has received prior chemotherapy for unresectable or metastatic disease. Note: Examples are paclitaxel, doxorubicin, liposomal doxorubicin, gemcitabine, capecitabine, vinorelbine, Halaven (eribulin intravenous infusion), cyclophosphamide, docetaxel. Non-Small Cell Lung Cancer- meets ALL (A, B, and C): A) locally advanced or metastatic disease AND B) EGFR-mutated disease AND C) meets BOTH (i and ii): i. tried at least one prior EGFR-directed therapy AND ii. tried platinum-based chemotherapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# DAURISMO

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## Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medications that will be used in combination, comorbidities
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	AML - approve if Daurismo will be used in combination with cytarabine.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# DEFERASIROX

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## Products Affected

- *deferasirox*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Serum ferritin level
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve if the patient is benefiting from therapy as confirmed by the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# DEFERIPRONE

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## Products Affected

- *deferiprone*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Serum ferritin level
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias Initial therapy - approve. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# DIABETIC SUPPLY - ALCOHOL PADS

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## Products Affected

- *alcohol pads*
- DROPSAFE ALCOHOL PREP PADS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# DIABETIC SUPPLY - GAUZE PADS

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## Products Affected

- GAUZE PADS 2 X 2

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# DIABETIC SUPPLY - NEEDLES

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## Products Affected

- NOVO PEN NEEDLE
- BD PEN NEEDLE
- EMBECTA PEN NEEDLE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# DIABETIC SUPPLY - SYRINGES

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## Products Affected

- EMBECTA INSULIN SYRINGE
- BD INSULIN SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# DIACOMIT

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## Products Affected

- DIACOMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of diagnosis.
<b>Age Restrictions</b>	6 months and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an neurologist (initial therapy)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Dravet Syndrome-Initial therapy-approve if the patient is concomitantly receiving clobazam or is unable to take clobazam due to adverse events. Dravet Syndrome-Continuation-approve if the patient is responding to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# DIMETHYL FUMARATE

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## Products Affected

- *dimethyl fumarate oral capsule, delayed release(dr/ec) 120 mg, 120 mg (14)- 240 mg (46), 240 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS).
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# DOPTELET

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## Products Affected

- DOPTELET (10 TAB PACK)
- DOPTELET (15 TAB PACK)
- DOPTELET (30 TAB PACK)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	For Doptelet Sprinkle: patient must be less than 6 years of age. For Doptelet tablets: Chronic ITP - no restriction, Thrombocytopenia in chronic liver disease - 18 years and older
<b>Prescriber Restrictions</b>	Chronic ITP-prescribed by or after consultation with a hematologist (initial therapy)
<b>Coverage Duration</b>	Pending CMS Review
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# DRONABINOL

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## Products Affected

- *dronabinol*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# DROXIDOPA

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## Products Affected

- *droxidopa*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medication history (as described in Other Criteria field)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	NOH, approve if the patient meets ALL of the following criteria: a) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND b) Patient has tried midodrine
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# DUAL OREXIN RECEPTOR ANTAGONIST

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## Products Affected

- BELSOMRA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Treatment of insomnia, characterized by difficulties with sleep onset and /or sleep maintenance-approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# DUPIXENT

## Products Affected

- DUPIXENT PEN SUBCUTANEOUS  
PEN INJECTOR 200 MG/1.14 ML, 300  
MG/2 ML
- DUPIXENT SYRINGE  
SUBCUTANEOUS SYRINGE 200  
MG/1.14 ML, 300 MG/2 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another Monoclonal Antibody (examples: Adbry, Cinqair, Ebglyss, Fasentra, Nemluvio, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical].
<b>Required Medical Information</b>	Diagnosis. CONTINUATION CRITERIA: AD: responding positively to therapy. ASTHMA: responding positively to therapy and concurrent use with ICS. COPD (all of A, B and C): A) received Dupixent for at least 6 months and B) continues LABA and LAMA, and C) beneficial response (e.g. reduced symptoms, exacerbations, hospitalizations, ED/urgent care visits, improved lung function). CRSwNP (all of A, B, and C): A) received Dupixent for at least 6 months, B) responding positively to therapy, and C) concurrent use with intranasal CS. EoE (A and B): A) received Dupixent for at least 6 months and B) reduction in intraepithelial eosinophil count, decreased dysphagia/pain upon swallowing, or reduced frequency/severity of food impaction. PRURIGO NODULARIS (A and B): A) received Dupixent for at least 6 months and B) reduction in nodular lesion count, pruritis, or nodular lesion size. CSU (A and B): A) received at least 6 months of Dupixent and B) experienced a beneficial clinical response, defined by decreased itch severity, decreased number of hives or decreased size of hives. Bullous Pemphigoid: meets both (i and ii): i. already received at least 6 months of therapy with Dupixent AND ii. experienced a beneficial clinical response, defined by decreased area of skin involvement, lesions, including blisters or erosions (bullae), urticaria, erythema, or reduced or no need for systemic or topical corticosteroid therapy. AFR (A and B): A) received at least 6 months of Dupixent and B) experienced a beneficial clinical response (e.g. reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sinonasal symptoms, improved sense of smell, or reduced use of systemic corticosteroids).
<b>Age Restrictions</b>	Initial therapy only: AD-6 months and older, asthma/AFR-6 years of age and older, Esophagitis-1 yr and older, Chronic Rhinosinusitis/CSU- 12 and older, Prurigo nodularis/COPD/BP-18 and older
<b>Prescriber Restrictions</b>	Init therapy only: AD/PN/CSU-Prescr/consult with an allergist, immunologist or derm, asthma-prescr/consult with an allergist,

PA Criteria	Criteria Details
	immunologist or pulmonologist. Rhinosinusitis-prescr/consult with an allergist, immunologist or otolaryngologist. Esophagitis-prescr/consult-allergist or gastro. COPD-prescr/consult with an allergist, immunologist, or pulmonologist. BP-prescr/consult with derm, AFR-prescr/consult with allergist, immunologist, otolaryngologist, rhinologist, pulmonologist, or ID specialist
<b>Coverage Duration</b>	AD-1 yr, asthma/Rhinosinusitis/esophagitis/PN/COPD/CSU/BP/AFR-init-6 mo, cont 1 yr
<b>Other Criteria</b>	<p>INITIAL CRITERIA: AD: approve. ASTHMA (all of A, B, and C): A) blood eosinophil greater than or equal to 150 cells per microliter within previous 6 weeks or prior to Dupixent or another monoclonal antibody or has oral CS-dependent asthma, B) used an ICS in combination with at least one additional asthma controller/maintenance medication, and C) uncontrolled asthma prior to any asthma monoclonal antibody as defined by one of the following (one of a, b, c, d, or e): a) two or more asthma exacerbations requiring oral CS in the past year, b) one or more asthma exacerbations requiring hospital/urgent care/ED visit in the past year, c) FEV1 less than 80 percent predicted or less than 90% predicted for pts less than 18, d) FEV1/FVC less than 0.8 or less than 0.9 for pts less than 18, or e) worsened asthma with oral CS taper. COPD: meets (all of A, B, and C): A) blood eosinophil at least 300 cells per microliter within previous 6 weeks or prior to Dupixent or another monoclonal antibody, and B) received at least 3 months of combination therapy with at least two of LAMA, LABA or ICS, and C) meets (i or ii): i) two or more COPD exacerbations in previous 12 months requiring systemic CS with or without antibiotics or ii) COPD exacerbation requiring hospitalization in previous 12 months. CRSwNP (all of A, B, C and D): A) concurrent use with nasal CS, B) presence of at least two of the following symptoms for 8 weeks: nasal congestion, nasal obstruction, nasal discharge, reduction/loss of smell, C) received oral CS at least 5 days in last 2 years (unless contraindicated) or patient had prior surgery for nasal polyps, and D) diagnosis confirmed by direct exam, endoscopy, or sinus CT. EoE (all of A, B, C, and D): A) weighs 15 kg or more, B) endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, C) does not have a secondary cause of EoE, and D) received an Rx-strength PPI for at least 8 weeks. PRURIGO NODULARIS: pruritus lasting at least 6 weeks. CSU: urticaria for greater than 6 weeks (prior to Dupixent), despite non-sedating H1 antihistamine tx. Bullous Pemphigoid Initial: Approve. ALLERGIC FUNGAL RHINOSINUSITIS (AFR): Approve if pt has AFR confirmed by IgE-mediated inflammatory response to fungal hyphae confirmed by specific IgE serology or skin test AND nasal polyps confirmed by direct exam,</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	endoscopy, or sinus CT AND signs characteristic of AFR on CT scan AND pt has had at least one prior sino-nasal surgery.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ELAHERE

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## Products Affected

- ELAHERE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer-approve if the patient has folate receptor alpha positive disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ELAPRASE

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## Products Affected

- ELAPRASE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, serum or plasma OR a molecular genetic test demonstrating iduronate-2-sulfatase gene variant.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ELREXFIO

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## Products Affected

- ELREXFIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Multiple myeloma-approve if per FDA approved labeling the patient has tried at least four systemic regimens and among the previous regimens tried, the patient has received at least one drug from each of the following classes: proteasome inhibitor, an immunomodulatory drug and an anti-CD38 monoclonal antibody.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# EMGALITY

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## Products Affected

- EMGALITY PEN
- EMGALITY SUBCUTANEOUS SYRINGE 120 MG/ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination therapy with another cGRP inhibitor for migraine headache prevention
<b>Required Medical Information</b>	Diagnosis, number of migraine or cluster headaches per month
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Migraine headache prevention-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) If pt is currently taking Emgality, pt has had significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Emgality was initiated. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# EMRELIS

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## Products Affected

- EMRELIS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. NON-SMALL CELL LUNG CANCER- ALL of the following (A, B and C): A. Patient has locally advanced or metastatic, non-squamous disease, AND B. Tumor has high c-Met protein overexpression, defined as a greater than or equal to 50 percent of tumor cells with strong [3+] staining, as determined by an approved test, AND C. Patient has received at least one prior systemic therapy. Note: Examples are cisplatin, carboplatin, pemetrexed, Keytruda (pembrolizumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Imfinzi (durvalumab intravenous infusion), Libtayo (cemiplimab-rwlc intravenous infusion)
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# ENBREL

## Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION
- ENBREL SUBCUTANEOUS SYRINGE
- ENBREL SURECLICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with biologic therapy or targeted synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	Initial therapy: AS/RA- 18 years and older, JIA/PsA/Behcet's-2 years and older, GVHD-6 years and older, PP-4 years and older
<b>Prescriber Restrictions</b>	Initial only-RA/AS/JIA/JRA,prescribed by or in consult w/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist.Plaque psoriasis (PP), prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center.Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist.
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA)/JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA/ANKYLOSING SPONDYLITIS: approve if the patient has tried one preferred adalimumab product (a trial of a non-preferred adalimumab also counts). PLAQUE PSORIASIS (PP)/PSORIATIC ARTHRITIS: approve if the patient has tried one preferred adalimumab product (a non-preferred adalimumab also counts), unless the patient is less than 18 years of age. GRAFT VERSUS HOST DISEASE (GVHD): approve. BEHCET'S: tried at least one conventional therapy (e.g., systemic corticosteroid, immunosuppressant, interferon alfa, mycophenolate), adalimumab, or infliximab. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Please Note: preferred adalimumab products include Hadlima, Simlandi.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Graft versus host disease (GVHD), Behcet's disease
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ENDARI

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## Products Affected

- *glutamine (sickle cell)*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prescriber specialty
<b>Age Restrictions</b>	Greater than or equal to 5 years of age
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (e.g., a hematologist)
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ENSACOVE

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## Products Affected

- ENSACOVE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NON-SMALL CELL LUNG CANCER- approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# EPIDIOLEX

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## Products Affected

- EPIDIOLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies
<b>Age Restrictions</b>	Patients 1 year and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist (initial therapy)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Dravet Syndrome (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs or if the patient has tried or is concomitantly receiving one of Diacomit or clobazam or Fintepla. Lennox Gastaut Syndrome (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Tuberous Sclerosis Complex (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Refractory epilepsy (initial therapy)-approve if patient tried or is concomitantly receiving at least two other antiseizure drugs. Continuation of therapy for all indications-approve if the patient is responding to therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Refractory epilepsy
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# EPKINLY

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## Products Affected

- EPKINLY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-cell lymphoma - approve if the patient has received one or more lines of systemic therapy. Classic follicular lymphoma - approve if pt has received one or more lines of systemic therapy. Human immunodeficiency virus (HIV)-Related B-Cell Lymphoma - approve if the patient has received one or more lines of systemic therapy. Note: HIV-related B-cell lymphomas includes HIV-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus-8 (HHV8) positive DLBCL. Post-transplant lymphoproliferative disorders - approve if the patient has received one or more lines of systemic therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Human immunodeficiency virus (HIV)-Related B-Cell Lymphoma. Post-transplant lymphoproliferative disorders.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Effective 05/01/2026

# EPOETIN ALFA

## Products Affected

- PROCRIT
- RETACRIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	MDS anemia = 18 years of age and older
<b>Prescriber Restrictions</b>	MDS anemia, myelofibrosis- prescribed by or in consultation with, a hematologist or oncologist.
<b>Coverage Duration</b>	Chemo-6m,Transfus-1m, CKD-1yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr
<b>Other Criteria</b>	<p>Anemia in a pt with Chronic Kidney Disease (CKD) not on dialysis- for initial therapy, approve if hemoglobin (Hb) is less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children, or for continuation of therapy in a pt currently on an erythropoiesis-stimulating agent (ESA) approve if Hb is less than or equal to 12 g/dL. Anemia in a pt with cancer due to chemotherapy- approve if pt is currently receiving myelosuppressive chemo as a non-curative treatment and (for initial therapy) Hb is less than 10.0 g/dL or (if currently on ESA) Hb is less than or equal to 12.0 g/dL. Anemia in HIV with zidovudine- for initial therapy, approve if Hb is less than 10.0 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA, approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Approve if Hb is less than or equal to 13, AND surgery is elective, nonvascular and non-cardiac AND pt is unwilling or unable to donate autologous blood prior to surgery. MDS- for initial therapy, approve if Hb is less than 10 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA approve if Hb is 12.0 g/dL or less. Myelofibrosis- for Initial therapy approve if patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 mU/mL, or for continuation of therapy in pt currently on ESA hemoglobin is less than or equal to 12g/dL. Anemia in patients with chronic renal failure on dialysis -</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anemia due to myelodysplastic syndrome (MDS), Myelofibrosis
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ERIVEDGE

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## Products Affected

- ERIVEDGE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Basal cell carcinoma, locally advanced-patients new to therapy-approve if (A or B): A) pt has recurrent BCC following surgery or radiation therapy OR B) pt is not a candidate for surgery and is not a candidate for radiation therapy. Basal cell carcinoma, locally advanced-patients currently on therapy-approve. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has medulloblastoma, the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway. Basal cell carcinoma, metastatic (this includes primary or recurrent nodal metastases and distant metastases)-approve. Diffuse Basal Cell Carcinoma Formation, including basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma - approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Central nervous System Cancer, diffuse basal cell carcinoma formation
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ERLEADA

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## Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ERLOTINIB

## Products Affected

- *erlotinib oral tablet 100 mg, 150 mg, 25 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Advanced or Metastatic NSCLC, approve if the patient has EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. RCC, approve if the patient meets (A, B, and C): A) has stage IV or relapsed non-clear cell histology RCC and B) has advanced papillary disease including hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated renal cell carcinoma and C) erlotinib will be used in combination with bevacizumab. Bone cancer-approve if the patient has chordoma and has tried at least one previous therapy. Pancreatic cancer-approve if the medication is used in combination with gemcitabine and if the patient has locally advanced, metastatic or recurrent disease. Vulvar cancer-approve if the patient has advanced, recurrent or metastatic disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma.
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# EVEROLIMUS

## Products Affected

- *everolimus (antineoplastic) oral tablet*
- *everolimus (antineoplastic) oral tablet for suspension 2 mg, 3 mg, 5 mg*
- *torpenz*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Breast Cancer-HER2 status, hormone receptor (HR) status.
<b>Age Restrictions</b>	All dx except TSC associated SEGA, renal angiomyolipoma or partial onset seizures-18 years and older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	<p>Breast Cancer-approve if pt meets ALL the following (A, B, C, D, E, and F):A)pt has recurrent or metastatic,HR+ disease AND B)pt has HER2-negative breast cancer AND C)pt has tried at least 1 prior endocrine therapy AND D)pt meets 1 of the following conditions (i or ii):i.pt is a postmenopausal woman or man OR ii.pt is pre/perimenopausal woman AND is receiving ovarian suppression/ablation with a GnRH agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND E)pt meets 1 of the following conditions (i or ii): i.Everolimus will be used in combo with exemestane and pt meets 1 of the following:pt is male and is receiving a GnRH analog or pt is a woman or ii. Everolimus will be used in combo with fulvestrant or tamoxifen AND F)pt has not had disease progression while on Everolimus. RCC, relapsed or Stage IV disease-approve if using for non-clear cell disease or if using for clear cell disease, pt has tried 1 prior systemic therapy (e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).TSC Associated SEGA-approve if pt requires therapeutic intervention but cannot be curatively resected. Thymomas and Thymic Carcinomas-approve if pt has tried chemotherapy or cannot tolerate chemotherapy.TSC associated renal angiomyolipoma -approve. WM/LPL - pt has tried at least one systemic regimen. Thyroid Carcinoma, differentiated-approve if pt is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if everolimus will be used in combo with</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>letrozole. GIST-approve if pt has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock or imatinib AND there is confirmation that everolimus will be used in combo with 1 of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. TSC-associated partial-onset seizures-approve. NET tumors of the pancreas, GI Tract, Lung and Thymus (carcinoid tumors)-approve. Soft tissue sarcoma-approve if pt has perivascular epitheloid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangiomyomatosis. Classic hodgkin lymphoma-approve if pt has relapsed or refractory disease AND not a candidate for high-dose therapy and autologous stem cell rescue. Histiocytic neoplasm-approve if pt has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis. Patient must also have PIK3CA mutation. Meningioma-(A, B and C): A) approve if pt has recurrent or progressive disease AND B) pt has surgically inaccessible disease and radiation therapy is not possible AND C) medication will be used in combination with a somatostatin analogue or bevacizumab. Uterine Sarcoma-approve if the patient has advanced, recurrent, metastatic, or inoperable disease, AND has a perivascular epithelioid cell tumor (PEComa), AND has tried at least one systemic regimen. Note: Examples of systemic regimen include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	<p>neuroendocrine tumors of the thymus (Carcinoid tumors). Soft tissue sarcoma, classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST), men with breast cancer, Pre-peri-menopausal women with breast cancer, Histiocytic Neoplasm, uterine sarcoma, meningioma</p>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# FABRAZYME

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## Products Affected

- FABRAZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Galafold (migalastat oral capsules) or Elfabrio (pegunigalsidase alfa intravenous infusion).
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has a laboratory test demonstrating deficient alpha-galactosidase A activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating a pathogenic variant in the galactosidase alpha (GLA) gene.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# FASENRA

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another monoclonal antibody therapy.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Asthma: 6 years of age and older, EGPA: 18 years and older
<b>Prescriber Restrictions</b>	Asthma: Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA: Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist
<b>Coverage Duration</b>	Asthma: 6 months initial, 12 months continuation. EGPA: 8 months initial, 12 months continuation.
<b>Other Criteria</b>	INITIAL THERAPY: ASTHMA (all of A, B, and C): A) blood eosinophil greater than or equal to 150 cells per microliter within previous 6 weeks prior to Fasenra or another monoclonal antibody, B) used an inhaled corticosteroid (ICS) in combination with at least one additional asthma controller/maintenance medication, and C) uncontrolled asthma prior to any asthma monoclonal antibody as defined by one of the following (a, b, c, d, or e): a) one or more exacerbations requiring a systemic CS in the past year, b) one or more exacerbations requiring hospital/urgent care/emergency department visit in the past year, c) FEV1 less than 80 percent predicted or less than 90 percent predicted for patients less than 18, d) FEV1/FVC less than 0.80, or e) worsened asthma with systemic CS taper. EGPA: (all of A, B, and C): A) active, non-severe disease, and B) currently on systemic CS for at least 4 weeks, and C) blood eosinophil greater than or equal to 150 cells per microliter within previous 4 weeks or prior to treatment with any monoclonal antibody that may alter eosinophil levels. CONTINUATION THERAPY: ASTHMA (A and B): A) patient has responded to therapy (e.g., decrease in any of the following: asthma exacerbations, asthma symptoms, hospitalizations, emergency department/urgent care visits, physician visits, requirement for oral corticosteroid therapy) and B) continues to receive therapy with an ICS.

<b>PA Criteria</b>	<b>Criteria Details</b>
	EGPA: patient has responded to therapy (e.g. reduced rate of relapse, CS dose reduction, reduced eosinophil levels).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# FINGOLIMOD

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## Products Affected

- *fingolimod*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use of fingolimod with other disease-modifying agents used for multiple sclerosis (MS).
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
<b>Age Restrictions</b>	10 years and older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist or an MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# FINTEPLA

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## Products Affected

- FINTEPLA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an neurologist (initial therapy)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex, Clobazam or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome, initial-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome, continuation-approve if the patient is responding to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# FIRMAGON

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## Products Affected

- FIRMAGON KIT W DILUENT SYRINGE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Patients new to therapy, are required to try Eligard prior to approval of Firmagon.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# FOTIVDA

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## Products Affected

- FOTIVDA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. Note: Examples of systemic regimens for renal cell carcinoma include axitinib tablets, axitinib + pembrolizumab injection, cabozantinib tablets, cabozantinib + nivolumab injection, sunitinib malate capsules, pazopanib tablets, sorafenib tablets, and lenvatinib capsules + everolimus.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# FRUZAQLA

## Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Colon cancer, rectal cancer, or appendiceal cancer-Approve if the patient meets the following (A, B and C): A.Patient has advanced or metastatic disease, AND B. Patient meets (i or ii): i. has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease, or ii. patient is ineligible for or progressed on checkpoint inhibitor therapy (examples: Keytruda [pembrolizumab intravenous infusion] and Opdivo [nivolumab intravenous infusion]) and meets ONE of the following (a or b): a. has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or b. is polymerase epsilon/delta (POLE/POLD1) mutation positive, AND C. Patient has previously been treated with the following (i, ii, and iii): i.Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine. AND ii.An anti-vascular endothelial growth factor (VEGF) agent, Note: Examples of anti-VEGF agents include bevacizumab. AND iii. If the tumor is RAS wild-type (KRAS wild-type and NRAS wild-type) [that is, the tumor or metastases are KRAS and NRAS mutation negative], the patient meets ONE of the following (a or b): a.According to the prescriber, anti-epidermal growth factor receptor (EGFR) therapy is NOT medically appropriate, OR b. The patient has received an anti-EGFR therapy. Note: Examples of anti-EGFR therapy</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	includes Erbitux (cetuximab intravenous infusion) and Vectibix (panitumumab intravenous infusion).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Appendiceal cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# FULPHILA

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## Products Affected

- FULPHILA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.
<b>Coverage Duration</b>	Cancer pts receiving chemo-6 mo. PBPC-30 days.
<b>Other Criteria</b>	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 2) patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts), or 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients undergoing PBPC collection and therapy

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# FYARRO

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## Products Affected

- FYARRO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Perivascular Epithelioid Cell Tumor (PEComa), Malignant-approve if the patient has locally advanced unresectable disease or metastatic disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# GATTEX

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## Products Affected

- GATTEX 30-VIAL
- GATTEX ONE-VIAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	1 year and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist (initial and continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced improvement.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# GAVRETO

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## Products Affected

- GAVRETO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	NSCLC-18 years and older, thyroid cancer-12 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NSCLC-approve if the patient has advanced, recurrent, or metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Differentiated Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has RET fusion-positive or RET-mutation-positive disease AND disease requires treatment with systemic therapy AND either (i or ii) i) pt has papillary or follicular thyroid carcinoma and the disease is radioactive iodine-refractory or ii) pt has oncocytic (formerly Hurthle cell) carcinoma. Anaplastic thyroid cancer or Medullary Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has disease positive for RET pathogenic variant.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Medullary Thyroid Cancer, Anaplastic Thyroid Cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# GEFITINIB

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## Products Affected

- *gefitinib*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NSCLC-approve if the patient has advanced or metastatic disease and the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	NSCLC with EGFR L861Q, G719X, or S768I mutations.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# GILOTRIF

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## Products Affected

- GILOTRIF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For NSCLC - EGFR exon deletions or mutations, or if NSCLC is squamous cell type
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	NSCLC EGFR pos - For the treatment of advanced or metastatic non small cell lung cancer (NSCLC)-approve if the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: examples of sensitizing EGFR mutation-positive NSCLC include the following mutations : exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. NSCLC metastatic squamous cell must have disease progression after treatment with platinum based chemotherapy. Head and neck cancer-approve if the patient has non-nasopharyngeal head and neck cancer and the patient has disease progression on or after platinum based chemotherapy. (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Head and neck cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

Effective 05/01/2026

# GLATIRAMER

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## Products Affected

- *glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml*
- *glatopa subcutaneous syringe 20 mg/ml, 40 mg/ml*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agent used for multiple sclerosis
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or after consultation with a neurologist or an MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# GLUCAGON-LIKE PEPTIDE-1 AGONISTS

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## Products Affected

- *exenatide subcutaneous pen injector 10 mcg/dose(250 mcg/ml) 2.4 ml, 5 mcg/dose (250 mcg/ml) 1.2 ml*
- *liraglutide*
- MOUNJARO
- OZEMPIC SUBCUTANEOUS PEN INJECTOR 0.25 MG OR 0.5 MG (2 MG/3 ML), 1 MG/DOSE (4 MG/3 ML), 2 MG/DOSE (8 MG/3 ML)
- RYBELSUS
- TRULICITY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# GNRH AGONIST IMPLANTS

## Products Affected

- ZOLADEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Endometriosis-18 years and older
<b>Prescriber Restrictions</b>	Prostate cancer/Breast cancer/Head and Neck/Ovarian/Uterine-prescribed by or in consultation with an oncologist. Endometriosis/abnormal uterine bleeding-prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health.
<b>Coverage Duration</b>	Abnormal uterine bleeding-2 months, Endometriosis-6 months, all other dx-1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Abnormal uterine bleeding-Zoladex 3.6mg is used as an endometrial-thinning agent prior to endometrial ablation.Endometriosis-approve Zoladex 3.6 mg. Prostate cancer-approve Zoladex 3.6 mg and/or 10.8 mg. Head and Neck Cancer - Salivary Gland Tumors: approve if patient has recurrent, unresectable, or metastatic disease AND has androgen receptor-positive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Zoladex 3.6mg only: head and neck cancer - salivary gland tumors, Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer, and Uterine Cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Effective 05/01/2026

# GOMEKLI

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## Products Affected

- GOMEKLI ORAL CAPSULE 1 MG, 2 MG
- GOMEKLI ORAL TABLET FOR SUSPENSION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	2 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NEUROFIBROMATOSIS TYPE 1- patient has or had symptomatic plexiform neurofibromas prior to starting Gomekli and the tumor is not amenable to complete resection.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

## Products Affected

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)
- *leuprolide subcutaneous kit*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prostate cancer- prescribed by or in consultation with an oncologist or urologist. Head and neck-salivary gland tumors- prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Head and neck cancer- salivary gland tumors (Eligard only)
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# GRALISE/HORIZANT/LYRICA CR

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## Products Affected

- *gabapentin oral tablet extended release 24 hr 300 mg, 450 mg, 600 mg, 750 mg, 900 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# GROWTH HORMONES

## Products Affected

- OMNITROPE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	GHD in Children/Adolescents. Pt meets one of the following-1-had 2 GH stim tests with the following-levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are less than 10ng/mL OR had at least 1 GH test and results are less than 10ng/mL and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). 2.brain radiation or tumor resection and pt has 1 GH stim test less than 10ng/mL or has def in at least 1 other pituitary hormone (that is, ACTH, TSH, gonadotropin deficiency [LH and/or FSH] are counted as 1 def], or prolactin).3. congenital hypopituitarism and has one GH stim test less than 10ng/mL OR def in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk 4.pt has multiple pituitary deficiencies and pt has 3 or more pituitary hormone deficiencies or pt has had one GH test less than 10ng/mL 5.pt had a hypophysectomy. Cont-pt responding to therapy
<b>Age Restrictions</b>	ISS 5 y/o or older, SGA 2 y/o or older
<b>Prescriber Restrictions</b>	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, ISS (initial), Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.
<b>Coverage Duration</b>	ISS - 6 mos initial, 12 months cont tx, SBS 1 month, others 12 mos
<b>Other Criteria</b>	GHD initial in adults and adolescents transitioning into adulthood 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment,

PA Criteria	Criteria Details
	<p>TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. has known perinatal insults, congenital or genetic defects or structural hypothalamic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin), AND age and gender adjusted IGF1 below the lower limits of the normal reference range AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine test with peak of less than or equal to 6.5 mcg/L, or Macrilen peak equal to or less than 2.8 ng/ml AND BMI is less than or equal to 40. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal to 5 or b. growth velocity is less than 10th percentile. CKD initial - CKD defined by abnormal CrCl, baseline ht less than 5th percentile and baseline ht velocity below 25th percentile. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile. SGA initial -baseline ht less than 5th percentile and born SGA (birth weight/length more than 2 SD below mean for gestational age/gender and insufficient catch up growth by 2-4 y/o). TS- dx by karyotype analysis and baseline ht less than 5th percentile. TS cont- dx by karyotype analysis and response to tx. Cont Tx for ISS, CKD, Noonan, PW in child/adoles, SHOX, SGA - prescriber confirms response to therapy. SBS - approve if pt already started on somatropin tx for this dx or responded to it in past.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Short bowel syndrome
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# HERNEXEOS

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## Products Affected

- HERNEXEOS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NON-SMALL CELL LUNG CANCER-BOTH (A and B): A) Unresectable or metastatic disease, AND B) Human epidermal growth factor receptor 2 (HER2) [ERBB2] activating mutation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# HIGH RISK MEDICATIONS - ANTIPARKINSON AGENTS

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## Products Affected

- *benztropine oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For all covered indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# HIGH RISK MEDICATIONS - BENZODIAZEPINES

## Products Affected

- *clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg*
- *diazepam injection*
- *diazepam intensol*
- *diazepam oral concentrate*
- *diazepam oral solution*
- *diazepam oral tablet*
- *lorazepam injection*
- *lorazepam intensol*
- *lorazepam oral concentrate*
- *lorazepam oral tablet 0.5 mg, 1 mg, 2 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Procedure-related sedation = 1mo. All other conditions = 6 months.
<b>Other Criteria</b>	All medically accepted indications other than insomnia, approve if the physician has assessed risk versus benefit in using the High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy. Insomnia, may approve lorazepam if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon and the physician has assessed risk versus benefit in using the HRM in this patient and has confirmed that he/she would still like initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

## Products Affected

- *hydroxyzine hcl oral tablet*
- *promethazine oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For promethazine, for the treatment of emesis, approve if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant). For hydroxyzine hydrochloride for the treatment of anxiety, approve if the patient has tried at least two other FDA-approved products. Additionally for all covered indications, the prescriber must confirm that he/she has assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# HIGH RISK MEDICATIONS - PHENOBARBITAL

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## Products Affected

- *phenobarbital*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for use in sedation/insomnia.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For the treatment of seizures, approve only if the patient is currently taking phenobarbital. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# HIGH RISK MEDICATIONS - SKELETAL MUSCLE RELAXANTS

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## Products Affected

- *cyclobenzaprine oral tablet 10 mg, 5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 6 months.
<b>Other Criteria</b>	For all covered indications, approve if the prescriber confirms he/she has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# HYRNUO

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## Products Affected

- HYRNUO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NON-SMALL CELL LUNG CANCER- all of (A, B AND C): A. Locally advanced or metastatic disease, AND B. Human epidermal growth factor receptor 2 (HER2) [ERBB2] activating mutations, AND C. Received at least one prior systemic therapy. Note: Examples include checkpoint inhibitors such as Keytruda (pembrolizumab intravenous infusion), Libtayo (cemiplimab-rwlc intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), or Imjudo (tremelimumab-actl intravenous infusion) in combination with chemotherapy (e.g., carboplatin, cisplatin, pemetrexed, paclitaxel, albumin-bound paclitaxel, bevacizumab), chemotherapy alone (e.g., docetaxel, gemcitabine, etoposide, vinorelbine, other chemotherapy noted above).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# IBRANCE

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## Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast cancer (including endocrine-resistant PIK3CA-mutated, HR-positive, HER2-negative locally advanced or metastatic breast cancer) - approve locally advanced, recurrent or metastatic, hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and this medication will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND this medication will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) and meets (a or b): a) is receiving GnRH analog AND this medication will be used in combination with anastrozole, exemestane or letrozole or b) this medication will be used in combination with fulvestrant. Liposarcoma-approve if the patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Liposarcoma

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# IBTROZI

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## Products Affected

- IBTROZI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NON-SMALL CELL LUNG CANCER-locally advanced or metastatic disease and ROS1-positive non-small cell lung cancer as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ICATIBANT

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## Products Affected

- *icatibant*
- *sajazir*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant -the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment. HAE with Normal C1-INH [Type III], Treatment of Acute Attacks: Approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# ICLUSIG

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## Products Affected

- ICLUSIG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
<b>Age Restrictions</b>	All indications except ALL - 18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Acute lymphoblastic leukemia, Philadelphia chromosome positive or ABL-class translocation: approve if the patient meets (1, 2 or 3): 1) will use in combination with chemotherapy, or 2) ALL is T315I-positive, or 3) pt tried at least one other tyrosine kinase inhibitor (examples: imatinib or dasatinib). Chronic myeloid leukemia, Philadelphia chromosome positive or BCR::ABL1-positive-approve if patient meets (1, 2 or 3): 1) CML is T315I-positive, or 2) pt tried at least one other tyrosine kinase inhibitor (examples: imatinib, dasatinib, nilotinib), or 3) pt has accelerated-phase or blast-phase CML and no other tyrosine kinase inhibitor is indicated. GIST - approve if the patient tried all of the following therapies first to align with NCCN recommendations which include: Imatinib or Ayvakit (avapritinib tablets), AND Sunitinib or Sprycel (dasatinib tablets), AND Stivarga (regorafenib tablets), AND Qinlock (ripretinib tablets). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has ABL1 rearrangement or FGFR1 rearrangement.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia
<b>Part B Prerequisite</b>	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# IDHIFA

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## Products Affected

- IDHIFA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	IDH2-mutation status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	AML - approve if the patient is IDH2-mutation status positive as detected by an approved test
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ILARIS

## Products Affected

- ILARIS (PF)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	When used in combination with concurrent biologic therapy (e.g. TNF antagonists, etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or riloncept.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	CAPS-4 years of age and older (initial). SJIA/HIDS/MKD/FMF/TRAPS-2 years of age and older (initial). Still's disease-18 years and older (initial) Note-patients less than 18 should be referred to criteria for systemic juvenile idiopathic arthritis. Acute gout flare-18 years of age and older
<b>Prescriber Restrictions</b>	CAPS initial- Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. SJIA/Still's disease (initial), Acute gout flare (initial/cont)- prescribed by or in consultation with a rheumatologist. FMF initial - rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, hematologist. HIDS/MKD/TRAPS initial - rheumatologist, nephrologist, geneticist, oncologist, hematologist.
<b>Coverage Duration</b>	Acute gout flare-6 mos, all other diagnoses-6 months initial, 1 year cont.
<b>Other Criteria</b>	For renewal of CAPS/SJIA/FMF/HIDS/MKD/TRAPS/Still's - After pt had been started on Ilaris, approve if the pt had a response to therapy as determined by prescribing physician. SJIA, initial therapy - approve. Adult Onset Still's Disease-Initial-approve. Acute gout flare- approve if (i and ii): (i) pt has intolerance, contraindication, or lack of response to NSAIDs and colchicine for the treatment of acute gout flares OR pt is unable to be retreated with a repeat course of corticosteroids (oral or injectable) for acute gout flare, and (ii) patient is receiving or will be taking concomitant urate lowering medication for prevention of gout unless contraindicated (ex: allopurinol, febuxostat, probenecid). FMF, initial-approve if pt has tried colchicine, unless contraindicated and will be taking Ilaris in combination with colchicine, unless colchicine is contraindicated or not tolerated, AND prior to starting Ilaris, the patient meets BOTH of the

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>following (a and b): a) C-reactive protein level is greater than or equal to 10 mg/L OR elevated to at least two times the upper limit of normal AND b) pt has a history of at least one flare per month despite use of colchicine, OR was hospitalized for a severe flare. HIDS/MKD, initial-approve if prior to starting Ilaris, the patient meets BOTH of the following (a and b): a)C-reactive protein level is greater than or equal to 10 mg/L OR elevated to at least two times the upper limit of normal AND b) Pt has a history of at least three febrile acute flares within the previous 6-month period OR was hospitalized for a severe flare. TRAPS, initial-approve if prior to starting Ilaris, the patient meets BOTH of the following (a and b): a) C-reactive protein level is greater than or equal to 10 mg/L OR elevated to at least two times the upper limit of normal AND b) Pt has a history of at least six flares per year OR was hospitalized for a severe flare.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# IMATINIB

## Products Affected

- *imatinib oral tablet 100 mg, 400 mg*
- IMKELDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
<b>Age Restrictions</b>	ASM, DFSP, HES, MDS/MPD/Myeloid/Lymphoid Neoplasms/Kaposi Sarcoma/Cutaneous Melanoma-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For ALL-approve for Ph-positive or ABL-class translocation ALL. CML-approve for Ph-positive or BCR::ABL1-mutation positive CML. Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or Romvimza or according to the prescriber, the patient cannot take Turalio or Romvimza. Myelodysplastic/myeloproliferative disease-approve if the condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.Graft versus host disease, chronic-approve if the patient has tried at least one conventional systemic treatment (e.g., imbruvica). Cutaneous melanoma-approve if the patient has an activating KIT mutation, metastatic or unresectable melanoma, and has tried at least one systemic regimen. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement or an FIP1L1-PDGFR A or PDGFRB rearrangement. Approve Imkeldi if the patient has had a trial of imatinib tablets (brand or generic) dispersed in a glass of water or apple juice (per product labeling).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chordoma, desmoid tumors (aggressive fibromatosis), metastatic or unresectable cutaneous melanoma with activating kit mutation, Kaposi's

<b>PA Criteria</b>	<b>Criteria Details</b>
	Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# IMBRUVICA

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	GVHD-1 year and older, other-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	CLL- Approve. GVHD-Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, Jakafi [ruxolitinib tablets]). B-cell lymphoma-approve if the patient has tried at least one systemic regimen (e.g., cisplatin, cytarabine, rituximab, oxaliplatin, gemcitabine, ifosfamide, carboplatin, etoposide, or rituximab). Central nervous system Lymphoma (primary)- approve if the patient is not a candidate for or is intolerant to high-dose methotrexate OR has tried at least one therapy (e.g., methotrexate, rituximab, vincristine, procarbazine, cytarabine, thiotepa, carmustine, intrathecal methotrexate, cytarabine, or rituximab). Hairy Cell Leukemia - approve if the patient has tried at least two systemic regimens (cladribine, Nipent [pentostatin injection], rituximab, or Pegasys [peginterferon alfa-2a subcutaneous injection]).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# IMDELLTRA

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## Products Affected

- IMDELLTRA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. SMALL CELL LUNG CANCER-patient has primary progressive, relapsed or refractory extensive stage disease and has previously received platinum-based chemotherapy. Note: Examples of platinum medications include cisplatin and carboplatin.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# IMJUDO

## Products Affected

- IMJUDO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	HCC, Esophageal/Esophagogastric Junction Ca, Gastric Ca-30 days, NSCLC-6 months
<b>Other Criteria</b>	<p>Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. HCC-approve if the patient meets (A or B): A) Imjudo will be used as first-line systemic therapy in combination with Imfinzi and either (i or ii): i) has liver-confined unresectable disease and is deemed ineligible for transplant or (ii) has extrahepatic or metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy or B) Imjudo will be used as subsequent therapy in combination with Imfinzi. Non-Small Cell Lung Cancer-Approve if the patient meets ALL of the following criteria (A, B, and C ): A) Patient has recurrent, advanced, or metastatic disease, AND B) Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion), AND C) Patient meets ONE of the following (i, ii, iii, or iv): i. Patient meets BOTH of the following (a and b): a) The tumor is negative for actionable molecular markers-Note: Examples of actionable molecular markers include epidermal growth factor receptor (EGFR) mutations, anaplastic lymphoma kinase (ALK) genomic tumor aberrations, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), [patient may be KRAS G12C mutation positive] AND b) Imjudo is used as first-line therapy, OR ii. Patient meets both of the following (a and b): a) The tumor is positive for ONE of the following [(1) or (2)]: (1) Epidermal growth factor receptor (EGFR) exon 20 mutation positive, OR (2) ERBB2 (HER2) mutation positive, AND b) Imjudo is used as first-line therapy, OR iii. Patient meets BOTH of the</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>following (a and b): a) The tumor is positive for ONE of the following [(1), (2), (3), or (4)]: (1) BRAF V600E mutation positive, OR (2) NTRK1/2/3 gene fusion positive, OR (3) MET exon 14 skipping mutation positive, OR (4) RET rearrangement positive, AND b) Imjudo is used as first-line or subsequent therapy, OR iv. Patient meets ALL of the following (a, b, and c): a) The tumor is positive for ONE of the following [(1), (2), (3), or (4)]: (1) EGFR exon 19 deletion or exon 21 L858R mutation positive, OR (2) EGFR S768I, L861Q, and/or G719X mutation positive, OR (3) ALK rearrangement positive, OR (4) ROS1 rearrangement, AND b) The patient has received targeted drug therapy for the specific mutation AND c) Imjudo is used as subsequent therapy. Esophageal and Esophagogastric Junction Cancers- approve if pt has adenocarcinoma tumor AND has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease AND Imjudo is used as neoadjuvant therapy AND Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion) AND patient is medically fit for surgery. Gastric cancer-approve if pt has locoregional disease AND has MSI-H or dMMR disease AND Imjudo is used as neoadjuvant therapy AND Imjudo is used in combination with Imfinzi AND patient is medically fit for surgery.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Esophageal and Esophagogastric Junction Cancers, Gastric Cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# IMPAVIDO

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## Products Affected

- IMPAVIDO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious diseases specialist
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	Ameba related infections: approve if the patient is being treated for an infection due to one of the following: Acanthameoba, Balamuthia mandrillaris, or Naegleria fowleri. Note: Examples of ameba related infections are Acanthamoeba keratitis, granulomatous amebic encephalitis (GAE), and primary amebic meningoencephalitis (PAM).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Ameba related infections
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# INBRIJA

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## Products Affected

- INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Asthma, COPD, other chronic underlying lung disease
<b>Required Medical Information</b>	Diagnosis, medications that will be used in combination
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient is currently taking carbidopa-levodopa and is experiencing off episodes.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# INGREZZA

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## Products Affected

- INGREZZA
- INGREZZA INITIATION PK(TARDIV)
- INGREZZA SPRINKLE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	TD - Prescribed by or in consultation with a neurologist or psychiatrist. Chorea HD - prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Chorea associated with Huntington's Disease- approve if diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# INJECTABLE TESTOSTERONE PRODUCTS

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## Products Affected

- *testosterone cypionate*
- *testosterone enanthate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, lab results
<b>Age Restrictions</b>	Delayed puberty or induction of puberty in males-14 years and older, 12 years and older (testosterone cypionate)
<b>Prescriber Restrictions</b>	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
<b>Coverage Duration</b>	Delayed puberty or induction of puberty in males-6 months, all others-12 months
<b>Other Criteria</b>	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. Delayed puberty or induction of puberty in males - Approve testosterone enanthate or testosterone cypionate. Breast cancer in females-approve testosterone enanthate. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression. Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-

<b>PA Criteria</b>	<b>Criteria Details</b>
	Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# INLEXZO

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## Products Affected

- INLEXZO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. NON-MUSCLE INVASIVE BLADDER CANCER-patient has carcinoma in situ (CIS) and Bacillus Calmette-Guerin (BCG)-unresponsive disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# INLURIYO

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## Products Affected

- INLURIYO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>BREAST CANCER-All of (A, B, C, D, E and F): A) Recurrent, advanced or metastatic disease, AND B) Hormone receptor-positive (HR+) disease (example: estrogen receptor (ER)-positive), AND C) Human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Estrogen receptor 1 gene (ESR1)-mutated disease, AND E) Tried at least one endocrine therapy, Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen. AND F) ONE of the following (i or ii): i. Patient is a postmenopausal woman or man [See note 1], OR ii. Patient is a pre/perimenopausal woman [See note 1] and meets ONE of the following (a or b): a) Receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), and Zoladex (goserelin acetate subcutaneous injection). OR b) Patient has had surgical bilateral oophorectomy or ovarian irradiation. Note 1- a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression, a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Recurrent breast cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# INLYTA

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## Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Advanced renal cell carcinoma, approve. Differentiated thyroid cancer - approve if the patient meets (i or ii): i) Patient meets both (a and b): a) Has papillary or follicular thyroid carcinoma AND b) the disease is refractory to radioactive iodine therapy OR ii) has oncocytic (formulary Hurthle cell) carcinoma. Soft tissue sarcoma-approve if the patient has alveolar soft part sarcoma and the medication will be used in combination with Keytruda. Thymic carcinoma - Approve if the patient has tried at least one chemotherapy regimen and the medication will be used in combination with Bavencio (aveluman intravenous infusion).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma, Soft tissue sarcoma, thymic carcinoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# INPEFA

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## Products Affected

- INPEFA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Heart Failure, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit-approve. Type 2 Diabetes, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit-approve if the patient has chronic kidney disease AND has one or more cardiovascular risk factor(s).Note: Patients with heart failure should be reviewed under criteria for Heart Failure.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# INQOVI

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## Products Affected

- INQOVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myelodysplastic Syndrome With Myeloproliferative Neoplasm Overlap Syndrome
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# INREBIC

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## Products Affected

- INREBIC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has higher-risk disease. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myeloid/Lymphoid Neoplasms with Eosinophilia, accelerated or blast phase myeloproliferative neoplasm
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ITOVEBI

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## Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	BREAST CANCER (all of A, B, C, D, E and F): A. Patient meets ONE of the following (i or ii): i. Patient is a postmenopausal female or male, OR ii. Patient meets BOTH of the following (a and b): a. Patient is a pre/perimenopausal female, AND b. Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist OR had surgical bilateral oophorectomy or ovarian irradiation, Note: Examples of a GnRH agonist include leuprolide acetate, leuprolide acetate intramuscular injection, triptorelin pamoate intramuscular injection, goserelin acetate subcutaneous injection. AND B. Patient has locally advanced or metastatic hormone receptor (HR)-positive disease, AND C. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D. Patient has PIK3CA-mutated breast cancer as detected by an approved test, AND E. Patient meets (i or ii): i) has disease progression while on adjuvant endocrine therapy or ii) had disease recurrence within 12 months after completing adjuvant endocrine therapy, Note: Examples of endocrine therapy include tamoxifen, anastrozole, letrozole, exemestane, toremifene. AND F. The medication will be used in combination with palbociclib capsules/tablets and fulvestrant injection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# IVERMECTIN (ORAL)

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## Products Affected

- *ivermectin oral tablet 3 mg, 6 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	Pediculosis-approve if the patient has infection caused by pediculus humanus capitis (head lice), pediculus humanus corporis (body lice), or has pediculosis pubis caused by phthirus pubis (pubic lice). Scabies-approve if the patient has classic scabies, treatment resistant scabies, is unable to tolerate topical treatment, has crusted scabies or is using ivermectin tablets for prevention and/or control of scabies.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, Mansonella ozzardi infection, Mansonella streptocerca infection, Pediculosis, Scabies. Trichuriasis, Wucheria bancrofti infection
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# IVIG

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## Products Affected

- GAMUNEX-C

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Part B versus D determination per CMS guidance to establish if drug used for PID in pt's home.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# IWILFIN

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## Products Affected

- IWILFIN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Neuroblastoma-Approve if the patient meets the following (A, B and C): A) Patient has high-risk disease, AND B) The medication is being used to reduce the risk of relapse, AND C) Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy. Note: Examples of anti-GD2 immunotherapy includes Unituxin (dinutuximab intravenous infusion).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# JAKAFI

## Products Affected

- JAKAFI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	ALL-1 to 21 years of age, GVHD-12 and older, MF/PV/accelerated or blast phase MPN/CMML-2/essential thrombo/myeloid/lymphoid neoplasm/T-cell Lymphoma-18 and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For polycythemia vera patients must have tried hydroxyurea or peginterferon alfa-2a or Besremi (ropeginterferon alfa-2b-njft subcutaneous injection). ALL-approve if the mutation/pathway is Janus associated kinase (JAK)-related. GVHD, chronic-approve if the patient has tried one conventional systemic treatment for graft versus host disease (for example: prednisone, ibrutinib capsules/tablets). GVHD, acute-approve if the patient has tried one systemic corticosteroid. Atypical chronic myeloid leukemia-approve if the patient has a CSF3R mutation or a janus associated kinase 2 (JAK2) mutation. Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent. Essential thrombocythemia-approve if the patient has tried hydroxyurea, peginterferon alfa-2a or anagrelide. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the tumor has a janus associated kinase 2 (JAK2) rearrangement. T-Cell Lymphoma - approve if pt has (A or B): A) peripheral T-cell lymphoma or B) meets (i and ii): i) pt has T-cell prolymphocytic leukemia, T-cell large granular lymphocytic leukemia, hepatosplenic T-cell lymphoma, or breast implant-associated anaplastic large cell lymphoma and ii) pt has tried at least one systemic regimen. Accelerated or blast phase myeloproliferative neoplasm-approve if pt has at least one disease-related symptom (examples: fatigue, fever, night sweats,

<b>PA Criteria</b>	<b>Criteria Details</b>
	weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms, T-Cell lymphoma, accelerated or blast phase myeloproliferative neoplasm
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# JAYPIRCA

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## Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Mantle cell lymphoma-approve if the patient has tried at least one systemic chemotherapy regimen or patient is not a candidate for a systemic regimen, AND the patient has tried one Bruton tyrosine kinase inhibitor (BTK) for mantle cell lymphoma. Note: Examples of a systemic regimen contain one or more of the following products: rituximab, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, methotrexate, bendamustine, Velcade (bortezomib intravenous or subcutaneous injection), lenalidomide, gemcitabine, and Venclexta (venetoclax tablets). Note: Examples of BTK inhibitors indicated for mantle cell lymphoma include Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib capsules), and Imbruvica (ibrutinib capsules, tablets, and oral suspension). CLL/SLL-patient tried at least one Bruton tyrosine kinase (BTK) inhibitor. Examples of BTK inhibitor include: Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules). Richter's Transformation to DLBCL- pt has tried at least one chemotherapy regimen or is not a candidate for a chemotherapy regimen. Marginal Zone Lymphoma - approve if pt has tried at least one Bruton tyrosine kinase inhibitor. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma - approve if pt has tried at least one systemic regimen. Note: Examples of a systemic regimen contain one or more of the following products: Brukinsa (zanubrutinib</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	capsules), Imbruvica (ibrutinib tablets, capsules, and oral solution), rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, Kyprolis (carfilzomib intravenous infusion), or Ninlaro (ixazomib capsule).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Richter's Transformation to Diffuse Large B-Cell Lymphoma, Marginal Zone Lymphoma, Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# JEMPERLI

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## Products Affected

- JEMPERLI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Endometrial cancer-approve if the patient has recurrent, advanced or metastatic disease. Mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) Solid tumors-approve. Small Bowel Adenocarcinoma-approve if the patient has dMMR or MSI-H disease or DNA polymerase epsilon/delta (POLE/POLD1) mutation and has advanced or metastatic disease. Colon, Rectal, or Appendiceal Cancer- approve if patient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease or DNA polymerase epsilon/delta (POLE/POLD1) mutation AND is being used for neoadjuvant therapy or advanced or metastatic disease. Anal carcinoma- approve if medication will be used as a single agent and (A or B): A) pt has locally recurrent or progressive disease and medication is administered before proceeding to abdominoperineal resection, or B) pt has metastatic disease, and medication is used as subsequent therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Small Bowel Adenocarcinoma, Colon, Rectal or Appendiceal Cancer, Anal carcinoma
<b>Part B Prerequisite</b>	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# JYNARQUE

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## Products Affected

- *tolvaptan (polycystic kidney dis)*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patient is currently receiving another tolvaptan product
<b>Required Medical Information</b>	Diagnosis, renal function
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist
<b>Coverage Duration</b>	1 year (initial and continuation)
<b>Other Criteria</b>	Approve if the patient has rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]), according to the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# KADCYLA

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## Products Affected

- KADCYLA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	Breast Cancer-Recurrent/metastatic-1 yr, Breast Cancer-Adjuvant tx-approve 1 yr total, other-1yr
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-approve if the patient has human epidermal growth factor receptor 2 (HER2)-positive disease and the patient is using for recurrent or metastatic breast cancer OR if using for adjuvant therapy. NSCLC-approve if pt meets (A, B and C): A) the disease has activating human epidermal growth factor receptor 2 (HER2) [ERBB2] mutations and B) the patient has recurrent, advanced, or metastatic disease and C) pt has tried at least one prior systemic therapy. Salivary gland tumor-approve if the patient has recurrent, unresectable, or metastatic disease and the patient has human epidermal growth factor receptor 2 (HER2)-positive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-small cell lung cancer (NSCLC), salivary gland tumor
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# KALYDECO

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## Products Affected

- KALYDECO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with other CF Transmembrane Regulator Modulators
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	1 month of age and older
<b>Prescriber Restrictions</b>	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	CF - must meet A, B, and C: A) pt must have one mutation in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# KANUMA

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## Products Affected

- KANUMA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has a laboratory test demonstrating deficient lysosomal acid lipase activity in leukocytes, fibroblasts, or liver tissue OR a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic lysosomal acid lipase gene variants.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# KERENDIA

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## Products Affected

- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with spironolactone or eplerenone
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Diabetic kidney disease-initial-approve if the patient meets the following criteria (i, ii and iii): i. Patient has a diagnosis of type 2 diabetes AND ii. Patient meets one of the following (a or b): a) Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b) According to the prescriber, patient has a contraindication or has experienced significant intolerance to ACE inhibitor and ARB therapy AND iii. At baseline (prior to the initiation of Kerendia), patient meets all of the following (a, b, and c): a) Estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73 m<sup>2</sup> AND b) Urine albumin-to-creatinine ratio greater than or equal to 30 mg/g AND c) Serum potassium level less than or equal to 5.0 mEq/L. Diabetic kidney disease-continuation-approve if the patient meets the following criteria (i and ii): i. Patient has a diagnosis of type 2 diabetes AND ii. Patient meets one of the following (a or b): a) Patient is currently receiving a maximally tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b) According to the prescriber, patient has a contraindication or has experienced significant intolerance to ACE inhibitor and ARB therapy. Heart failure-initial-Pt meets all (i, ii, and iii): i) has left ventricular ejection fraction of at least 40 percent AND ii) tried or is currently receiving one of the following SGLT-2 inhibitors: Farxiga (dapagliflozin tabs, authorized generic) Inpefa (sotagliflozin tabs), or Jardiance (empagliflozin tabs) OR has</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>contraindication or has experienced significant intolerance to SGLT-2 inhibitors AND iii) at baseline (prior to initiation of Kerendia), meets all (a and b): a) estimated glomerular filtration rate of at least 25 mL/min/1.73m<sup>2</sup> AND b) serum potassium level of less than or equal to 5.0 mEq/L. Heart failure-continuation-Pt meets all (i and ii): i) has left ventricular ejection fraction of at least 40 percent AND ii) tried or is currently receiving one of the following SGLT-2 inhibitors: Farxiga (dapagliflozin tabs, authorized generic) Inpefa or (sotagliflozin tabs), or Jardiance (empagliflozin tabs) or has contraindication or has experienced significant intolerance to SGLT-2 inhibitors.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# KESIMPTA

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## Products Affected

- KESIMPTA PEN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# KEYTRUDA

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## Products Affected

- KEYTRUDA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	Melanoma, bone cancer - 12 and older, Glioma - less than 18 years, all others- 18 and older (except Merkel cell, MSI-H/dMMR tumors, large B-cell lymph, TMB-H, Classic Hodgkin Lymphoma)
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	adrenal gland tumor, anal carcinoma, bone cancer, extranodal NK/T-Cell Lymphoma, nasal type, Gestational trophoblastic neoplasia, mycosis fungoides/Sezary syndrome, primary cutaneous anaplastic large cell lymphoma, small cell lung cancer, soft tissue sarcoma, thymic carcinoma, vulvar cancer, pediatric diffuse high grade glioma, Kaposi sarcoma, small bowel adenocarcinoma (without MSI-H or dMMR), thyroid carcinoma (without MSI-H or dMMR), vaginal cancer, chronic lymphocytic leukemia/small lymphocytic leukemia, penile cancer
Part B Prerequisite	No
Prerequisite Therapy Required	No

# KEYTRUDA QLEX

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## Products Affected

- KEYTRUDA QLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Merkel cell carcinoma/TMB-H cancer, melanoma, bone cancer - 12 and older. All others - 18 and older (except MSI-H/dMMR solid tumors), pediatric diffuse high-grade glioma - less than 18 years
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Thymic carcinoma, anal carcinoma, appendiceal cancers, bone cancer, gestational trophoblastic neoplasia, pediatric diffuse high-grade glioma, penile cancer, small bowel adenocarcinoma, soft tissue sarcoma, vaginal cancer, vulvar cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# KINERET

## Products Affected

- KINERET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another biologic DMARD or targeted synthetic DMARD
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	RA/AOSD/Pericarditis-18 years and older, SJIA-2 years and older
<b>Prescriber Restrictions</b>	Initial therapy only-RA, SJIA and Still's disease, prescribed by or consult with a rheumatologist. CAPS (Neonatal-Onset Multisystem Inflammatory Disease or Chronic Infantile Neurological Cutaneous and Articular syndrome), prescribed by or consult with a rheumatologist, geneticist, allergist/immunologist, or dermatologist.DIRA-rheum, geneticist, dermatologist, or physician specializing in autoinflammatory disorder. Pericarditis, prescribed by or consult with cardiologist or rheumatologist.
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	RA initial. Approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq, Xeljanz/XR, or a preferred tocilizumab product. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: a non-preferred tocilizumab product, Orencia, Cimzia, infliximab, Kevzara, golimumab IV/SC or another non-preferred adalimumab product.] DIRA initial-approve if genetic testing has confirmed bi-allelic pathogenic variants in the IL1RN gene. Adult Onset Still's Disease, approve. SJIA-initial-approve. cont tx - approve if the patient had responded to therapy as determined by the prescriber. Immunotherapy-related toxicities associated with CAR-T cell therapy: approve if patient has or will be treated with CAR-T cell therapy. Pericarditis, initial: approve if (A, B, and C): A) recurrent pericarditis, B) C-reactive protein level greater than 1 mg/dL, and C) for current episode pt is receiving standard treatment or standard treatment is contraindicated [examples of standard treatment: NSAIDs such as ibuprofen, colchicine, systemic corticosteroids]. Pericarditis, cont: experienced beneficial

<b>PA Criteria</b>	<b>Criteria Details</b>
	response. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred tocilizumab products include Actemra, Tyenne.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Adult onset Still's disease (SD). Systemic Juvenile Idiopathic Arthritis (SJIA). Immunotherapy-related toxicities associated with Chimeric Antigen Receptor (CAR) T-cell therapy. Pericarditis
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# KISQALI

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## Products Affected

- KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast cancer - approve for hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative early (stage II or III), recurrent, or metastatic breast cancer [for early breast cancer must be adjuvant treatment and high risk of recurrence] when the pt meets ONE of the following (1, 2, 3 or 4): 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. meets (a, b and c): a) pt is premenopausal or perimenopausal and b) is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND c) Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient meets (a and b): a) is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and b) Kisqali will be used in combination with fulvestrant. Endometrial cancer - approve if pt meets all of (A, B and C): A) pt has recurrent or metastatic disease, and B) has

<b>PA Criteria</b>	<b>Criteria Details</b>
	estrogen receptor (ER)-positive tumors, and C) if request is for Kisqali, Kisqali will be used in combination with letrozole.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Endometrial cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# KOMZIFTI

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## Products Affected

- KOMZIFTI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	ACUTE MYELOID LEUKEMIA-relapsed or refractory disease and disease is positive for a susceptible nucleophosmin 1 (NPM1) mutation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# KORLYM

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## Products Affected

- *mifepristone oral tablet 300 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Endogenous Cushing's Syndrome-Approve if mifepristone is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance AND pt meets (i, ii or iii): i) patient is not a candidate for surgery or surgery has not been curative, or (ii) patient is awaiting surgery for endogenous Cushing's Syndrome or (iii) patient is awaiting therapeutic response after radiotherapy for endogenous Cushing's Syndrome.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# KOSELUGO

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## Products Affected

- KOSELUGO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Neurofibromatosis Type 1-approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas. Circumscribed Glioma-approve if (A and B): A) the patient has recurrent, refractory or progressive disease AND B) one of (i, ii, or iii): i) the tumor is BRAF fusion positive OR ii) BRAF V600E activating mutation positive OR iii) patient has neurofibromatosis type 1 mutated glioma. Langerhans Cell Histiocytosis- approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Circumscribed Glioma, Langerhans Cell Histiocytosis
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# KRAZATI

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## Products Affected

- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Non-Small Cell Lung Cancer (NSCLC)-approve if (A and B): A) the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND B) patient meets either (i or ii): i) has been previously treated with at least one systemic regimen [Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine.] or ii) patient has brain metastases. Colon or Rectal Cancer- approve if pt has unresectable, advanced, or metastatic disease AND pt has KRAS G12C mutation-positive disease AND medication is prescribed as part of a combination regimen or the patient is unable to tolerate combination therapy AND pt has has previously received a chemotherapy regimen for colon or rectal cancer. Ampullary adenocarcinoma-approve if (A, B and C): A) metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy. Biliary tract cancer- approve if (A, B and C): A) unresectable or metastatic disease, B) KRAS G12C mutation-positive disease, and C) previously treated with at least one systemic regimen. Pancreatic adenocarcinoma- approve if (A and B): A) KRAS G12C mutation-positive</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	disease, and B) either (i or ii): (i) locally advanced or metastatic disease and previously treated with at least one systemic regimen, or (ii) recurrent disease after resection. Small bowel adenocarcinoma- approve if (A, B and C): A) advanced or metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Ampullary adenocarcinoma, biliary tract cancer, pancreatic adenocarcinoma, small bowel adenocarcinoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# LANREOTIDE

## Products Affected

- *lanreotide subcutaneous syringe 120 mg/0.5 ml*
- SOMATULINE DEPOT SUBCUTANEOUS SYRINGE 60 MG/0.2 ML, 90 MG/0.3 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous treatments/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescribed by or in consultation with an endo/onc/neuro.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Acromegaly-approve if the patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)-approve. Carcinoid Syndrome/Pheochromocytoma/paraganglioma-approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pheochromocytoma/paraganglioma

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# LAPATINIB

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## Products Affected

- *lapatinib*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which lapatinib is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	HER2-positive advanced, recurrent or metastatic breast cancer, approve if lapatinib will be used in combination with capecitabine OR trastuzumab and the patient has tried at least two prior anti-HER2 based regimens OR the medication will be used in combination with an aromatase inhibitor and and the patient has HR+ disease and the patient is a postmenopausal woman or the patient is premenopausal or perimenopausal woman and is receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian irradiation OR the patient is a man and is receiving a GnRH analog. Colon or rectal cancer-approve if the patient has unresectable advanced or metastatic disease that is human epidermal receptor 2 (HER2) amplified and with wild-type RAS and BRAF disease and the patient has tried at least one chemotherapy regimen or is not a candidate for intensive therapy and the medication is used in combination with trastuzumab (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan) and the patient has not been previously treated with a HER2-inhibitor. Bone Cancer-approve if the patient has recurrent chordoma and if the patient has epidermal growth-factor receptor (EGFR)-positive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Bone cancer-chordoma, colon or rectal cancer, breast cancer in pre/perimenopausal women and men

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# LAZCLUZE

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## Products Affected

- LAZCLUZE ORAL TABLET 240 MG,  
80 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NON-SMALL CELL LUNG CANCER-ALL of the following (A, B and C): A. Locally advanced or metastatic disease, AND B. Epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test, AND C. Used in combination with Rybrevant.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# LEDIPASVIR/SOFOSBUVIR

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## Products Affected

- LEDIPASVIR-SOFOSBUVIR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	3 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# LENALIDOMIDE

## Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (except Kaposi Sarcoma, Castleman Disease, Primary CNS Lymphoma)
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	<p>Follicular lymphoma-approve if (A, B or C): A) the patient is using lenalidomide in combination with rituximab or B) using in combination with Gazyva (obinutuzumab intravenous infusion), or C) pt has tried at least one prior therapy. MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least one other regimen. MZL-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one other regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]), OR 4) meets (i, ii and iii): i) pt has myelodysplastic syndrome/myeloproliferative neoplasm overlap neoplasm, and ii) has SF3B1 mutation, and iii) pt has thrombocytosis . B-cell-lymphoma (other) [examples: diffuse large B-cell lymphoma, high grade B-cell lymphoma, post-transplant lymphoproliferative disorders, HIV-related B-cell lymphoma]-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia with presence of del(5q) and will use this in combination with prednisone. Primary CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease, or is not a candidate for high-dose MTX,</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>or had intolerance to high-dose MTX. Hodgkin lymphoma, classic-approve if (A and B): A) pt has relapsed or refractory disease, and B) pt is not a candidate for high-dose therapy and autologous stem cell rescue. Castleman disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide is used in combination with dexamethasone. Histiocytic neoplasms-approve if (A or B): A) the patient has Langerhans cell histiocytosis with either (i or ii): i) single-system multifocal skin disease or ii) relapsed or refractory disease, or B) pt has Rosai-Dorfman disease. T-Cell lymphoma- approve if (A, B or C): A) pt has peripheral T-cell lymphoma, or B) pt has T-cell leukemia/lymphoma and has tried at least one other regimen, or C) pt has hepatosplenic T-cell lymphoma and has tried at least two other regimens. Chronic lymphocytic leukemia/Small lymphocytic leukemia- approve if (A, B and C): A) relapsed or refractory disease, and B) tried at least one Bruton-tyrosine kinase inhibitor, and C) tried at least one B-cell lymphoma (BCL)2 inhibitor. POEMS Syndrome- approve if used in combination with dexamethasone.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Systemic Amyloidosis Light Chain, B-Cell Lymphoma (other), Myelofibrosis, Castleman Disease, Hodgkin lymphoma (Classic), T-Cell Lymphoma, Primary Central nervous system Lymphoma, Kaposi sarcoma, histiocytic neoplasms, Chronic Lymphocytic Leukemia, Small Lymphocytic Leukemia, POEMS syndrome.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# LENVIMA

## Products Affected

- LENVIMA ORAL CAPSULE 10 MG/DAY (10 MG X 1), 12 MG/DAY (4 MG X 3), 14 MG/DAY(10 MG X 1-4 MG X 1), 18 MG/DAY (10 MG X 1-4 MG X2), 20 MG/DAY (10 MG X 2), 24 MG/DAY(10 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY (4 MG X 2)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	DTC - Approve if pt meets (i OR ii): i) pt meets (a AND b): a) pt has papillary or follicular thyroid carcinoma and b) the disease is refractory to radioactive iodine therapy OR ii) pt has oncocytic carcinoma. RCC - approve if the pt meets ALL of the following criteria: 1) pt has advanced disease AND if the patient meets i or ii-i. Lenvima is is being used in combination with Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b-a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets (A AND B): A) Pt meets (i OR ii): i) Pt meets (a, b AND c): a) The patient has advanced endometrial carcinoma that is mismatch repair proficient (pMMR) or not microsatellite instability-high (MSI-H) AND b) The medication is used in combination with Keytruda (pembrolizumab for intravenous injection) AND c) the patient has tried at least one systemic therapy OR ii) Lenvima is used as a single agent for second-line or subsequent therapy AND B) The patient is not a candidate for curative surgery or radiation. HCC-approve if the patient has unresectable or metastatic disease. Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. Melanoma - approve if the patient has

<b>PA Criteria</b>	<b>Criteria Details</b>
	unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy. Anaplastic thyroid carcinoma-approve if the medication is used in combination with Keytruda (pembrolizumab intravenous infusion).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Melanoma, Anaplastic thyroid carcinoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# LIBTAYO

## Products Affected

- LIBTAYO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous surgeries or radiation. Anal Carcinoma-meets ALL of the following (A, B and C): A) locally recurrent, metastatic, or progressive disease AND B) meets ONE (i or ii): i. The medication is administered before proceeding to abdominoperineal resection OR ii. The medication is used for subsequent therapy AND C) medication is used as a single agent. Colon, Rectal, and appendiceal Cancer-meets ALL of the following (A and B): A) Disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) OR polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutational burden greater than 50 mutations/megabase) AND B) Patient meets ONE of the following (i or ii): i. locally unresectable, advanced, recurrent, metastatic, or medically inoperable disease OR ii. medication is used for neoadjuvant therapy. Small Bowel Adenocarcinoma-meets ALL of the following (A and B): A) Disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) or is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutational burden greater than 50 mutations/megabase) AND B) meets ONE (i or ii): i. has locally unresectable or medically inoperable disease OR ii. advanced or metastatic disease.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. CSCC-approve if the patient meets one of the following (i, ii, or iii): (i): pt has locally advanced, recurrent, or metastatic disease and is not a candidate for curative surgery or curative radiation or (ii): pt has very-high risk, locally advanced, unresectable, in-transit metastasis, or regional disease and this medication

PA Criteria	Criteria Details
	<p>will be used as neoadjuvant therapy, or (iii): pt has disease that is at a high or very-high risk for recurrence, and this medication will be used as adjuvant therapy [Note: High or very-high risk for disease recurrence is defined as nodal features (extracapsular extension with largest node at least 20 mm in diameter or at least 3 involved nodes) or non-nodal features (in-transit metastases, T4 lesion [with bone invasion], perineural invasion, or locally recurrent tumor with at least 1 addition risk feature)]. Basal Cell Carcinoma-approve if the patient has locally advanced, nodal or metastatic disease. NSCLC (recurrent, advanced or metastatic disease)-approve if the tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase (ALK), RET, and ROS1 and meets one of the following (i, ii, iii, or iv): (i): medication is used for first-line or continuation maintenance therapy AND tumor has no actionable mutations, or (ii): medication will be used first line AND the tumor is positive for one of EGFR exon 20 mutation or ERBB2 (HER2) mutation, or NRG1 gene fusion, or (iii): medication will be used as first-line or subsequent therapy AND the tumor is positive for one of BRAF V600E mutation or NTRK1/2/3 gene fusion or MET exon 14 skipping mutation, or (iv): medication will be used as subsequent therapy AND the tumor is positive for one of EGFR S768I, L861Q, and/or G719X mutation. Cervical cancer-approve if pt has local or regional recurrence or distant metastic disease AND this medication is used as subsequent therapy. Vulvar cancer-approve if pt has advanced, recurrent, or metastatic disease AND this medication is used as subsequent therapy. Vaginal cancer- approve if pt meets (A and B): A) meets (i or ii): i) local or regional recurrence, or ii) distant metastatic disease, and B) used as subsequent therapy.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Cervical cancer, vulvar cancer, vaginal cancer, anal carcinoma, colon/rectal/appendiceal cancer, small bowel adenocarcinoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# LIDOCAINE PATCH

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## Products Affected

- *dermacinrx lidocan*
- *lidocaine topical adhesive patch, medicated 5 %*
- *lidocan iii*
- *lidocan iv*
- *lidocan v*
- *tridacaine ii*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Diabetic neuropathic pain, chronic back pain
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# LIVDELZI

## Products Affected

- LIVDELZI

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with Iqirvo
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)
Coverage Duration	6 months initial, 1 year cont.
Other Criteria	<p>INITIAL THERAPY: PRIMARY BILIARY CHOLANGITIS/CIRRHOSIS-All of (A and B): A): Diagnosis confirmed by TWO of the following i, ii, or iii: i) Alkaline phosphatase is elevated above the upper limit of normal, ii) positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific auto-antibodies, including sp100 or gp210, if anti-mitochondrial antibodies are negative or iii) histologic evidence of primary biliary cholangitis from a liver biopsy, B): Receiving ursodiol therapy and had inadequate response or was unable to tolerate ursodiol therapy. Note: examples of ursodiol therapy include ursodiol generic tablets and capsules, Urso 250, Urso Forte, and Actigall.</p> <p>CONTINUATION THERAPY: PRIMARY BILIARY CHOLANGITIS/CIRRHOSIS- patient has demonstrated a response to therapy. Note: Examples of a response to therapy are improved biochemical markers of primary biliary cholangitis (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT]).</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# LIVTENCITY

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## Products Affected

- LIVTENCITY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with ganciclovir or valganciclovir
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center. (initial therapy)
<b>Coverage Duration</b>	2 months
<b>Other Criteria</b>	Cytomegalovirus Infection, Treatment, initial therapy-approve if the patient meets the following criteria (A, B, and C): A) Patient weighs greater than or equal to 35 kg, AND B) Patient is post-transplant, AND Note: This includes patients who are post hematopoietic stem cell transplant or solid organ transplant. C) Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir or patient has a significant intolerance to ganciclovir or valganciclovir. Cytomegalovirus Infection, Treatment, continuation of therapy - approve if patient has responded as demonstrated by cytomegalovirus polymerase chain DNA laboratory results within 4 weeks demonstrating improvement in cytomegalovirus levels.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# LONG ACTING OPIOIDS

## Products Affected

- BELBUCA
- *buprenorphine transdermal patch*
- *hydromorphone oral tablet extended release 24 hr*
- *methadone intensol*
- *methadone oral concentrate*
- *methadone oral solution 10 mg/5 ml, 5 mg/5 ml*
- *methadone oral tablet 10 mg, 5 mg*
- *methadose oral concentrate*
- *morphine oral tablet extended release*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute (ie, non-chronic) pain
<b>Required Medical Information</b>	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, in hospice, sickle cell disease or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# LONSURF

## Products Affected

- LONSURF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Colon, rectal or appendiceal cancer- approve if patients meets (A, B, and C): A) advanced or metastatic disease, B) meets (i or ii): i) has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease or ii) is ineligible for or progressed on checkpoint inhibitor therapy and meets ONE of the following (a or b): a) has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease, or b) is polymerase epsilon/delta (POLE/POLD1) mutation positive, and C) has previously been treated with ALL of the following per labeling (i, ii and iii): i) fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, ii) an anti-vascular endothelial growth factor (VEGF) agent (ex: bevacizumab), and iii) if the tumor is wild-type RAS (KRAS wild-type and NRAS wild-type), patient has received anti-EGFR therapy (ex: Erbitux or Vectibix) or EGFR therapy is not medically appropriate. Gastric or Gastroesophageal Junction Adenocarcinoma, approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Appendiceal cancer
<b>Part B Prerequisite</b>	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# LOQTORZI

## Products Affected

- LOQTORZI

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	<p>Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Nasopharyngeal carcinoma- approve if the patient has recurrent, unresectable, oligometastatic, or metastatic disease. Anal carcinoma- approve if patient meets (A and B): A) meets (i or ii): i) locally recurrent, progressive disease and medication is administered before proceeding to abdominoperineal resection, or ii) metastatic disease, medication is used as subsequent therapy and patient has not received prior checkpoint inhibitors, and B) medication is used as a single agent. Small bowel adenocarcinoma- approve if patient meets (A, B, and C): A) (i or ii): i. locally unresectable or medically inoperable disease or ii. has advanced or metastatic disease and has not received prior checkpoint inhibitors AND, B) patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation positive disease with ultra-hypermutated phenotype (tumor mutation burden greater than 50 mutations/megabase), and C) medication is used as a single agent. Colon and Rectal Cancer- Approve if the patients meets (A, B, and C): A) ONE of the following (i or ii): i. the disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) OR ii. is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden greater than 50 mutations/megabase) AND B) ONE of the following (i or ii): i. BOTH of the following (a and b): a)</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	locally unresectable, advanced, recurrent, metastatic, or medically inoperable disease AND b) has NOT received prior checkpoint inhibitors OR ii. if the medication is used for neoadjuvant therapy AND C) The medication is used as single agent.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anal carcinoma, small bowel adenocarcinoma, colon and rectal cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# LORBRENA

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## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Pediatric Diffuse High-Grade Glioma- less than 18 years old, All others- 18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Erdheim Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has ALK-positive disease and (i or ii): i) advanced, recurrent, or metastatic disease or ii) tumor is inoperable. NSCLC - Approve if the patient has ALK-positive advanced or metastatic NSCLC, as detected by an approved test. NSCLC-ROS1 Rearrangement-Positive, advanced or metastatic NSCLC-approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib. Large B-Cell Lymphoma- approve if ALK-positive disease and disease is relapsed or refractory. Pediatric Diffuse High-Grade Glioma- approve if ALK-positive disease and (i or ii): i) used as adjuvant therapy, or ii) used for recurrent or progressive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive, Erdheim Chester Disease, Inflammatory Myofibroblastic Tumor (IMT), Large B-Cell Lymphoma, Pediatric Diffuse High-Grade Glioma
<b>Part B Prerequisite</b>	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# LUMAKRAS

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## Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 240 MG, 320 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	<p>Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Ampullary adenocarcinoma - approve if pt has KRAS G12C-mutated disease as determined by an approved test AND this is used as subsequent therapy. Colon or rectal cancer - approve if pt meets all (A, B, C and D): A) advanced or metastatic disease, and B) KRAS G12C mutation-positive disease, and C) used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion) or patient is unable to tolerate combination therapy, and D) previously received a chemotherapy regimen for colon or rectal cancer. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease, as determined by an approved test AND either (i or ii): (i) patient has locally advanced or metastatic disease and has been previously treated with at least one systemic regimen OR (ii) patient has recurrent disease after resection. Small bowel adenocarcinoma- approve if pt meets all of (A, B and C): A) has advanced or metastatic disease, and B) has KRAS G12C mutation-positive disease, and C) medication will be used as subsequent therapy.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Small Bowel Adenocarcinoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# LUMIZYME

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## Products Affected

- LUMIZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue OR patient has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic acid alpha-glucosidase (GAA) gene variants.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# LUNSUMIO

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## Products Affected

- LUNSUMIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. Follicular Lymphoma-approve if the patient has received at least two lines of systemic therapy. Note: Examples of systemic therapy for follicular lymphoma include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (obinutuzumab intravenous infusion) and CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva. B-Cell Lymphoma (examples: diffuse large B-cell lymphoma, high-grade B-cell lymphoma, HIV-related B-cell lymphomas, post-transplant lymphoproliferative disorders)- approve if patient has received at least one line of systemic therapy and will be used in combination with Polivy. Note: Examples of systemic therapy for B-Cell lymphoma include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and Pola-R-CHP (Polivy [polatuzumab vedotin-piiq intravenous infusion], rituximab, cyclophosphamide, doxorubicin, prednisone).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	B-Cell Lymphoma
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# LUNSUMIO VELO

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## Products Affected

- LUNSUMIO VELO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. FOLLICULAR LYMPHOMA-patient has received at least two lines of systemic therapy. Note: Examples of systemic therapy include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (obinutuzumab intravenous infusion), CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva, lenalidomide plus rituximab with or without Epkinly (epcoritamab-bysp subcutaneous injection) or Monjuvi (tafasitamab-cxix intravenous infusion), bendamustine plus Gazyva or rituximab, or Tazverik (tazemetostat tablets). MANTLE CELL LYMPHOMA- all of (A and B): A. Tried at least one covalent Bruton tyrosine kinase inhibitor, Note: Examples of a covalent Bruton tyrosine kinase inhibitors include Brukinsa (zanubrutinib capsules and tablets), Calquence (acalabrutinib tablets), and Imbruvica (ibrutinib capsules, oral suspension, and tablets). AND B. Medication will be used in combination with Polivy (polatuzumab vedotin-piiq intravenous infusion) .
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Mantle cell lymphoma
Part B Prerequisite	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# LUPRON DEPOT

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## Products Affected

- LUPRON DEPOT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Premenstrual disorders - 18 years and older
<b>Prescriber Restrictions</b>	Prostate cancer-prescribed by/consultation with oncologist or urologist. Other cancer diagnosis- prescribed by/consultation with an oncologist. Gender dysphoria/reassignment- prescribed by/consultation with endocrinologist or physician who specializes in treatment of transgender patients
<b>Coverage Duration</b>	uterine leiomyomata - 3 months, abnormal uterine bleeding - 6 months, all others - 12 months
<b>Other Criteria</b>	Endometriosis-approve if the pt has tried one of the following, unless contraindicated: a contraceptive, an oral progesterone or depo-medroxyprogesterone injection. An exception can be made if the pt has previously tried a gonadotropin-releasing hormone [GnRH] agonist (e.g. Lupron Depot) or antagonist (e.g. Orilissa). Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease. Premenstrual disorders including PMS and PMDD- approve if pt has severe refractory premenstrual symptoms AND pt has tried an SSRI or combined oral contraceptive. Prostate cancer - for patients new to therapy requesting Lupron Depot 7.5mg, patients are required to try Eligard prior to approval.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	abnormal uterine bleeding, breast cancer, gender dysphoria/gender reassignment, head and neck cancer-salivary gland tumors, ovarian cancer including fallopian tube and primary peritoneal cancers, premenstrual disorders including premenstrual syndrome and premenstrual dysphoric disorder, prophylaxis or treatment of uterine bleeding or menstrual

<b>PA Criteria</b>	<b>Criteria Details</b>
	suppression in pts with hematologic malignancy or undergoing cancer treatment or prior to bone marrow or stem cell transplant, uterine cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# LYNOZYFIC

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## Products Affected

- LYNOZYFIC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. MULTIPLE MYELOMA-all of the following (A and B): A) Tried at least four systemic regimens, AND B) Among the previous regimens tried, the patient has received at least one drug from each of the following classes (i, ii, and iii): i. Proteasome inhibitor, Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), Ninlaro (ixazomib capsules) AND ii. Immunomodulatory drug, Note: Examples include lenalidomide, Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules) AND iii. Anti-CD38 monoclonal antibody, Note: Examples include Darzalex (daratumumab intravenous infusion), Darzalex Faspro (daratumumab and hyaluronidase-fihj subcutaneous injection), or Sarclisa (isatuximab-irfc intravenous infusion).</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# LYNPARZA

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## Products Affected

- LYNPARZA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND The patient is in complete or partial response to at least one platinum-based chemotherapy regimen (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has recurrent or metastatic disease and has (i or ii): i) germline BRCA mutation-positive breast cancer or ii) germline PALB2 mutation-positive breast cancer. Pancreatic Cancer-maintenance therapy-approve if the patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate cancer-castration resistant-approve if the patient has metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>or the pateint has had a bilateral orchiectomy, and the patient meets either (i or ii): i) the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test and the patient has been previously treated with at least one androgen receptor directed therapy or ii) the patient has a BRCA mutation and the medication is used in combination with abiraterone plus one of prednisone or prednisolone. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried at least one systemic regimen.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Uterine Leiomyosarcoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# LYTGOBI

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## Products Affected

- LYTGOBI ORAL TABLET 12 MG/DAY (4 MG X 3), 16 MG/DAY (4 MG X 4), 20 MG/DAY (4 MG X 5)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements as detected by an approved test and if the patient has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, and gemcitabine + cisplatin + Abraxane.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# MAVYRET

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## Products Affected

- MAVYRET ORAL PELLETS IN PACKET
- MAVYRET ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	3 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
<b>Coverage Duration</b>	Chronic HCV- Criteria will be applied consistent with AASLD/IDSA guidance, Acute HCV-8 weeks
<b>Other Criteria</b>	For Chronic Hepatitis C Virus, criteria will be applied consistent with current AASLD/IDSA guidance. For Acute Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6: Approve if the patient meets (A, B and C): A) Does not have cirrhosis OR has compensated cirrhosis AND B) has quantifiable HCV RNA AND C) ONE of the following (i, ii, or iii): i. conversion of negative to positive results in anti-HCV antibody, HCV RNA, and/or HCV core antigen OR ii. signs and symptoms of acute hepatitis C virus OR iii. has engaged in a risk behavior for HCV infection within the prior 6 months.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# MEGESTROL

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## Products Affected

- *megestrol oral suspension 400 mg/10 ml (10 ml), 400 mg/10 ml (40 mg/ml), 625 mg/5 ml (125 mg/ml)*
- *megestrol oral tablet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for weight gain for cosmetic reasons.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# MEKINIST

## Products Affected

- MEKINIST ORAL RECON SOLN
- MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	<p>Melanoma (not including uveal melanoma)- must be used in patients with BRAF V600 mutation or BRAF fusion-positive, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. Uveal melanoma - approve if metastatic or unresectable disease. For NSCLC - approve if (A, B and C): A) recurrent, advanced or metastatic disease and B) pt has BRAF V600 Mutation and C) pt will use in combination with Tafenlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafenlar AND the patient has BRAF V600-positive disease.</p> <p>Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for (a or b): a) low-grade serous carcinoma or b) the patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar.</p> <p>Glioma-patient meets (A or B): A) has BRAF V600 mutation positive or BRAF fusion-positive disease and B) meets (i or ii): i) the medication will be used in combination with Tafenlar or ii) pt has circumscribed glioma.</p> <p>Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease. Solid Tumors [Note: Examples of solid tumors are: biliary tract cancer, brain metastases</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>due to melanoma, differentiated thyroid carcinoma, gastrointestinal stromal tumors, gastric cancer, esophageal and esophagogastric junction cancers, salivary gland tumors, pancreatic adenocarcinoma, neuroendocrine tumors, occult primary, ampullary adenocarcinoma, small bowel adenocarcinoma]- Approve if the patient meets the following (A and B): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafinlar (dabrafenib capsules). Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Tafinlar.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Histiocytic Neoplasm, Hairy Cell Leukemia, Epithelioid Hemangioendothelioma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# MEKTOVI

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## Products Affected

- MEKTOVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, BRAF V600 status, concomitant medications
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Melanoma - approve if the patient meets (A and B): A) has unresectable, advanced or metastatic melanoma AND B) meets (i or ii): i) has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi or ii) has NRAS mutation AND has tried at least one immune checkpoint inhibitor therapy. Histiocytic neoplasm-approve if the patient has Langerhans cell histiocytosis. NSCLC-approve if pt has BRAF V600E mutation-positive recurrent, advanced or metastatic disease AND this medication will be taken in combination with Braftovi (encorafenib capsules).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Histiocytic Neoplasms, NRAS-mutated unresectable, advanced or metastatic melanoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# MEMANTINE

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## Products Affected

- *memantine oral capsule, sprinkle, er 24hr*
- *memantine oral solution*
- *memantine oral tablet*
- *memantine-donepezil*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Indication for which memantine is being prescribed.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with mild to moderate vascular dementia.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# MEPSEVII

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## Products Affected

- MEPSEVII

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has a laboratory test demonstrating deficient beta-glucuronidase activity in leukocytes, fibroblasts, or serum OR has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic glucuronidase gene variants.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# METHYLERGONOVINE

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## Products Affected

- *methylergonovine oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	7 days
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# MODAFINIL/ARMODAFINIL

## Products Affected

- *armodafinil*
- *modafinil oral tablet 100 mg, 200 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Excessive daytime sleepiness associated with narcolepsy-prescribed by or in consultation with a sleep specialist physician or neurologist
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD)-approve. Adjunctive/augmentation treatment for depression in adults-if the patient is concurrently receiving other medication therapy for depression. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome-approve. Excessive daytime sleepiness associated with Narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Idiopathic hypersomnia - approve if diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Excessive daytime sleepiness (EDS) associated with myotonic dystrophy - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only. Idiopathic hypersomnia - modafinil only.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# MODEYSO

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## Products Affected

- MODEYSO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	HIGH-GRADE GLIOMA (Note: Examples of high-grade glioma include World Health Organization (WHO) Grade 3 or 4 gliomas, such as diffuse midline glioma or glioblastoma)-all the following (A, B and C): A) Histone 3 (H3) K27M mutation, AND B) Recurrent or progressive disease, AND C) Received at one least prior therapy. Note: Examples of prior therapy include radiation, temozolomide, procarbazine, lomustine, or vincristine.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# MONJUVI

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## Products Affected

- MONJUVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-Cell Lymphoma - Approve if the patient has been treated with at least one prior chemotherapy regimen. B-cell lymphoma-Approve if the patient has been treated with at least one prior chemotherapy regimen. Follicular lymphoma - approve if pt meets (A and B): A) pt has been treated with at least one prior systemic regimen and B) medication will be used in combination with lenalidomide and rituximab.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	B-Cell Lymphoma (Examples include high-grade B-cell lymphoma, HIV-related B-cell lymphoma, post-transplant lymphoproliferative disorders, histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma)
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# MYFEMBREE

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## Products Affected

- MYFEMBREE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, test results
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Fibroids-Prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of women's health
<b>Coverage Duration</b>	24 months of total therapy between Myfembree or Oriahnn
<b>Other Criteria</b>	Uterine Fibroids (Leiomyomas)-approve if the patient is premenopausal (before menopause) and is experiencing heavy menstrual bleeding associated with the uterine fibroids, the uterine fibroids have been confirmed by a pelvic ultrasound, including transvaginal ultrasonography or sonohysterography, hysteroscopy, or magnetic resonance imaging. Endometriosis-approve if the patient is premenopausal and patient has previously tried one of the following (i or ii): i. A contraceptive (e.g., combination oral contraceptives, levonorgestrel-releasing intrauterine systems, a depo-medroxyprogesterone injection), unless contraindicated OR ii. An oral progesterone (e.g., norethindrone tablets), unless contraindicated.Note: An exception to this requirement can be made if the patient has previously used a gonadotropin-releasing hormone agonist (e.g., Lupron Depot [leuprolide depot suspension]) or Orilissa (elagolix tablets).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# NAGLAZYME

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## Products Affected

- NAGLAZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine 4-sulfatase (arylsulfatase B) activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic arylsulfatase B gene variants.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# NAYZILAM

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## Products Affected

- NAYZILAM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other medications used at the same time
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# NEMLUVIO

## Products Affected

- NEMLUVIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another monoclonal antibody therapy
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	AD: 12 years and older (initial therapy), PN: 18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>INITIAL CRITERIA: ATOPIC DERMATITIS-approve if this medication will be used with a topical corticosteroid (CS) and/or topical calcineurin inhibitor or AD has improved sufficiently with Nemluvio and topical therapy has been discontinued. PRURIGO NODULARIS-All of (A and B): A) Pruritis for greater than or equal to 6 weeks, AND B) Meets i or ii: i) prurigo nodularis is NOT medication induced or secondary to a non-dermatologic condition such as neuropathy or a psychiatric disease, OR ii) secondary cause of prurigo nodularis has been identified and adequately managed. CONTINUATION CRITERIA: ATOPIC DERMATITIS-patient has received at least 4 months of therapy with Nemluvio and has responded to therapy. PRURIGO NODULARIS-patient has received at least 4 months of therapy with Nemluvio, and experienced beneficial clinical response defined by ONE of the following (A, B, or C): A) reduced nodular lesion count, OR B) Decreased pruritus, OR C) Reduced nodular lesion size. Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Nemluvio should be considered under initial therapy.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# NERLYNX

## Products Affected

- NERLYNX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Stage of cancer, HER2 status, previous or current medications tried
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Adjuvant tx breast cancer-Approve for 1 year (total), all others-1 year
<b>Other Criteria</b>	<p>Breast cancer, adjuvant therapy - approve if the patient meets all of the following criteria: patient will not be using this medication in combination with HER2 antagonists, patient has HER2-positive breast cancer AND Patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy. Breast cancer, recurrent or metastatic disease HER2 positive disease-approve if the patient has HER-2 positive breast cancer, and patient meets (i or ii): i) Nerlynx will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens OR ii) the medication is used in combination with one of the following: capecitabine, paclitaxel, or Kadcyla (ado-trastuzumab emtansine intravenous infusion) and the patient has brain metastases. Breast Cancer, Recurrent or Metastatic HER2 Negative Disease: Approve if pt meets (A, B, C and D): A) has HER2-negative breast cancer AND B) cancer has a HER2-activating mutation AND C) meets (i or ii): i) Pt is a postmenopausal female or a male OR ii) pre/perimenopausal female and meets (a or b): a) receiving ovarian suppression/ovarian ablation with a gonadotropin-releasing hormone (GnRH) agonist OR b) has had surgical bilateral oophorectomy or ovarian irradiation AND D) meets (i or ii): i) meets (a and b): a) has hormone receptor (HR)-positive disease AND b) has tried at least one CDK4/6 inhibitor therapy OR ii) has (HR)-negative disease. Cervical Cancer:</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	Approve if patient meets (A, B and C): A) HER2-mutant disease AND B) recurrent or metastatic disease AND C) tried at least one systemic regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Breast Cancer - Recurrent or Metastatic HER2 Negative Disease, Cervical Cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# NEXLETOL

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## Products Affected

- NEXLETOL

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL, b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, AND B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and ezetimibe and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and ezetimibe and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD or HeFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# NEXLIZET

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## Products Affected

- NEXLIZET

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL, b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, AND B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below).</p> <p>ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD or HeFH) [A or B]: A) tried one high-intensity statin for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# NILOTINIB

## Products Affected

- DANZITEN
- nilotinib hcl oral capsule 150 mg, 200 mg, 50 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older, ALL - 15 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Acute lymphoblastic leukemia, philadelphia chromosome positive-approve. CML, philadelphia chromosome positive or BCR::ABL1-mutation positive chronic myeloid leukemia- approve. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafenib or ripretinib. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement. Pigmented villonodular synovitis/tenosynovial giant cell tumor-approve if the patient has tried Turalio or Romvimza or cannot take Turalio or Romvimza, according to the prescriber. For melanoma, cutaneous - approve if the patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST), Pigmented villonodular synovitis/tenosynovial giant cell tumor, Myeloid/Lymphoid neoplasms with Eosinophilia, melanoma cutaneous.
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# NILUTAMIDE

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## Products Affected

- *nilutamide*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Prostate cancer-approve if nilutamide is used in beneficiaries who have had surgical castration or in combination with a luteinizing hormone-releasing hormone (LHRH) agonist.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# NINLARO

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## Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	MM - approve if (A, B, C or D): A) this medication will be used in combination with lenalidomide or cyclophosphamide and dexamethasone, OR B) pt had received at least ONE prior regimen for multiple myeloma OR C) this medication will be used following hematopoietic stem cell transplantation or D) the patient is not a candidate for bortezomib or Kyprolis (carfilzomib intravenous infusion) and is also not a transplant candidate. Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma-approve if used in combination with a rituximab product and dexamethasone (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma, Multiple myeloma after previous treatment (either monotherapy or in combination other than lenalidomide/dexamethasone) or stem cell transplant
Part B Prerequisite	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# NITISINONE

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## Products Affected

- *nitisinone*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant therapy with nitisinone products
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Hereditary Tyrosinemia, Type 1-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming biallelic pathogenic/likely pathogenic variants in the FAH gene OR elevated levels of succinylacetone in the serum or urine.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# NIVESTYM

## Products Affected

- NIVESTYM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Cancer/AML, MDS, ALL-oncologist or a hematologist. Cancer patients receiving BMT and PBPC-prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation. SCN-hematologist. HIV/AIDS neutropenia-infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
<b>Coverage Duration</b>	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT, Radiation-1 mo
<b>Other Criteria</b>	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 2)patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status, or HIV infection patients with low CD4 counts), 3)patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia

<b>PA Criteria</b>	<b>Criteria Details</b>
	[absolute neutrophil count less than 100 cells/mm <sup>3</sup> ], neutropenia expected to be greater than 10 days in duration, pneumonia or other clinically documented infections, invasive fungal infection, hospitalization at the time of fever, prior episode of febrile neutropenia).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Acute lymphocytic leukemia (ALL), Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome)
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# NON-INJECTABLE TESTOSTERONE PRODUCTS

## Products Affected

- *testosterone transdermal gel* 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)
- *testosterone transdermal gel in metered-dose pump* 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %)
- *testosterone transdermal gel in packet* 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram),
- *testosterone transdermal solution in metered pump w/app*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] Gender-

<b>PA Criteria</b>	<b>Criteria Details</b>
	Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# NUBEQA

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## Products Affected

- NUBEQA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (See Note 1) or if the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration sensitive-approve if the medication will be used in combination with a GnRH analog (See Note 1) or if the patient had a bilateral orchiectomy. Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# NUCALA

## Products Affected

- NUCALA SUBCUTANEOUS AUTO-INJECTOR
- NUCALA SUBCUTANEOUS RECON SOLN
- NUCALA SUBCUTANEOUS SYRINGE 100 MG/ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another monoclonal antibody therapy.
<b>Required Medical Information</b>	<p>COPD initial - Approve if pt meets all (A, B AND C): A) pt has a blood eosinophil level at least 300 cells per microliter within the previous 6 weeks or prior to treatment with Nucala or another monoclonal antibody therapy that may alter blood eosinophil levels AND B) received at least 3 months of combination therapy with at least two of LAMA, LABA or ICS, AND C) pt meets (i or ii): i) experienced two or more COPD exacerbations requiring treatment with a systemic corticosteroid with or without an antibiotic in the previous 12 months OR ii) experienced one or more COPD exacerbations requiring a hospitalization in the previous 12 months. Cont - Approve if pt meets all (A, B and C): A) has already received at least 6 months of therapy with Nucala AND B) continues to receive combination therapy with an inhaled LABA and LAMA AND C) patient has experienced a beneficial clinical response, defined by one of the following: reduced symptoms, exacerbations, hospitalizations, ED/urgent care visits, improved lung function).</p>
<b>Age Restrictions</b>	(Initial therapy only): Asthma-6 years of age and older. EGPA/Polyps/COPD-18 years of age and older. HES-12 years and older.
<b>Prescriber Restrictions</b>	(Initial therapy only): Asthma/COPD-Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA-prescribed by or in consultation with an allergist, immunologist, pulmonologist or rheumatologist. HES-prescribed by or in consultation with an allergist, immunologist, hematologist, pulmonologist or rheumatologist. Polyps-prescribed by or in consult with allergist, immunologist or Otolaryngologist
<b>Coverage Duration</b>	Initial-Asthma/polyps/COPD-6 months, EGPA/HES-8 months. 12 months continuation.
<b>Other Criteria</b>	Asthma initial - must have blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks (or prior to tx with Nucala or another monoclonal antibody therapy that may lower blood eosinophil levels) AND has received combo tx w/inhaled corticosteroid

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>AND at least 1 additional asthma controller/maintenance med (Examples: LAMA, LABA, leukotriene receptor antagonist, monoclonal antibody) AND pt's asthma cont to be uncontrolled, or was uncontrolled prior to starting Nucala or another monoclonal antibody therapy for asthma as defined by 1 of following-pt experi 2 or more asthma exacer req tx w/systemic corticosteroids in prev yr, pt experienced 1 or more asthma exacer requiring hospitalization, urgent care visit or ED visit in the prev yr, pt has a FEV1 less than 80% predicted (90% for pt under 18), Pt has FEV1/FVC less than 0.80 (0.9 for pt under 18), or Pt's asthma worsens upon taper of oral (systemic) corticosteroid therapy. Cont-pt responded to Nucala tx as determined by the prescribing physician AND Pt cont to receive tx with an inhaled corticosteroid. EGPA initial-approve if pt has active, non-severe disease, has/had a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks or prior to any monoclonal antibody that may lower blood eosinophil levels. Cont-pt responded to Nucala tx as determined by the prescribing physician.HES initial-pt has had hypereosinophilic synd for greater than or equal to 6 months AND has FIP1L1-PDGFRalpha-negative dis AND pt does NOT have identifiable non-hematologic secondary cause of hypereosinophilic synd AND prior to initiating tx with monoclonal antibody that may lower blood eosinophil levels, pt has/had a blood eosinophil level of greater than or equal to 1,000 cells per microliter. Cont-approve if the patient has responded to Nucala tx. Nasal polyps, initial-approve if pt meets ALL of the following criteria(A, B, C and D):A) pt has chronic rhinosinusitis w/nasal polyposis as evidenced by direct examination, endoscopy, or sinus CT scan AND B)pt experienced 2 or more of the following sympt for at least 8 weeks:nasal congest/obstruct/discharge, and/or reduction/loss of smell AND C)pt meets BOTH of the following (a and b): a)Pt has received tx with intranasal corticosteroid AND b)Pt will continue to receive tx with intranasal corticosteroid concomitantly with Nucala AND D)pt meets 1 of the following (a, b or c): a)Pt has received at least 1 course of tx with a systemic corticosteroid for 5 days or more within the previous 2 years, OR b)Pt has a contraindication to systemic corticosteroid tx, OR c)Pt had prior surgery for nasal polyps.Cont-approve if the pt has received at least 6 months of therapy, continues to receive tx with an intranasal corticosteroid and has responded to tx.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# NUEDEXTA

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## Products Affected

- NUEDEXTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# NUPLAZID

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## Products Affected

- NUPLAZID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# NURTEC

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## Products Affected

- NURTEC ODT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention if Nurtec ODT is being taking for the preventive treatment of episodic migraine.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Migraine, Acute treatment-approve if the patient has tried at least one triptan or has a contraindication to triptans. Preventive treatment of episodic migraine-approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication) and if the patient is currently taking Nurtec ODT, the patient has had a significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Nurtec ODT was initiated.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# NYVEPRIA

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## Products Affected

- NYVEPRIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.
<b>Coverage Duration</b>	Cancer pts receiving chemo-6 mo. PBPC-1 mo
<b>Other Criteria</b>	Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 2) patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts), or 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients undergoing PBPC collection and therapy

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# OCTREOTIDE INJECTABLE

## Products Affected

- *octreotide acetate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-presc/consult with oncologist. Diarrhea assoc w chemo-presc/consult with oncologist/gastro. Small bowel bleed/angiodysplasia-presc/consult gastroenterologist.
<b>Coverage Duration</b>	Enterocutaneous fistula/diarrhea assoc w chemo - 3 months, all others - 1 year
<b>Other Criteria</b>	ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender. DIARRHEA ASSOC W CHEMO (A and B): A) grade 3 or 4 diarrhea [Examples: more than 6 bowel movements above baseline per day, colitis symptoms, interference with activities of daily living, hemodynamic instability, hospitalization, serious complications (eg, ischemic bowel, perforation, toxic mega-colon), or other colitis-related life-threatening conditions] and B) patient has tried at least one antimotility medication. SMALL BOWEL BLEEDS/ANGIODYSPLASIA RELATED BLEEDING: pt has chronic, recurrent gastrointestinal bleeds lasting greater than or equal to 3 months.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma, enterocutaneous fistulas, diarrhea associated with chemotherapy, small bowel bleeds/angiodysplasia related bleeding
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ODOMZO

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## Products Affected

- ODOMZO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	BCC - Must not have had disease progression while on Erivedge (vismodegib).
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metastatic BCC - approve, if the disease is limited to nodal metastases. (Note-This includes primary or recurrent nodal metastases. A patient with distant metastasis does not meet this requirement.) Diffuse Basal Cell Carcinoma Formation, including basal cell nevus syndrome (Gorlin syndrome) or other genetic forms of multiple basal cell carcinoma - approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Metastatic BCC, diffuse basal cell carcinoma formation
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# OFEV

## Products Affected

- OFEV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	IDIOPATHIC PULMONARY FIBROSIS (IPF), INITIAL [A and B]: A) diagnosis confirmed by presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) or surgical lung biopsy and B) forced vital capacity (FVC) greater than or equal to 40 percent of the predicted value at baseline (before any antifibrotic therapy such as Ofev, Jascayd, pirfenidone). INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS, INITIAL (A and B): A) diagnosis confirmed by HRCT and B) FVC greater than or equal to 40 percent of the predicted value. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE (Progressive Pulmonary Fibrosis), INITIAL (all of A, B and C): A) FVC greater than or equal to 40 percent of the predicted value, B) fibrosing lung disease impacting more than 10 percent of lung volume on HRCT, and C) clinical signs of progression. ALL INDICATIONS, CONTINUATION: approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# OGSIVEO

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## Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Desmoid tumors (aggressive fibromatosis)-approve if the patient has progressing desmoid tumors and if the patient requires systemic treatment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# OJEMDA

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## Products Affected

- OJEMDA ORAL SUSPENSION FOR RECONSTITUTION MG/WEEK (100 MG X 5), 600 MG/WEEK (100 MG X 6)
- OJEMDA ORAL TABLET 400 MG/WEEK (100 MG X 4), 500

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	6 months of age and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PEDIATRIC LOW GRADE GLIOMA-patient has relapsed or refractory disease and the tumor is positive for one of the following: BRAF fusion, BRAF rearrangement or BRAF V600 mutation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# OJJAARA

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## Products Affected

- OJJAARA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Myelofibrosis-approve if the patient has (A, B or C): A) higher-risk disease, or B) lower-risk disease and has one disease-related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis), or C) myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease- related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Accelerated or blast phase myeloproliferative neoplasm
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ONUREG

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## Products Affected

- ONUREG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	AML - Approve if the medication is used for post-remission maintenance therapy AND allogeneic hematopoietic stem cell transplant is not planned. Peripheral T-cell lymphoma - approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Peripheral T-cell lymphoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# OPDIVO

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## Products Affected

- OPDIVO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	colon/rectal/melanoma-12 years and older, pediatric hodgkin lymphoma-less than 18 years old, All other (except gestational trophoblastic)-18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	anal carcinoma, cervical carcinoma, endometrial carcinoma, extranodal NK/T-Cell Lymphoma, gestational trophoblastic neoplasia, merkel cell carcinoma, neuroendocrine tumors, pediatric hodgkin lymphoma, small bowel adenocarcinoma, small cell lung cancer, vulvar cancer, ampullary adenocarcinoma, bone cancer, diffuse high-grade gliomas, Kaposi sarcoma, primary mediastinal large B-cell lymphoma, biliary tract cancers, soft tissue sarcoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, pancreatic cancer, squamous cell skin carcinoma, thyroid carcinoma, vaginal cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

Effective 05/01/2026

# OPDIVO QVANTIG

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## Products Affected

- OPDIVO QVANTIG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (all diagnoses except gestational trophoblastic neoplasia)
<b>Prescriber Restrictions</b>	Prescribed by or on consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	appendiceal cancer, ampullary adenocarcinoma, anal carcinoma, biliary tract cancers, cervical cancer, endometrial carcinoma, gestational trophoblastic neoplasia, Kaposi sarcoma, merkel cell carcinoma, mesothelioma, neuroendocrine tumors, small bowel adenocarcinoma, small cell lung cancer, squamous cell skin carcinoma, thyroid carcinoma, vaginal cancer, vulvar cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# OPDUALAG

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## Products Affected

- OPDUALAG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. Melanoma-approve if the patient is greater than or equal to 40 kg and either (i or ii): (i) the patient has unresectable or metastatic disease or (ii) medication is used as neoadjuvant therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# OPSUMIT

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## Products Affected

- OPSUMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	PAH WHO group, right heart catheterization results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Pulmonary arterial hypertension (PAH) WHO Group 1 patients are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# OPSYNVI

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## Products Affected

- OPSYNVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with guanylate cyclase stimulators
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Pulmonary arterial hypertension (PAH) WHO Group 1-approve if patient has had a right-heart catheterization to confirm the diagnosis.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ORGOVYX

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## Products Affected

- ORGOVYX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Prostate Cancer-approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ORKAMBI

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## Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with other CF Transmembrane Conductance Regulator Modulators
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	1 year of age and older
<b>Prescriber Restrictions</b>	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	CF - Approve if the pt meets A, B and C: A) pt has two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator gene, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ORSERDU

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## Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Breast cancer-approve if the patient meets the following criteria (A, B, C, D, E and F): A) Patient has recurrent or metastatic disease, AND B) Patient has hormone receptor positive (HR+) [i.e. estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has estrogen receptor 1 gene (ESR1)-mutated disease, AND E) Patient has tried at least one endocrine therapy, Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen. AND F) meets one of the following (i or ii): i) pt is a postmenopausal woman or a man, or ii) pt is a pre/perimenopausal woman and meets (a or b): a) receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist [examples: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection)] or b) pt has had surgical bilateral oophorectomy or ovarian irradiation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# OTEZLA

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## Products Affected

- OTEZLA MG (51), 10 MG (4)-20 MG (4)-30 MG (47)
- OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)- 20
- OTEZLA XR
- OTEZLA XR INITIATION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	PP/PsA- 6 years and older (initial), All other dx - 18 years and older (initial)
<b>Prescriber Restrictions</b>	All dx-initial only-PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist. Behcet's-prescribed by or in consultation with a dermatologist or rheumatologist
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: PLAQUE PSORIASIS (PP): Approve. PSORIATIC ARTHRITIS (PsA): approve. BEHCET'S-oral ulcers or other mucocutaneous involvement. CONTINUATION THERAPY (PP/PsA/Behcet's): received 4 months of therapy and had a response.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# OXERVATE

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## Products Affected

- OXERVATE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Treatment duration greater than 16 weeks per affected eye(s)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by an ophthalmologist or an optometrist.
<b>Coverage Duration</b>	Initial-8 weeks, continuation-approve for an additional 8 weeks
<b>Other Criteria</b>	Patients who have already received Oxervate-approve if the patient has previously received less than or equal to 8 weeks of treatment per affected eye(s) and the patient has a recurrence of neurotrophic keratitis.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# PADCEV

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## Products Affected

- PADCEV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Urothelial carcinoma-approve if the patient has locally advanced or metastatic disease and meets either (i or ii): (i): Padcev is used as first-line therapy and will be used in combination with Keytruda (pembrolizumab intravenous infusion), or (ii): Padcev is used as subsequent therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# PANRETIN

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## Products Affected

- PANRETIN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Kaposi Sarcoma-approve if the patient is not receiving systemic therapy for Kaposi Sarcoma.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# PAVBLU

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## Products Affected

- PAVBLU

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Administered by or under the supervision of an ophthalmologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# PEMAZYRE

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## Products Affected

- PEMAZYRE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	<p>Cholangiocarcinoma-approve if the patient has unresectable locally advanced, gross residual, or metastatic disease and the tumor has a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen.</p> <p>Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the cancer has fibroblast growth factor receptor 1 (FGFR1) rearrangement, as detected by an approved test.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# PENICILLAMINE

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## Products Affected

- *penicillamine oral tablet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Wilson's Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Cystinuria-approve. Wilson's disease-approve if diagnosis is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, d): a) Presence of Kayser-Fleischer rings, b) Serum ceruloplasmin level less than 20 mg/dL, c) Liver biopsy findings consistent with Wilson's disease, d) 24-hour urinary copper greater than 40 mcg/24 hours.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# PHENYL BUTYRATE

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## Products Affected

- *sodium phenylbutyrate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
<b>Coverage Duration</b>	Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval
<b>Other Criteria</b>	Urea cycle disorders-approve if genetic or enzymatic testing confirmed a urea cycle disorder or if the patient has hyperammonemia diagnosed with an ammonia level above the upper limit of the normal reference range for the reporting laboratory.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# PHEOCHROMOCYTOMA

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## Products Affected

- *metyrosine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior medication trials
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial and continuation therapy for metyrosine)
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin). If the requested drug is metyrosine for continuation therapy, approve if the patient is currently receiving metyrosine or has received metyrosine in the past.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# PHOSPHATE BINDERS AND SIMILAR AGENTS

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## Products Affected

- *calcium acetate(phosphat bind)*
- *sevelamer carbonate oral tablet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients on dialysis [non-D use].
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# PHOSPHODIESTERASE-5 INHIBITORS

## Products Affected

- *alyq*
- *sildenafil (pulmonary arterial hypertension) oral tablet 20 mg*
- *tadalafil (pulmonary arterial hypertension) oral tablet 20 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use With Guanylate Cyclase Stimulators.
<b>Required Medical Information</b>	Diagnosis, right heart cath results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Pulmonary arterial hypertension (PAH), are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Raynaud's Phenomenon-approve if the patient has tried one calcium channel blocker or if use of a calcium channel blocker is contraindicated. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets require confirmation that the indication is PAH or Raynaud's prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Raynaud's Phenomenon
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# PIQRAY

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## Products Affected

- PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X 1), 300 MG/DAY (150 MG X 1), 300 MG/DAY (150 MG X 2)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, E and F): A) The patient is a postmenopausal female, male or pre/perimenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene or fulvestrant) AND F) Piqray will be used in combination with fulvestrant injection.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# PIRFENIDONE

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## Products Affected

- *pirfenidone oral capsule*
- *pirfenidone oral tablet 267 mg, 801 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	IPF (initial therapy)- must have FVC greater than or equal to 40 percent of the predicted value at baseline (before any antifibrotic therapy such as pirfenidone, Ofev, Jascayd) AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. IPF (continuation of therapy)-approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# PLEGRIDY

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## Products Affected

- PLEGRIDY INTRAMUSCULAR
- PLEGRIDY SUBCUTANEOUS PEN INJECTOR 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML
- PLEGRIDY SUBCUTANEOUS SYRINGE 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS).
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist or an MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# POLIVY

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## Products Affected

- POLIVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-cell lymphoma- Approve if the patient has International Prognostic Index score of greater than or equal to 2 and will use Polivy as first line therapy OR the patient has been treated with at least one prior chemotherapy regimen. Note: Diffuse large B-cell lymphoma includes histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma. B-Cell Lymphoma (Examples include HIV-related B-cell lymphoma and post-transplant lymphoproliferative disorders) - approve if the patient has an International Prognostic Index score of at least 2 or has been treated with at least one prior chemotherapy regimen. High-Grade B-Cell Lymphoma - Approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	B-Cell Lymphoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# POMALYST

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## Products Affected

- *pomalidomide*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Kaposi Sarcoma/MM/Systemic light chain amyloidosis-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Primary CNS Lymphoma-approve if the patient has relapsed or refractory disease or is not a candidate for high-dose MTX or had intolerance to high-dose MTX. Kaposi Sarcoma-Approve if the patient meets one of the following (i or ii): i. patient is Human Immunodeficiency Virus (HIV)-negative OR ii. patient meets both of the following (a and b): a) The patient is Human Immunodeficiency Virus (HIV)-positive AND b) The patient continues to receive highly active antiretroviral therapy (HAART). MM-approve if the patient has tried at least one other regimen. Systemic light chain amyloidosis- approve if this is used in combination with dexamethasone and pt tried at least one other regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Systemic Light Chain Amyloidosis, Primary Central Nervous System (CNS) Lymphoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# POSACONAZOLE (ORAL)

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## Products Affected

- *posaconazole oral tablet, delayed release (dr/ec)*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# POTELIGEO

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## Products Affected

- POTELIGEO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Mycosis fungoides/Sezary-prescribed by, or in consultation with an oncologist or dermatologist. ATLL-prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Mycosis Fungoides/Sezary Syndrome-Approve. ATLL- approve if pt meets (A and B): A) pt has chronic high risk, acute, or lymphoma subtypes, and B) medication is used as second-line or subsequent therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Adults with T-cell leukemia/lymphoma (ATLL)
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# PREVYMIS

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## Products Affected

- PREVYMIS INTRAVENOUS
- PREVYMIS ORAL TABLET 240 MG, 480 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# PROMACTA

## Products Affected

- *eltrombopag olamine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Immune Thrombocytopenia or Aplastic Anemia, prescribed by, or after consultation with, a hematologist (initial therapy). Hep C, prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease (initial therapy). MDS-presc or after consult with heme/onc (initial therapy). Post-transplant, prescribed by or in consult with a hematologist, oncologist or stem cell transplant specialist physician (initial)
<b>Coverage Duration</b>	ImmuneThrombo/MDS init3mo,cont1yr,AAinit4mo,cont1yr,Thrombo/HepC1yr,Transplant-init3mo,cont6mo
<b>Other Criteria</b>	Thrombocytopenia in patients with immune thrombocytopenia, initial-approve if the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate, Tavalisse, Doptelet, rituximab) or has undergone a splenectomy. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Treatment of thrombocytopenia in patients with Chronic Hepatitis C initial - approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND if the patient has low platelet counts at baseline (eg, less than 75,000 microliters). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000 microliter) AND tried one immunosuppressant therapy (e.g., cyclosporine) OR patient will be using eltrombopag in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response.

<b>PA Criteria</b>	<b>Criteria Details</b>
	MDS initial-approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Thrombocytopenia post-allogeneic transplantation, initial - approve if, according to the prescriber, the patient has poor graft function AND has a platelet count less than 50,000/mcL. Cont- patient demonstrated a beneficial clinical response.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Thrombocytopenia in Myelodysplastic Syndrome (MDS), Thrombocytopenia in a patient post-allogeneic transplantation
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# PYRIMETHAMINE

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## Products Affected

- *pyrimethamine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist. All other indications - prescribed by or in consultation with an infectious disease specialist or a physician specializing in the treatment of human immunodeficiency virus (HIV) infection
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis, chronic maintenance and prophylaxis of cystoisosporiasis, chronic maintenance and prophylaxis of Pneumocystis pneumonia
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# QINLOCK

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## Products Affected

- QINLOCK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other therapies tried
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Gastrointestinal stromal tumor (GIST)-approve if the patient has tried imatinib or avapritinib tablets, AND the patient meets one of the following criteria (i, ii, or iii): i. Patient has tried sunitinib and regorafenib tablets, OR ii. Patient has tried dasatinib tablets, OR iii. Patient is intolerant of sunitinib. Melanoma, cutaneous-approve if the patient has metastatic or unresectable disease, AND the patient has an activating KIT mutation, AND the patient has tried at least one systemic regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Melanoma, cutaneous
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# QULIPTA

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## Products Affected

- QULIPTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Migraine headache prevention-approve if the patient meets (A and B): A) has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication, and B) if the pt is currently taking Qulipta, the pt has had significant clinical benefit. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Qulipta was initiated.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# RADICAVA ORS

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## Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT SUSP

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	ALSFRS-R score
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS (initial and continuation).
<b>Coverage Duration</b>	Initial, 6 months. Continuation, 6 months
<b>Other Criteria</b>	ALS, initial therapy - approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, based on the application of the El Escorial or the revised Airlie house diagnostic criteria AND 2. Patient has a score of two points or more on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. Patient has adequate respiratory function according to the prescriber, AND 4. Patient has received or is currently receiving riluzole tablets. Note-a trial of Tiglutik or Exservan would also count. ALS, continuation therapy - approve if, according to the prescribing physician, the patient continues to benefit from therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# RECLAST

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## Products Affected

- *zoledronic acid-mannitol-water*  
*intravenous piggyback 5 mg/100 ml*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with Other Medications for Osteoporosis (e.g., other bisphosphonates, Evenity, Prolia, Forteo/Bonsity, Tymlos, calcitonin nasal spray)
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Paget's 1 month. Others 12 months.
<b>Other Criteria</b>	Tx of osteo in post menopausal pt or osteo in men (a man defined as an individual with biological traits of man, regardless of the individual's gender identity/gender expression), must meet ONE of the following: pt had inadequate response after 12 mo (eg, ongoing and sign loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or pt experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot swallow or has difficulty swallowing or pt cannot remain in upright position post oral bisphos admin or pt has pre-existing GI condition (eg, pt with esophageal lesions/ulcers, or abnormal of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt had an osteo fracture or a fragility fracture OR pt has tried IV Reclast (zoledronic acid). Tx of PMO may have also tried IV Boniva (ibandronate) for approval. Prevent or tx of GIO, approve if: pt is initiating or cont therapy with systemic glucocorticoids, AND had an inadequate response after 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had an osteo fracture or fragility fracture while on therapy or pt experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because pt cannot

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>swallow or has difficulty swallowing or pt cannot remain in an upright position post oral bisphos administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), or has tried Reclast OR patient had an osteo fracture or a fragility fracture. Tx of Paget's disease, approve if pt has elevations in serum alkaline phos of two times higher than the upper limit of the age-specific normal reference range, OR pt is symptomatic (eg, bone pain, hearing loss, osteoarthritis), OR pt is at risk for complications from their disease (eg, immobilization, bone deformity, fractures, nerve compression syndrome). Prevent of PMO - meets 1 of the following had inadequate response after trial duration of 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or pt had osteo fracture or fragility fracture while receiving therapy or patient experienced intol (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take oral bisphos because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphos admin or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions/ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried Reclast or the patient has had an osteo fracture or fragility fracture.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# RELEUKO

## Products Affected

- RELEUKO SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Cancer/AML, MDS, ALL-oncologist or a hematologist. Cancer patients receiving BMT and PBPC-prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN-hematologist. HIV/AIDS neutropenia-infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. Radiation syndrome-prescribed by or in consultation with expert in acute radiation.
Coverage Duration	chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N, ALL,BMT,Radi-1 mo
Other Criteria	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), 2)patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status, or HIV infection patients with low CD4 counts), 3)patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy, has febrile neutropenia and has at

<b>PA Criteria</b>	<b>Criteria Details</b>
	least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm <sup>3</sup> ], neutropenia expected to be greater than 10 days in duration, pneumonia or other clinically documented infection, invasive fungal infection, hospitalization at the time of fever, prior episode of febrile neutropenia)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Neutropenia associated with HIV or AIDS, Treatment of myelodysplastic syndromes (MDS), Drug induced agranulocytosis or neutropenia, Acute lymphocytic leukemia (ALL), peripheral blood progenitor cell transplantation in patients with cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# REMICADE

## Products Affected

- INFLIXIMAB
- REMICADE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medication, previous medications tried
<b>Age Restrictions</b>	CD/UC/Behcet's/GVHD/JIA/UV - Pts aged 6 years or more (initial therapy). AS/PsA/RA/HS/PG/Sarcoidosis/Scleritis, sterile corneal ulceration/Still's/PP-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	All dx-initial therapy only-Prescribed by or in consult w/RA/AS/Still's/JIA/JRA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis/scleritis, sterile corneal ulceration-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's-rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarcoidosis-pulmonol, ophthalmol, or dermatol, cardio/neuro.
<b>Coverage Duration</b>	Init:GVHD1mo,PG4mo,Scler6mo,Other3mo.Cont:GVHD3mo,Other1yr
<b>Other Criteria</b>	INITIAL THERAPY: RHEUMATOID ARTHRITIS: tried one conventional synthetic DMARD for at least 3 months (e.g., MTX, leflunomide, hydroxychloroquine, sulfasalazine. 3-month trial of a biologic also counts). CROHN'S DISEASE: approve. ULCERATIVE COLITIS: approve. BEHCET'S (A or B): A) tried one conventional therapy (e.g., systemic CS, immunosuppressants such as AZA, MTX, mycophenolate, CSA, tacrolimus, chlorambucil, cyclophosphamide, interferon alfa. TNF inhibitor also counts.) or B) ophthalmic manifestations. STILL'S DISEASE (A and B): A) tried one CS and B) tried one DMARD for at least 2 months or intolerant (e.g., MTX. Trial of a biologic also counts.) UVEITIS: tried periocular, intraocular or systemic CS or immunosuppressive (e.g., MTX, mycophenolate, CSA. Trial of a biologic also counts.) SARCOIDOSIS (A and B): A) tried one CS and B) tried one immunosuppressant (e.g., MTX, AZA, leflunomide, mycophenolate, hydroxychloroquine, chloroquine.) PYODERMA GANGRENOSUM (A or B): A) tried one systemic CS or B)

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>tried one immunosuppressant for at least 2 months or intolerant (e.g., mycophenolate, CSA). HIDRADENITIS SUPPURATIVA: Tried one other therapy (e.g., intralesional or oral CS, systemic antibiotics, isotretinoin). GRAFT VS HOST DISEASE: Tried one conventional systemic treatment (e.g., CS, antithymocyte globulin, CSA, tacrolimus, mycophenolate.) JUVENILE IDIOPATHIC ARTHRITIS: (A or B): A) tried one systemic medication (e.g., MTX, sulfasalazine, leflunomide, NSAID. Trial of a biologic also counts.) or B) has aggressive disease. PLAQUE PSORIASIS (A or B): A) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Trial of a biologic will also count) or B) contraindication to MTX. SCLERITIS/STERILE CORNEAL ULCERATION: tried one other therapy for this condition (e.g., oral non-steroidal anti-inflammatory drugs (NSAIDs), oral, topical (ophthalmic), or intravenous corticosteroids, MTX, CSA, or other immunosuppressants). CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis, Scleritis/ sterile corneal ulceration
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# REMODULIN

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## Products Affected

- *treprostinil sodium*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with Other Oral or Inhaled Prostacyclin Agents Used for Pulmonary Hypertension.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH WHO Group 1, prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation).
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Pulmonary Arterial Hypertension (PAH) [World Health Organization (WHO) Group 1], Initial Therapy- Approve if the patient meets all of the following criteria (i, ii, iii, and iv): i. Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH), AND ii. Patient meets the following criteria (a and b): a) Patient has had a right heart catheterization, AND b) Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH, AND iii. Patient meets ONE of the following criteria (a or b): a) Patient is in Functional Class III or IV, OR b) Patient is in Functional Class II and meets ONE of the following criteria [(1) or (2)]: (1) Patient has tried or is currently receiving one oral agent for PAH, OR (2) Patient has tried one inhaled or parenteral prostacyclin product for PAH, AND iv. Patient with idiopathic PAH must meet ONE of the following criteria (a, b, c, d, or e): a) Patient meets both of the following criteria [(1) and (2)]: (1) the patient has had an acute response to vasodilator testing that occurred during the right heart catheterization, AND (2) Patient has tried one calcium channel blocker (CCB) therapy, OR b) According to the prescriber, the patient did not have an acute response to vasodilator testing, OR c) According to the prescriber, the patient cannot undergo a vasodilator test, OR d) Patient cannot take CCB therapy, OR e) Patient has tried one CCB. Continuation-Approve if the patient meets ALL of the following

<b>PA Criteria</b>	<b>Criteria Details</b>
	conditions (a and b): a) Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH), AND b) Patient meets the following criteria [(1) and (2)]: (1) Patient has had a right heart catheterization, AND (2) Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# REPATHA

## Products Affected

- REPATHA
- REPATHA SURECLICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of Leqvio or Praluent.
<b>Required Medical Information</b>	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field)
<b>Age Restrictions</b>	ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Approve for 1 year
<b>Other Criteria</b>	<p>HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL (or 155 mg/dL if less than 16 years old), b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) or b) statin intolerant (throughout, see Definition 2 below). ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant.</p> <p>PRIMARY HYPERLIPIDEMIA (not associated with established CVD, HeFH, or HoFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. TO REDUCE MAJOR ADVERSE CV EVENTS IN PTS AT INCREASED RISK THAT DO NOT HAVE ESTABLISHED CVD [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer or B) statin intolerant. HYPERLIPIDEMIA WITH HoFH (both A and B): A) meets (a or b): a) phenotypic confirmation of HoFH, or b) meets (i and ii): i) untreated LDL-C greater than 400 mg/dL or treated LDL-C greater than or equal to 300 mg/dL, and ii) clinical manifestations of HoFH before 20</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	years of age or at least one parent with untreated LDL-C or total cholesterol consistent with FH, AND B) meets (a or b): a) tried one high-intensity statin or b) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# RETEVMO

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors-2 years and older, all others 18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has recurrent, advanced or metastatic disease AND the tumor is RET fusion-positive. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion positive or RET mutation positive disease or RET pathogenic variant AND the patient meets i, ii or iii: i. patient has anaplastic thyroid cancer OR ii. the disease requires treatment with systemic therapy and patient has medullary thyroid cancer or iii. the disease requires treatment with systemic therapy and the disease is radioactive iodine-refractory if radioactive iodine is appropriate. Solid tumors-approve if the patient has recurrent, advanced or metastatic disease and the tumor is rearranged during transfection (RET) fusion-positive. Histiocytic neoplasm-approve if the patient has a rearranged during transfection (RET) fusion and has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anaplastic thyroid carcinoma, histiocytic neoplasm
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# REVCOVI

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## Products Affected

- REVCOVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, lab values, genetic tests (as specified in the Other Criteria field)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with, an immunologist, hematologist/oncologist, or physician that specializes in ADA-SCID or related disorders.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	ADA-SCID - approve if the patient had absent or very low (less than 1% of normal) ADA catalytic activity at baseline (i.e., prior to initiating enzyme replacement therapy) OR if the patient had molecular genetic testing confirming bi-allelic pathogenic variants in the ADA gene.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# REVUFORJ

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## Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	ACUTE LEUKEMIA-patient has relapsed or refractory disease and either (i or ii): i) acute myeloid leukemia and either (a or b): a) the disease is positive for a lysine methyltransferase 2A (KMT2A) gene translocation or rearrangement or b) the disease is positive for a susceptible nucleophosmin 1 (NPM1) mutation, OR ii) acute lymphoblastic leukemia and disease is positive for a lysine methyltransferase 2A (KMT2A) gene translocation or rearrangement.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# REZDIFFRA

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## Products Affected

- REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist (initial/continuation)
Coverage Duration	1 year
Other Criteria	<p>INITIAL THERAPY: METABOLIC-DYSFUNCTION ASSOCIATED STEATOHEPATITIS (MASH)/NON-ALCOHOLIC STEATOHEPATITIS (NASH): All of (i, ii and iii): i) Diagnosed by (a or b): a) Liver biopsy performed within 3 years preceding treatment with Rezdifra or Wegovy, or b) One of the following within 6 months preceding treatment with Rezdifra or Wegovy (1, 2, 3 or 4): 1) Elastography (e.g. vibration-controlled transient elastography (e.g., FibroScan), transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography) or 2) Computed tomography or 3) Magnetic resonance imaging, or 4) Enhanced Liver Fibrosis (ELF) test with score greater than or equal to 9.2 and less than or equal to 10.5, and ii) stage F2 or F3 fibrosis prior to Rezdifra or Wegovy and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise). CONTINUATION THERAPY (on therapy less than 1 year or restarting, review as initial therapy): MASH/NASH: All of (i, ii and iii): i) completed greater than or equal to 1 year of therapy and has not had worsening of fibrosis or MASH/NASH, and ii) has not progressed to stage F4 (cirrhosis) and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise).</p>
Indications	All FDA-approved Indications.

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# REZLIDHIA

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## Products Affected

- REZLIDHIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Acute myeloid leukemia-approve if the patient has relapsed or refractory disease and the patient has isocitrate dehydrogenase-1 (IDH1) mutation positive disease as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# REZUROCK

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## Products Affected

- REZUROCK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older (initial therapy)
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Graft-versus-host disease, initial-approve if the patient has chronic graft-versus-host disease and has tried at least two systemic medications (examples: Jakafi [ruxolitinib], Nektimvo [axatilimab-csfr], ibrutinib) for chronic graft-versus-host disease. Graft-versus-host disease, continuation-approve if patient has demonstrated a beneficial clinical response.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# RILUZOLE

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## Products Affected

- *riluzole*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# RINVOQ

## Products Affected

- RINVOQ ORAL TABLET EXTENDED RELEASE 24 HR 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic oral small molecule drug, Concurrent use with other potent immunosuppressants, or concurrent use with a biologic immunomodulator.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	PsA/JIA - 2 years and older (initial therapy), RA/UC/AS/CD/nraxSpA/GCA-18 years and older (initial therapy), AD-12 years and older (initial therapy)
<b>Prescriber Restrictions</b>	RA/AS/Non-Radiographic Spondy/JIA/GCA, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or dermatologist. UC/CD-prescribed by or in consultation with a gastroenterologist. (all apply to initial therapy only)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA)/PSORITIC ARTHRITIS (PsA)/ANKYLOSING SPONDYLITIS (AS)/JUVENILE IDIOPATHIC ARTHRITIS (JIA): 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. ULCERATIVE COLITIS (UC)/CROHN'S DISEASE (CD): 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial or use of TNFi is clinically inadvisable per the prescriber. ATOPIC DERMATITIS (AD): 90 day trial of at least one systemic therapy (e.g., Dupixent [dupilumab subcutaneous injection], Ebglyss (lebrikizumab-lbkz subcutaneous injection), Nemluvio (nemolizumab-ilt subcutaneous injection), and Adbry [tralokinumab-ldrm subcutaneous injection]. Azathioprine, cyclosporine, or mycophenolate mofetil also count.) or unable to tolerate a 90 day trial. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (A and B): A) objective signs of inflammation defined as having at least one of the following (a or b): a) C-

<b>PA Criteria</b>	<b>Criteria Details</b>
	reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI and B) 3-month trial of at least one TNFi or was unable to tolerate a 3-month trial. GIANT CELL ARTERITIS: tried one or is currently taking a systemic corticosteroid or corticosteroids are contraindicated. CONTINUATION THERAPY: ALL INDICATIONS: patient responded to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# RINVOQ LQ

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## Products Affected

- RINVOQ LQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic DMARD, other potent immunosuppressants, other janus kinase inhibitors, or a biologic immunomodulator.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	PsA-2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	JIA-prescribed by or in consultation with a rheumatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or a dermatologist (initial therapy)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: JUVENILE IDIOPATHIC ARTHRITIS (JIA)/ PSORIATIC ARTHRITIS (PsA) - 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. CONTINUATION THERAPY: ALL INDICATIONS - patient responded to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ROFLUMILAST (ORAL)

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## Products Affected

- *roflumilast*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial therapy - 6 months, Continuation of therapy - 1 year
Other Criteria	<p>INITIAL THERAPY, COPD: all of (A, B, C and D): A) patient has forced expiratory volume in 1 second (FEV1) less than 50 percent predicted, and B) history of two or more moderate COPD exacerbations or one or more severe COPD exacerbations [Note: A moderate exacerbation is an exacerbation that required treatment with a short-acting bronchodilator and a systemic corticosteroid. A severe COPD exacerbation is an exacerbation that required hospitalization or an Emergency Department visit.], and C) patient has chronic bronchitis, and D) patient tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, olodaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone).</p> <p>CONTINUATION THERAPY, COPD: both (A and B): A) patient continues to receive combination therapy with a LABA and a LAMA, and B) patient has beneficial response defined by one of the following: reduced COPD symptoms, reduced COPD exacerbations, reduced COPD-related hospitalizations, reduced emergency department or urgent care visits, or improved lung function parameters.</p>
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ROMVIMZA

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## Products Affected

- ROMVIMZA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	TENOSYNOVIAL GIANT CELL TUMOR (PIGMENTED VILLONODULAR SYNOVITIS)-tumor is not amenable to improvement with surgery.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ROZLYTREK

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## Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PELLETS IN PACKET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	NSCLC-18 years and older, Solid Tumors-1 month and older, Pediatric Diffuse High-Grade Glioma-less than 18 years old
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Solid Tumors-Approve if the patient's tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease and the mutation was detected by an approved test. Pediatric Diffuse High-Grade Glioma- approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used either as adjuvant therapy or for recurrent or progressive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pediatric Diffuse High-Grade Glioma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# RUBRACA

## Products Affected

- RUBRACA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if (A, B and C): A) the patient is in complete or partial response after a platinum-based chemotherapy regimen, and B) meets (i or ii): i) the patient is in complete or partial response to first-line primary treatment or ii) patient has recurrent disease and has a BRCA mutation, and C) for new starts, the patient has tried the preferred product Lynparza, unless the prescriber indicates that Lynparza is inappropriate for the patient's specific clinical situation. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy, and D) for new starts, the patient has tried one of the preferred products, Lynparza or Talzenna, unless the prescriber indicates that both Lynparza and Talzenna are inappropriate for the patient's specific clinical situation. Pancreatic adenocarcinoma-approve if pt has a BRCA mutation or PALB2 mutation AND pt has tried platinum-based chemotherapy AND has not had disease progression following the most recent platinum-based chemotherapy.</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# RUFINAMIDE

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## Products Affected

- *rufinamide*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Patients 1 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial therapy-approve if rufinamide is being used for adjunctive treatment. Continuation-approve if the patient is responding to therapy
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Treatment-Refractory Seizures/Epilepsy
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# RUXIENCE

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## Products Affected

- RUXIENCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# RYBREVANT

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## Products Affected

- RYBREVANT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Non-Small Cell Lung Cancer (NSCLC) - approve if pt has locally advanced or metastatic disease AND either (A, B or C): (A) the pt has epidermal growth factor receptor (EGFR) exon 20 insertion mutations, or B) EGFR exon 19 deletion, or C) EGFR exon 21 L858R mutation (for all mutations- as detected by an approved test).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# RYBREVANT FASPRO

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## Products Affected

- RYBREVANT FASPRO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. NON-SMALL CELL LUNG CANCER-locally advanced or metastatic disease and ONE of the following: epidermal growth factor receptor (EGFR) exon 20 insertion mutations, EGFR exon 19 deletions, or EGFR exon 21 L858R substitution mutations.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# RYDAPT

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## Products Affected

- RYDAPT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For AML, FLT3 status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	AML-approve if the patient is FLT3-mutation positive as detected by an approved test. Myeloid or lymphoid Neoplasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement. Indolent systemic mastocytosis-pt has symptomatic disease and has tried at least one systemic regimen. Smoldering systemic mastocytosis-pt has tried at least one systemic regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myeloid or lymphoid Neoplasms with eosinophilia, indolent systemic mastocytosis, smoldering systemic mastocytosis
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# RYTELO

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## Products Affected

- RYTELO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older (initial)
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist (initial)
Coverage Duration	1 year
Other Criteria	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. INITIAL THERAPY: MYELODYSPLASTIC SYNDROME-All of (i, ii, iii, and iv): i.Very low- to intermediate risk myelodysplastic syndrome (MDS), Note: MDS risk category is determined using the International Prognostic Scoring System (IPSS). AND, ii.Transfusion-dependent anemia, defined as requiring transfusion of greater than or equal to 4 red blood cell units over an 8-week period, AND iii. Has not responded, lost response to, or is ineligible for erythropoiesis-stimulating agents, Note: Examples of erythropoiesis-stimulating agents (ESA): epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera). Note: a patient with a serum erythropoietin level greater than 500 mU/mL is considered ineligible for ESA. AND, iv. Rytelo will NOT be used in combination with an ESA.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# SANDOSTATIN LAR

## Products Affected

- *octreotide,microspheres* SUSPENSION,EXTENDED REL
- SANDOSTATIN LAR DEPOT RECON 10 MG  
INTRAMUSCULAR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous treatments/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Acromegaly-prescr/consult w/endocrinologist. All neuroendocrine tumors-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist or neurosurgeon. Merkel cell/Thymoma/Thymic carcinoma-prescr/consult w/oncologist. Diarrhea assoc w chemo-prescr/consult oncologist/gastro. Small bowel bleed/angiodysplasia-prescr/consult gastroenterologist.
<b>Coverage Duration</b>	Enterocutaneous fistula/diarrhea chemo - 3 months, small bowel bleed - 6 mos, all others - 1 year
<b>Other Criteria</b>	Acromegaly-approve if the patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Diarrhea assoc w chemo (A and B): A) grade 3 or 4 diarrhea [Examples: more than 6 bowel movements above baseline per day, colitis symptoms, interference with activities of daily living, hemodynamic instability, hospitalization, serious complications (eg, ischemic bowel, perforation, toxic mega-colon), or other colitis-related life-threatening conditions] and B) patient has tried at least one antimotility medication. Merkel cell carcinoma (A and B): A) patient has regional or distant metastatic disease and B) has contraindications to or has progressed on checkpoint immunotherapy. Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas

<b>PA Criteria</b>	<b>Criteria Details</b>
	(including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas)-approve. Small bowel bleeds/angiodyspasia related bleeding: pt has chronic, recurrent gastrointestinal bleeds lasting greater than or equal to 3 months.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pheochromocytoma/paraganglioma, Meningioma, Thymoma and thymic carcinoma, enterocutaneous fistulas, diarrhea associated with chemotherapy, Merkel cell carcinoma, small bowel bleeds/angiodyspasia related bleeding
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# SAPROPTERIN

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## Products Affected

- *sapropterin*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Palynziq
<b>Required Medical Information</b>	Diagnosis, Phe concentration
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)
<b>Coverage Duration</b>	Initial-12 weeks, Continuation-1 year
<b>Other Criteria</b>	Initial - approve. Continuation (Note-if the patient has received less than 12 weeks of therapy or is restarting therapy with sapropterin should be reviewed under initial therapy) - approve if the patient has had a response to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# SARCLISA

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## Products Affected

- SARCLISA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Multiple myeloma-approve if pt meets (A, B, or C): A) the requested medication will be used as primary therapy in combination with (i or ii): i) bortezomib, lenalidomide, and dexamethasone, or ii) Kyprolis (carfilzomib intravenous infusion), lenalidomide, and dexamethasone, or B) the requested medication will be used in combination with Pomalyst and dexamethasone and the patient has tried at least TWO prior regimens for multiple myeloma and a proteasome inhibitor was a component of at least one previous regimen and Revlimid was a component of at least one previous regimen, or C) medication will be used in combination with Kyprolis and dexamethasone and pt has tried at least one prior regimen.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# SCSEMBLIX

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Chronic Myeloid Leukemia (CML)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive or BCR::ABL1-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i, ii or iii): i. Patient has newly diagnosed disease, OR ii. The chronic myeloid leukemia is T315I-positive, OR iii. Patient has tried at least one other tyrosine kinase inhibitor. Note: Examples of tyrosine kinase inhibitors include imatinib, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), dasatinib, and nilotinib capsules. Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has an ABL1 rearrangement. Acute lymphoblastic leukemia (ALL)- approve if the pt has Philadelphia chromosome-positive ALL and this medication will be used in combination with dasatinib.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myeloid/Lymphoid Neoplasms with Eosinophilia, Acute Lymphoblastic Leukemia (ALL)
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# SIGNIFOR

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## Products Affected

- SIGNIFOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy)
<b>Coverage Duration</b>	Cushing's disease/syndrome-Initial therapy - 4 months, Continuation therapy - 1 year.
<b>Other Criteria</b>	Cushing's disease, initial therapy - approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushing's disease, continuation therapy - approve if the patient has already been started on Signifor/Signifor LAR and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# SIRTURO

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## Products Affected

- SIRTURO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients weighing less than 8 kg
<b>Required Medical Information</b>	Diagnosis, concomitant therapy
<b>Age Restrictions</b>	Patients 2 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with an infectious diseases specialist or pulmonologist
<b>Coverage Duration</b>	9 months
<b>Other Criteria</b>	Tuberculosis (Pulmonary) -Approve if the patient has Mycobacterium tuberculosis resistant to at least rifampin and isoniazid and the requested medication is prescribed as part of a combination regimen with other anti-tuberculosis agents
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# SKYRIZI

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## Products Affected

- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR 180 MG/1.2 ML (150 MG/ML), 360 MG/2.4 ML (150 MG/ML)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis, Previous medication use
<b>Age Restrictions</b>	PP/UC/CD/PsA-18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	PP-Prescribed by or in consultation with a dermatologist (initial therapy), PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy), CD/UC-presc/consult-gastro (initial therapy)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or PUVA) for at least 3 months, unless intolerant. (Note: a 3-month trial or previous intolerance to at least one biologic also counts) or B) contraindication to MTX. PSORIATIC ARTHRITIS (PsA): approve. CROHN'S DISEASE (CD): approve. UICERATIVE COLITIS (UC)-approve. CD/UC: Patient must be receiving induction dosing with Skyrizi IV within 3 months of initiating therapy with Skyrizi subcutaneous. CONTINUATION THERAPY: ALL INDICATIONS: patient has responded to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# SKYRIZI IV

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## Products Affected

- SKYRIZI INTRAVENOUS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis, Previous medication use
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	Approve for 3 doses
<b>Other Criteria</b>	Crohn's Disease- approve if this medication will be used as induction therapy. Ulcerative colitis- approve if this medication will be used as induction therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# SOFOSBUVIR/VELPATASVIR

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## Products Affected

- SOFOSBUVIR-VELPATASVIR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	3 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied according to AASLD guidelines.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# SOLARAZE

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## Products Affected

- *diclofenac sodium topical gel 3 %*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 6 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# SOMAVERT

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## Products Affected

- SOMAVERT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapy, concomitant therapy
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# SORAFENIB

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## Products Affected

- *sorafenib*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Bone cancer, approve if the patient has recurrent chordoma or has osteosarcoma and has tried one standard chemotherapy regimen. GIST, approve if the patient has tried TWO of the following: imatinib mesylate, avapritinib, sunitinib, dasatinib, ripretinib or regorafenib. Differentiated thyroid carcinoma (DTC), approve if the patient meets (A or B): A) has papillary or follicular thyroid carcinoma and the disease is refractory to radioactive iodine treatment or B) has oncocytic (formerly Hurthle cell) carcinoma. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test and the medication is used in combination with azacitidine or decitabine or patient has had an allogeneic stem cell transplant and is in remission. Renal cell carcinoma (RCC)-approve if the patient has relapsed or advanced clear cell histology and the patient has tried at least one systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and sorafenib is used in combination with topotecan. HCC-approve if the patient has unresectable or metastatic disease. Soft tissue sarcoma-approve if the patient has angiosarcoma or desmoid tumors (aggressive fibromatosis) or solitary fibrous tumor/hemangiopericytoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. Please note

<b>PA Criteria</b>	<b>Criteria Details</b>
	for all diagnoses: Part B before Part D Step Therapy applies only to beneficiaries enrolled in an MA-PD plan
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Bone cancer, Soft tissue sarcoma, gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, ovarian, fallopian tube, primary peritoneal cancer, myeloid/lymphoid neoplasms with eosinophilia
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# SPRAVATO

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## Products Affected

- SPRAVATO NASAL SPRAY, NON-AEROSOL 56 MG (28 MG X 2), 84 MG (28 MG X 3)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by a psychiatrist or mental health provider
<b>Coverage Duration</b>	MDD w/Acute Suicidal Ideation or Behavior - 2 months, Treatment-Resistant Depression - 6 months
<b>Other Criteria</b>	Major Depressive Disorder with Acute Suicidal Ideation or Behavior: approve if the patient has major depressive disorder that is considered to be severe, AND if the patient is concomitantly receiving at least one oral antidepressant, AND the patient has no history of psychosis or has a history of psychosis but the prescriber believes that the benefits of Spravato outweigh the risks. Treatment-Resistant Depression: approve if the patient has demonstrated nonresponse (less than or equal to 25 percent improvement in depression symptoms or scores) to at least two different antidepressants, each from a different pharmacologic class and each antidepressant was used at therapeutic dosages for at least 6 weeks in the current episode of depression, AND the patient has no history of psychosis or has a history of psychosis but the prescriber believes that the benefits of Spravato outweigh the risks, AND patient's history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# SPRYCEL

## Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which dasatinib is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For melanoma, cutaneous- KIT mutation and previous therapies.
<b>Age Restrictions</b>	GIST/bone cancer/ melanoma, cutaneous-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	For CML, patient must have Ph-positive or BCR::ABL1-positive CML. For ALL, patient must have Ph-positive ALL or ABL-class translocation. For Bone Cancer-approve if patient has chondrosarcoma or chordoma. GIST - approve if the patient has tried imatinib or avapritinib. For melanoma, cutaneous - approve if patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	GIST, bone cancer, melanoma cutaneous
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# STIVARGA

## Products Affected

- STIVARGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For GIST, (A or B): A) patient has previously been treated with (i and ii): i) imatinib or Ayvakit and ii) sunitinib or Sprycel, or B) medication is used as first-line therapy for succinate dehydrogenase (SDH)-deficient disease. For HCC, patient must have previously been treated with at least one systemic regimen. Soft tissue sarcoma, advanced or metastatic disease-approve if the patient has non-adipocytic sarcoma, angiosarcoma, or pleomorphic rhabdomyosarcoma. Bone Cancer-approve if the patient has relapsed/refractory or metastatic disease AND the patient has tried one systemic chemotherapy regimen AND pt has Ewing sarcoma or osteosarcoma. Colon and Rectal cancer/Appendiceal cancer-approve if the patient has advanced or metastatic disease, has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient meets one of the following (i or ii): i. patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type), the patient has tried Erbitux or Vectibix or the patient's tumor did not originate on the left side of the colon (from the splenic fixture to rectum) or ii. the patient's tumor or metastases has a RAS mutation (either KRAS mutation or NRAS mutation). Uterine sarcoma- (A and B): A) pt has recurrent, advanced, inoperable, or metastatic disease, and B) tried at least one systemic regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Soft tissue Sarcoma, Bone Cancer, Appendiceal cancer, Uterine sarcoma

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# STRENSIQ

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## Products Affected

- STRENSIQ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, genetic and lab test results
Age Restrictions	Disease onset-less than or equal to 18
Prescriber Restrictions	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of hypophosphatasia or related disorders.
Coverage Duration	1 year
Other Criteria	Hypophosphatasia - Perinatal/Infantile- and Juvenile-Onset-Patient must meet both A and B for approval. A) Diagnosis is supported by one of the following (i, ii, or iii): i. Molecular genetic testing documenting tissue non-specific alkaline phosphatase (ALPL) gene variants OR ii. Low baseline serum alkaline phosphatase activity OR iii. An elevated level of a tissue non-specific alkaline phosphatase substrate (i.e., serum pyridoxal 5'-phosphate, serum or urinary inorganic pyrophosphate, urinary phosphoethanolamine) AND B) Patient meets one of the following (i or ii): i. Patient currently has, or has a history of clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, premature tooth loss, muscle weakness, poor feeding, failure to thrive, respiratory problems, Vitamin B6-dependent seizures) OR ii. Patient has a family history (parent or sibling) of hypophosphatasia without current clinical manifestations of hypophosphatasia
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# SUCRAID

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## Products Affected

- SUCRAID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results (as specified in the Other Criteria field)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient meets the following criteria (A and B): A) The diagnosis is established by one of the following (i or ii): i. Patient has endoscopic biopsy of the small bowel with disaccharidase levels consistent with congenital sucrose-isomaltase deficiency as evidenced by ALL of the following (a, b, c, and d): a) Decreased (usually absent) sucrase (normal reference: greater than 25 U/g protein), b) Decreased or normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein], c) Decreased maltase (normal reference: greater than 100 U/g protein), d) Decreased or normal lactase (normal reference: greater than 15 U/g protein) OR ii. Patient has a molecular genetic test demonstrating homozygous or compound heterozygous pathogenic or likely pathogenic sucrase-isomaltase gene variant AND B) Patient has symptomatic congenital sucrose-isomaltase deficiency (e.g., diarrhea, bloating, abdominal cramping).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# SUNITINIB

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## Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Gastrointestinal stromal tumors (GIST), approve if the patient has tried imatinib or if the patient has succinate dehydrogenase (SDH)-deficient GIST. Chordoma, approve if the patient has recurrent disease.</p> <p>Differentiated thyroid carcinoma, approve if the patient meets (A or B): A) has papillary or follicular thyroid carcinoma and the disease is refractory to radioactive iodine therapy or B) has oncocytic (formerly Hurthle cell) carcinoma. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried at least one systemic chemotherapy. Renal Cell Carcinoma (RCC)- approve if the patient has relapsed or advanced disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease.</p> <p>Pheochromocytoma/paraganglioma-approve if the patient has unresectable or metastatic disease. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), extraskeletal myxoid chondrosarcoma, differentiated (ie, papillary, follicular, and oncocytic carcinoma) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma, pheochromocytoma/paraganglioma, myeloid/lymphoid neoplasms with

<b>PA Criteria</b>	<b>Criteria Details</b>
	eosinophilia, GIST-unresectable succinate dehydrogenase (SDH)-deficient GIST.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# SYMDEKO

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## Products Affected

- SYMDEKO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination therapy with other CF transmembrane conductance regulator modulators
<b>Required Medical Information</b>	Diagnosis, specific CFTR gene mutations
<b>Age Restrictions</b>	Six years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	CF - Approve if the pt meets A, B and C: A) pt has at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic or patient has TWO copies of the F508 del mutation, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TABRECTA

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## Products Affected

- TABRECTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has advanced or metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping or high-level MET amplification, as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-small cell lung cancer with high-level MET amplification.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TADALAFIL

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## Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Treatment of erectile dysfunction (ED)
<b>Required Medical Information</b>	Indication for which tadalafil is being prescribed.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 mos.
<b>Other Criteria</b>	Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TAFAMIDIS

## Products Affected

- VYNDAMAX
- VYNDAQEL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other medications indicated for polyneuropathy of hereditary transthyretin-mediated amyloidosis or transthyretin-mediated amyloidosis-cardiomyopathy (e.g., Amvuttra (vutrisiran subcutaneous injection), Attruby (acoramidis tablets), Onpattro (patisiran lipid complex intravenous infusion), Tegsedi (inotersen subcutaneous injection), or Wainua [eplontersen subcutaneous injection]).
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis-approve if patient meets (A, B and C): A) the diagnosis was confirmed by one of the following (i, ii or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy), ii. tissue biopsy with confirmatory TTR amyloid typing by mass spectrometry, immunoelectron microscopy or immunohistochemistry OR iii. patient had genetic testing which, according to the prescriber, identified a TTR pathogenic variant AND B) Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum), and C) patient has heart failure but does not have NYHA class IV disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# TAFINLAR

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## Products Affected

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Glioma- approve if pt has BRAF V600 mutation-positive disease and this medication will be taken with Mekinist (trametinib). Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. NSCLC-approve if pt has recurrent, advanced, or metastatic disease AND BRAF V600 mutation-positive disease. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or oncocytic) AND the patient has BRAF-positive disease. Histiocytic neoplasm-approve if (A and B): A) patient has Langerhans cell histiocytosis or Erdheim Chester disease AND B) patient has BRAF V600-mutation positive disease. Solid tumors [examples: biliary tract cancer, brain metastases due to melanoma, ovarian/fallopian tube/primary peritoneal cancer, gastrointestinal stromal tumors, gastric cancer, esophageal and esophagogastric junction cancers, salivary gland tumors, occult primary, pancreatic adenocarcinoma, neuroendocrine tumors, ampullary adenocarcinoma, small bowel adenocarcinoma]-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib). Hairy Cell Leukemia, approve if</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Mekinist.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Histiocytic neoplasm, hairy cell leukemia
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TAGRISSO

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## Products Affected

- TAGRISSO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>NSCLC-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)- approve if the patient has advanced or metastatic disease, has EGFR mutation-positive NSCLC as detected by an approved test. Note-examples of EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has advanced or metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC- Post resection-approve if the patient has completely resected disease and has received previous adjuvant chemotherapy or if the patient is ineligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test. NSCLC- Unresectable Stage III - approve if the patient has locally advanced, unresectable (stage III) disease AND EGFR exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an approved test AND not had disease progression during or following platinum-based chemoradiation therapy. (Note: Patients could have received concurrent or sequential chemoradiation therapy.)</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TALVEY

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## Products Affected

- TALVEY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Multiple myeloma-approve if per FDA approved labeling the patient has tried at least four systemic regimens and among the previous regimens tried, the patient has received at least one drug from each of the following classes: proteasome inhibitor, an immunomodulatory drug and an anti-CD38 monoclonal antibody.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TALZENNA

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## Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Recurrent or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive disease. Prostate cancer - approve if the patient has metastatic castration resistant prostate cancer, AND is using this medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy AND the patient has homologous recombination repair (HRR) gene-mutated disease [Note: HRR gene mutations include ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C] AND the medication is used in combination with Xtandi (enzalutamide capsules and tablets).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	No

# TAZAROTENE

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## Products Affected

- *tazarotene topical cream*
- *tazarotene topical gel*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Cosmetic uses
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TAZVERIK

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## Products Affected

- TAZVERIK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Epithelioid Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if the patient has relapsed or refractory disease and there are no appropriate alternative therapies or the patient has tried at least two prior systemic therapies.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TECVAYLI

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## Products Affected

- TECVAYLI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. Multiple Myeloma-approve if the patient has tried at least four systemic regimens which must include at least one drug from each of the following classes: proteasome inhibitor, immunomodulatory drug and Anti-CD38 monoclonal antibody
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TEPMETKO

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## Products Affected

- TEPMETKO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NSCLC-approve if the patient has advanced or metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutations or patient has high-level MET amplification, as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-small cell lung cancer with high-level MET amplification.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TERIPARATIDE

## Products Affected

- BONSITY
- *teriparatide (only ndcs starting with 47781)*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/lifetime.
<b>Other Criteria</b>	<p>INITIAL THERAPY: Postmenopausal Osteoporosis (PMO) Treatment, Increase Bone Mass in Men (see Note 1 below) with Primary or Hypogonadal Osteoporosis, and Treatment of Glucocorticosteroid-Induced Osteoporosis (GIO): (one of A, B, C, D or E): A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (PMO-ibandronate or zoledronic acid, all other diagnoses-zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past.</p> <p>CONTINUATION THERAPY: ALL INDICATIONS: if the patient has taken teriparatide for two years, approve if the patient is at high risk for fracture. Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density. Note 1: a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.</p>
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TETRABENAZINE

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## Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TEVIMBRA

## Products Affected

- TEVIMBRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis. Hepatocellular carcinoma-approve if (A or B): A) medication is used first-line and meets (i or ii): i) pt has liver-confined, unresectable disease and is deemed ineligible for transplant, or ii) pt has extrahepatic/metastatic disease and are deemed ineligible for resection, transplant, or locoregional therapy, or B) medication is being used for subsequent-line therapy. Nasopharyngeal carcinoma-approve if (A and B): A) pt has recurrent, unresectable, oligometastatic, or metastatic disease, and B) meets (i or ii): i) used as first-line treatment in combination with cisplatin and gemcitabine or ii) used as subsequent treatment. Small bowel adenocarcinoma-approve if (A, B and C): A) locally unresectable or medically inoperable disease, or advanced or metastatic disease, and B) either (i or ii): i) deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or ii) polymerase epsilon/delta (POLE/POLD1) mutation positive disease with ultra-hypermutated phenotype (tumor mutation burden greater than 50 mutations/megabase), and C) is used as a single agent.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. ESOPHAGEAL and ESOPHAGOGASTRIC JUNCTION CANCERS-All of (A, B and C): A. Unresectable locally advanced, recurrent, or metastatic disease, AND B. Meets (i or ii): i) pt has esophageal squamous cell carcinoma with (a or b): a) tumor expression for programmed death-ligand 1 (PD-L1) has a combined positive score (CPS) greater than or equal to 1 and is used in combination with chemotherapy, or b) medication is used as a single agent or ii) pt has esophageal adenocarcinoma that is HER2 overexpression negative and tumor

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>expression for PD-L1 has a CPS greater than or equal to 1, AND C. Patient has NOT previously received a checkpoint inhibitor or has NO tumor progression while on a checkpoint inhibitor. Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion). Gastric or gastroesophageal junction adenocarcinoma- approve if (A, B and C): A) unresectable locally advanced, recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-negative disease, B) tumor expresses programmed death-ligand 1 (PD-L1) greater than or equal to 1 percent, C) used in combination with platinum and fluoropyrimidine-based chemotherapy. Anal carcinoma-meets (A and B): A) used as a single agent and B) meets (i or ii): i) locally recurrent, progressive disease and administered before proceeding to abdominoperineal resection, or ii) metastatic disease and used as subsequent therapy. CLL/SLL-approve if (A and B): A) patient has histologic transformation to diffuse large B-cell lymphoma, and B) is used in combination with Brukinsa (zanubrutinib capsules). Colon, rectal or appendiceal cancer-approve if pt meets (A and B): A) meets (i or ii): i) pt has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease, or ii) has DNA polymerase epsilon/delta (POLE/POLD1) mutation, and B) pt has advanced or metastatic disease. Classic Hodgkin Lymphoma-approve if refractory or relapsed disease and medication is used with GEMOX (gemcitabine and oxaliplatin). Endometrial carcinoma-approve if (A, B and C): A) recurrent or metastatic disease, and B) pt has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors, and C) will be used as single agent.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anal carcinoma, Chronic lymphocytic leukemia/small lymphocytic lymphoma, hepatocellular carcinoma, nasopharyngeal carcinoma, small bowel adenocarcinoma, colon/rectal/appendiceal cancer, Classic Hodgkin Lymphoma, endometrial carcinoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# THALOMID

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## Products Affected

- THALOMID ORAL CAPSULE 100 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	MM, histiocytic neoplasms-18 years and older, medulloblastoma- less than 18 years old
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). Kaposi Sarcoma-approve if the patient has tried at least one medication AND has relapsed or refractory disease. Castleman disease-approve if the patient has multicentric disease and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). Histiocytic neoplasms-approve if (A or B): A) pt has Langerhans cell histiocytosis with either (i or ii): i) single-system multifocal skin disease or ii) relapsed or refractory disease, or B) pt has or Rosai-Dorfman cutaneous disease. Medulloblastoma- approve if pt has recurrent or progressive disease AND medication is being used as a part of the MEMMAT regimen (i.e. Thalomid, celecoxib, fenofibrate, oral etoposide, cyclophosphamide, bevacizumab, and intraventricular etoposide).

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Discoid lupus erythematosus or cutaneous lupus erythematosus, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi Sarcoma, Castleman Disease, histiocytic neoplasms, medulloblastoma.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TIBSOVO

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## Products Affected

- TIBSOVO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, IDH1 Status
<b>Age Restrictions</b>	All diagnoses (except chondrosarcoma)-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive, as detected by an approved test. Cholangiocarcinoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and has been previously treated with at least one chemotherapy regimen (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan). Chondrosarcoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Central nervous system cancer-approve if the patient has oligodendroglioma or astrocytoma. Myelodysplastic Syndrome-approve if patient has isocitrate dehydrogenase-1 (IDH1) mutation-positive disease AND relapsed or refractory disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chondrosarcoma, Central nervous system cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TIVDAK

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## Products Affected

- TIVDAK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Cervical cancer-approve if the patient has tried at least one chemotherapy agent. Vaginal cancer- approve if the patient has tried at least one chemotherapy agent.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Vaginal cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TOBRAMYCIN (NEBULIZATION)

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## Products Affected

- *tobramycin in 0.225 % nacl*
- *tobramycin inhalation*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Bronchiectasis, Non-cystic fibrosis-18 years and older
<b>Prescriber Restrictions</b>	CF-prescr/consult w/pulm/phys specializes in tx of CF.Bronchiectasis, non CF-prescr/consult w/pulm
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Cystic fibrosis/Bronchiectasis, non-cystic fibrosis-approve if the patient has pseudomonas aeruginosa in the culture of the airway.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Bronchiectasis, non-cystic fibrosis
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TOLVAPTAN

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## Products Affected

- *tolvaptan*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Jynarque.
<b>Required Medical Information</b>	Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 30 days for initial therapy, 3 months for continuation of therapy
<b>Other Criteria</b>	Hyponatremia, initial therapy (including new starts, patients on therapy for less than 30 days, and patients restarting therapy) - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on tolvaptan and has received less than 30 days of therapy. Hyponatremia, continuation of therapy for patients established on therapy for at least 30 days - approve if the serum sodium level has increased from baseline (prior to initiating the requested drug) OR if the patient experienced improvement in at least one symptom, such as nausea, vomiting, headache, lethargy, or confusion.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TOPICAL AGENTS FOR ATOPIC DERMATITIS

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## Products Affected

- EUCRISA
- *pimecrolimus*
- *tacrolimus topical*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# TOPICAL RETINOID PRODUCTS

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## Products Affected

- *tretinoin topical*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for cosmetic use.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TOPIRAMATE/ZONISAMIDE

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## Products Affected

- *topiramate oral capsule, sprinkle 15 mg, 25 mg*
- *topiramate oral solution*
- *topiramate oral tablet*
- ZONISADE
- *zonisamide*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for weight loss or smoking cessation.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TRANSDERMAL FENTANYL

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## Products Affected

- *fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Acute (i.e., non-chronic) pain.
<b>Required Medical Information</b>	Pain type (chronic vs acute)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) AND 3) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 4) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, in hospice, sickle cell diagnosis or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TRELSTAR

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## Products Affected

- TRELSTAR INTRAMUSCULAR  
SUSPENSION FOR RECONSTITUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prostate cancer: Prescribed by or in consultation with a oncologist or urologist. Head and neck cancer - salivary gland tumors: Prescribed by or in consultation with a oncologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Prostate cancer: Patients new to therapy, are required to try Eligard prior to approval of Trelstar. Head and neck cancer - salivary gland tumors: approve if patient has recurrent, unresectable, or metastatic disease and androgen receptor-positive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Head and neck cancer - salivary gland tumors
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TREMFYA IV

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## Products Affected

- TREMFYA INTRAVENOUS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic oral small molecule drug.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	3 doses for induction
<b>Other Criteria</b>	ULCERATIVE COLITIS-Approve if the medication will be used as induction therapy. CROHN'S DISEASE (CD): Approve if the medication will be used as induction therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TREMFYA SC

## Products Affected

- TREMFYA ONE-PRESS
- TREMFYA PEN
- TREMFYA PEN INDUCTION PK(2PEN)
- TREMFYA SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	PP/PsA - 6 years of age or older (initial therapy), UC/CD-18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	PP-Prescribed by or in consultation with a dermatologist (initial therapy only). PsA-prescribed by or in consultation with a dermatologist or rheumatologist (initial therapy). UC/CD-prescribed by or in consultation with a gastroenterologist (initial therapy).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	PP, initial therapy - approve if the pt meets (A and B): A) meets (1 or 2): 1) 18 years of age or older, or 2) 6 to 17 years old and weighs at least 40 kg, and B) meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: a biologic that is not a biosimilar of the requested product will also count) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. PsA, initial therapy - approve if pt meets (1 or 2): 1) 18 years of age or older, or 2) 6 to 17 years old and weighs at least 40 kg. ULCERATIVE COLITIS-approve. CROHN'S DISEASE (CD): approve. PP/PsA/UC/CD continuation of therapy - approve if the pt is responding to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# TRIENTINE

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## Products Affected

- *trientine oral capsule 250 mg*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
Coverage Duration	Authorization will be for 1 year
Other Criteria	For Wilson's Disease, approve if the patient meets A and B: A) Diagnosis of Wilson's disease is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, or d): a. Presence of Kayser-Fleischer rings, OR b. Serum ceruloplasmin levels less than 20mg/dL, OR c. Liver biopsy findings consistent with Wilson's disease, OR d. 24-hour urinary copper greater than 40 micrograms/24 hours, AND B) Patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant, OR 6) the patient has been started on therapy with trientine.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TRIKAFTA

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## Products Affected

- TRIKAFTA ORAL GRANULES IN PACKET, SEQUENTIAL
- TRIKAFTA ORAL TABLETS, SEQUENTIAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination therapy with other CF transmembrane conductance regulator modulators.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	CF -Approve if the pt meets A, B and C: A) pt has at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic variant, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TRODELVY

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## Products Affected

- TRODELVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Breast Cancer-approve if the patient has recurrent or metastatic, human epidermal growth factor receptor (HER2) negative breast cancer and patient meets (a or b): a) patient has hormone receptor (HR) negative disease AND has tried at least one systemic regimen in the metastatic setting, OR b) patient has HR positive disease, has tried endocrine therapy, has tried a cyclin-dependent kinase(CDK) 4/6 inhibitor, has tried at least two systemic chemotherapy regimens (one of which was tried in the metastatic setting), and patient is not a candidate for Enhertu (fam-trastuzumab deruxtecan-nxki intravenous infusion) therapy . Urothelial Cancer-approve if the patient has locally advanced or metastatic urothelial cancer AND has tried at least one systemic chemotherapy AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Urothelial cancer
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# TRUQAP

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## Products Affected

- TRUQAP

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Breast Cancer-Approve if the patient meets the following (A, B, C, D and E): A) Patient has locally advanced or metastatic disease, AND B) Patient has hormone receptor positive (HR+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has at least one phosphatidylinositol 3-kinase (PIK3CA), serine/threonine protein kinase (AKT1), or phosphatase and tensin homolog (PTEN)-alteration, AND E) Patient meets one of the following (i or ii): i. Patient has had progression with at least one endocrine-based regimen in the metastatic setting (Note: Examples of endocrine therapy include anastrozole, exemestane, and letrozole.) and has had progression with at least one cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting (Note: Examples of CDK4/6 inhibitor include: Ibrance (palbociclib tablets or capsules), Verzenio (abemaciclib tablets), Kisqali (ribociclib tablets), Kisqali Femara Co-Pack (ribociclib and letrozole tablets) OR ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# TUKYSA

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## Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Breast Cancer-approve if the patient has recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-amplified disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type). Biliary tract cancer- approve if the patient meets all of (a, b, c, and d): a) unresectable or metastatic disease, b) HER2 positive disease, c) tried at least one systemic regimen, d) will use in combination with trastuzumab.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Biliary tract cancer
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# TURALIO

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## Products Affected

- TURALIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis)-approve if, according to the prescriber, the tumor is not amenable to improvement with surgery. Histiocytic Neoplasms-approve if the patient has a colony stimulating factor 1 receptor (CSF1R) mutation AND has one of the following conditions (i, ii, or iii): i. Langerhans cell histiocytosis OR ii. Erdheim-Chester disease OR iii. Rosai-Dorfman disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Histiocytic Neoplasms
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# TYENNE IV

## Products Affected

- TYENNE INTRAVENOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or targeted synthetic DMARD. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	(Initial therapy only): GCA/RA-18 years and older. PJIA/SJIA-2 years and older.
<b>Prescriber Restrictions</b>	RA, SJIA, PJIA, GCA - Prescribed by or in consultation with a rheumatologist (initial therapy).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	<p>INITIAL THERAPY- RHEUMATOID ARTHRITIS (RA) [A OR B]: A) Try ONE of the following: Enbrel, a preferred adalimumab product, Rinvoq or Xeljanz. (Note: previous trial(s) with the following drugs: Cimzia, infliximab, Simponi (IV/SC), Kevzara, Orencia or another non-preferred adalimumab product will also count.) OR B) Patient has heart failure or a previously treated lymphoproliferative disorder.</p> <p>POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A OR B]: A) Try ONE of the following: Enbrel, Rinvoq, Xeljanz, a preferred adalimumab product, (Note: a trial with infliximab, Kevzara, Orencia or another non-preferred adalimumab product will also count.) OR B) Patient has heart failure or a previously treated lymphoproliferative disorder.</p> <p>SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): Approve.</p> <p>GIANT CELL ARTERITIS: tried or is currently taking a systemic corticosteroid or corticosteroid is contraindicated. CYTOKINE RELEASE SYNDROME ASSOCIATED WITH CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY-approve. Please Note: preferred adalimumab products include Hadlima, Simlandi. CONTINUATION THERAPY-RA, PJIA, SJIA, GCA:patient has responded to therapy.</p>
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TYENNE SC

## Products Affected

- TYENNE AUTOINJECTOR
- TYENNE SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	Interstitial lung disease-18 years and older (initial and continuation). GCA/RA-18 years and older (initial only). SJIA/PJIA-2 years and older (initial only).
<b>Prescriber Restrictions</b>	RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA) [A or B]: A) tried one of the following: Enbrel, preferred adalimumab product (see Example 1), Rinvoq or Xeljanz/XR (Note: trials with the following will also count: Cimzia, infliximab, Kevzara, golimumab SC/IV, non-preferred adalimumab product, Orencia), or B) heart failure or a previously treated lymphoproliferative disorder. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A or B]: A) tried one of the following: Enbrel, Rinvoq, Xeljanz, preferred adalimumab product. (Note: trials with Kevzara, infliximab, Orencia or a non-preferred adalimumab product will also count), or B) heart failure or a previously treated lymphoproliferative disorder. SYSTEMIC-ONSET JIA (SJIA): Approve. GIANT CELL ARTERITIS: tried or is currently taking a systemic CS or CS are contraindicated. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) elevated acute phase reactants and B) diagnosis confirmed by high-resolution computed tomography. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. Example 1: preferred adalimumab products include Hadlima, Simlandi.
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# TYMLOS

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## Products Affected

- TYMLOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, calcitonin nasal spray [Fortical], Forteo), Evenity, except calcium and Vitamin D. Previous use of Tymlos for a combined total no greater than 2 years duration during a patient's lifetime.
<b>Required Medical Information</b>	Previous medications tried, renal function
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 2 years of total therapy over a patient's lifetime
<b>Other Criteria</b>	Postmenopausal Osteoporosis (PMO) Treatment and Osteoporosis Treatment in Men (see Note 1 below) [one of A, B, C, D, or E]: A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (PMO-ibandronate or zoledronic acid, osteoporosis in men- zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past. ALL INDICATIONS: must have a trial of teriparatide prior to approval of Tymlos. Note 1: a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# UBRELVY

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## Products Affected

- UBRELVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Migraine, Acute treatment-approve if the patient has tried at least one triptan or has a contraindication to triptans.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# UPTRAVI

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## Products Affected

- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLETS,DOSE PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension.
<b>Required Medical Information</b>	Confirmation of right heart catheterization, medication history (as described in Other Criteria)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# USTEKINUMAB IV

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## Products Affected

- OTULFI INTRAVENOUS
- PYZCHIVA (ONLY NDCS STARTING WITH 61314) INTRAVENOUS SOLUTION 130 MG/26 ML
- SELARSDI INTRAVENOUS
- STELARA INTRAVENOUS
- USTEKINUMAB INTRAVENOUS
- YESINTEK INTRAVENOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	Approve a single dose
<b>Other Criteria</b>	INDUCTION THERAPY for USTEKINUMAB IV: UC: approve. Crohn's Disease: approve. ALL INDICATIONS, in addition to the above criteria: patients requesting a non-preferred ustekinumab product must try one of the following preferred ustekinumab products first: Otulfi, Pyzchiva, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# USTEKINUMAB SC

## Products Affected

- OTULFI SUBCUTANEOUS SOLUTION
- OTULFI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- PYZCHIVA (ONLY NDCS STARTING WITH 61314) SUBCUTANEOUS SOLUTION 45 MG/0.5 ML
- PYZCHIVA (ONLY NDCS STARTING WITH 61314) SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- SELARSDI SUBCUTANEOUS SOLUTION
- SELARSDI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- STELARA SUBCUTANEOUS SOLUTION
- USTEKINUMAB SUBCUTANEOUS SOLUTION
- USTEKINUMAB-AEKN SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML
- YESINTEK SUBCUTANEOUS SOLUTION
- YESINTEK SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	PP/PsA-6 years and older (initial therapy). UC/CD-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy).
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A or B]: A) tried one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, psoralen plus PUVA) for at least 3 months, unless intolerant or B) contraindication to MTX. (Note: a 3-month trial or intolerance of at least one biologic that is not ustekinumab also counts.) CROHN'S DISEASE (CD): approve if pt receiving/received single IV loading dose within 2 months of initiating therapy with ustekinumab SC. ULCERATIVE COLITIS (UC): receiving/received single IV loading dose within 2 months of initiating therapy with ustekinumab SC. CONTINUATION THERAPY:

<b>PA Criteria</b>	<b>Criteria Details</b>
	PP/PsA/CD/UC: patient has responded to therapy. ALL INDICATIONS, INITIAL AND CONTINUATION in addition to the above criteria: patients requesting Stelara must have a trial of one of the following preferred ustekinumab products first: Otulfi, Pyzchiva, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# VALCHLOR

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## Products Affected

- VALCHLOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Cutaneous lymphoma-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has smoldering subtype of adult T-cell leukemia/lymphoma. Langerhans cell histiocytosis-approve if the patient has unifocal Langerhans cell histiocytosis with isolated skin disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Adults with T-cell leukemia/lymphoma, Langerhans Cell Histiocytosis
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VALTOCO

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## Products Affected

- VALTOCO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other medications used at the same time
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiseizure medication(s).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# VANCOMYCIN

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## Products Affected

- *vancomycin oral capsule 125 mg, 250 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	2 weeks
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VANFLYTA

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## Products Affected

- VANFLYTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Acute Myeloid Leukemia: approve if the patient has FLT3-ITD mutation-positive disease as detected by an approved test. Myeloid or lymphoid neoplasms: approve if patient has eosinophilia and the tumor has FLT3 rearrangement.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myeloid or lymphoid neoplasms
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VENCLEXTA

## Products Affected

- VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapy
<b>Age Restrictions</b>	18 years and older (all diagnoses except ALL)
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	AML-approve if used in combination with azacitidine, decitabine, or cytarabine. CLL/SLL- approve. ALL- approve if relapsed/refractory disease and will be used in combination with chemotherapy. Hairy cell leukemia- approve if disease resistance to BRAF inhibitor therapy. Mantle Cell Lymphoma- approve if (A or B): A) the patient has tried at least one systemic regimen or B) patient has TP53 mutation and will use this as induction therapy in combination with Brukinsa (zanubrutinib) and Gazyva (obinutuzumab intravenous infusion). MDS- approve if pt meets (A and B): A) pt meets (i or ii): (i) has chronic myelomonocytic leukemia-2 or (ii) has higher risk disease (note: includes international prognostic scoring system (IPSS-R) intermediate-, high-, or very-high risk disease) and B) will use in combination with azacitidine or decitabine. Myeloproliferative neoplasm- approve if pt has accelerated or blast phase disease and will use in combination with azacitidine or decitabine. Multiple Myeloma- approve if the patient has t (11,14) translocation AND has tried at least one systemic regimen for multiple myeloma AND Venclexta will be used in combination with dexamethasone. Systemic light chain amyloidosis-approve if the patient has t (11, 14) translocation and has tried at least one systemic regimen. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Mantle Cell Lymphoma, waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, multiple myeloma, systemic light chain amyloidosis, acute lymphoblastic leukemia, hairy cell leukemia, myelodysplastic syndrome, myeloproliferative neoplasm
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# VERZENIO

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## Products Affected

- VERZENIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Breast cancer: HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Breast Cancer, Early-pt meets (A,B,C and D): A)Pt HR+disease, AND B) HER2-negative breast cancer, AND C)node-positive disease at high risk of recurrence AND D)meets 1 of the following (i or ii): i.Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one of the following (a,b, or c): a)Pt is postmenopausal woman, OR b)Pt is pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets 1 of the following (a or b): a)Pt is postmenopausal woman or man OR b)Pt is pre/perimenopausal woman and meets 1 of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Recurrent or Metastatic in Women-pt meets (A, B and C): A)has HR+ disease, AND B)Pt meets 1 of following criteria (i or ii): i.Pt is postmenopausal woman, OR ii.Pt is pre/perimenopausal woman and meets 1 of the following (a or b): a)receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt had surgical bilateral oophorectomy or ovarian irradiation, AND C) either (1 or 2): 1) HER2-negative breast cancer and Pt meets 1 of following criteria (i, ii, or iii): i.Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>fulvestrant, OR iii.pt meets following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)has tried chemo for metastatic breast cancer or 2)has HER2-positive breast cancer and has received at least 3 prior anti-HER2-based regimens in metastatic setting and will use this in combo with fulvestrant and trastuzumab.Breast Cancer-Recurrent or Metastatic in Men-pt meets following criteria (A and B): A)HR+ disease, AND B)either (1 or 2): 1) HER2-negative disease and Pt meets 1 of following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)receiving a GnRH analog, AND b)Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.Pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)Pt has tried chemo for metastatic breast cancer, or 2) has HER2-positive disease and has received at least 3 prior anti-HER2-based regimen in metastatic setting and will use this medication in combo with fulvestrant and trastuzumab. Endometrial cancer-pt meets all of (A, B, And C): A)has recurrent or metastatic disease, and B)has estrogen receptor (ER)-positive tumors, and C)will be using in combination with letrozole.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Endometrial cancer
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# VIGABATRIN

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## Products Affected

- *vigabatrin*
- *vigadrone*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medication history (complex partial seizures)
<b>Age Restrictions</b>	Refractory complex partial seizures - patients 2 years of age or older. Infantile spasms - patients less than or equal to 2 years of age
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a neurologist
<b>Coverage Duration</b>	Infantile spasms- 6 months. Treatment-Refractory Partial Seizures- initial 3 months, cont 1 year
<b>Other Criteria</b>	Infantile spasms-requested medication is being used as monotherapy. Treatment refractory complex partial seizures initial-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Treatment refractory complex partial seizures continuation- the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# VIMIZIM

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## Products Affected

- VIMIZIM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine-6-sulfatase activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating biallelic pathogenic or likely pathogenic N-acetylgalactosamine-6-sulfatase gene variants.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VITRAKVI

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## Products Affected

- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, NTRK gene fusion status
<b>Age Restrictions</b>	Pediatric Diffuse High-Grade Glioma- less than or equal to 21 years old
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Solid tumors - approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity. Pediatric diffuse high grade glioma - approve if (A and B): A) tumor is positive for NTRK gene fusion and B) meets (i or ii): i) medication is used as adjuvant therapy or ii) medication is used for recurrent or progressive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pediatric Diffuse High-Grade Glioma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VIZIMPRO

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## Products Affected

- VIZIMPRO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, EGFR status, exon deletions or substitutions
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NSCLC-approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VONJO

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## Products Affected

- VONJO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Myelofibrosis (MF), including primary MF, post-polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient meets either (A, B, or C): (A) meets (i and ii): i) the patient has a platelet count of less than $50 \times 10^9 /L$ (less than 50,000/mcL) and (ii): meets (a or b): a) has higher-risk disease or b) has lower-risk disease and at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis) OR (B) Patient has a platelet count of greater than or equal to $50 \times 10^9 /L$ (greater than or equal to 50,000/mcL) and has higher-risk disease and has at least one disease-related symptom, OR (C) patient has myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease-related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Accelerated or blast phase myeloproliferative neoplasm
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# VORANIGO

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## Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	12 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	GLIOMAS-All of (A, B and C): A. Susceptible isocitrate dehydrogenase-1 (IDH1) or IDH2 mutation-positive disease, AND B. Grade 2 or greater oligodendroglioma OR Grade 2 or greater astrocytoma, AND C. Prior surgery, including biopsy, sub-total resection, or gross total resection
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VORICONAZOLE (ORAL)

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## Products Affected

- *voriconazole*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VOSEVI

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## Products Affected

- VOSEVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
<b>Coverage Duration</b>	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VOTRIENT

## Products Affected

- *pazopanib oral tablet 200 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Soft tissue sarcoma other than GIST-approve if the patient has advanced or metastatic disease and has ONE of the following: alveolar soft part sarcoma, angiosarcoma, dedifferentiated chordoma, dedifferentiated liposarcoma, desmoid tumors (aggressive fibromatosis), dermatofibrosarcoma protuberans with fibrosarcomatous transformation, epithelioid hemangi endothelioma, extraskeletal myxoid chondrosarcoma, non-adipocytic sarcoma, pleomorphic rhabdomyosarcoma, or solitary fibrous tumor/hemangiopericytoma. Differentiated thyroid carcinoma, approve if the patient meets (A or B): A) has papillary or follicular thyroid carcinoma and the disease is refractory to radioactive iodine therapy or B) has oncocytic (formerly Hurthle cell) carcinoma. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or advanced disease or VonHippel-Lindau disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has succinate dehydrogenase (SDH)-deficient GIST OR the patient has tried TWO of the following: Gleevec, Ayvakit, Sutent, Sprycel, Qinlock or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried at least one systemic therapy. Bone cancer-approve if the patient has chondrosarcoma and has metastatic widespread disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Differentiated (ie, papillary, follicular, oncocytic carcinoma) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma, bone cancer.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# VOWST

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## Products Affected

- VOWST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	Prevention of recurrence of clostridioides difficile infection (CDI)-approve if the patient has completed a bowel prep (or will start a bowel prep the day before and at least 8 hours prior to taking the first dose), will not eat or drink for at least 8 hours prior to the first dose and will complete their antibacterial treatment for recurrent CDI 2-4 days before initiating treatment with Vowst and Vowst will not be used for the TREATMENT of CDI.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VUMERITY

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## Products Affected

- VUMERITY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
<b>Required Medical Information</b>	Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VYLOY

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## Products Affected

- VYLOY

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA (all of A, B, C, and D): A. Unresectable locally advanced, recurrent, metastatic disease, or palliative therapy, AND B. Tumor is claudin 18.2 positive, Note: Claudin 18.2 positivity is defined as greater than or equal to 75 percent of tumor cells demonstrating moderate to strong membranous claudin 18.2 immunohistochemical staining. AND C. Tumor is human epidermal growth factor receptor 2 (HER2)-negative, AND D. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy. Note: Examples of fluoropyrimidines include 5-fluorouracil and capecitabine. Examples of platinum chemotherapy agents include oxaliplatin. Esophageal adenocarcinoma- all of (A, B, C, and D): A. unresectable locally advanced, recurrent, metastatic disease, or palliative therapy, AND B. tumor is is claudin 18.2 positive, AND C. tumor is human epidermal growth factor receptor 2 (HER2)-negative, and D. used in combination with fluoropyrimidine- and platinum-containing chemotherapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Esophageal adenocarcinoma

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# VYVGART

## Products Affected

- VYVGART
- VYVGART HYTRULO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial and continuation)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist (initial and continuation)
<b>Coverage Duration</b>	Initial-6 months, Continuation-1 year
<b>Other Criteria</b>	<p>CIDP (Vyvgart Hytrulo only), Initial Therapy - approve if diagnosis was supported by electrodiagnostic studies AND pt previously received treatment with an intravenous or subcutaneous immune globulin and had inadequate efficacy or significant intolerance or patient has a contraindication to IV or SC immune globulin. Generalized myasthenia gravis, Initial Therapy-Approve if the patient meets the following criteria (A, B, and C): A. Patient has confirmed anti-acetylcholine receptor antibody positive generalized myasthenia gravis, AND B. Patient has evidence of unresolved symptoms of generalized myasthenia gravis, such as difficulty swallowing, difficulty breathing, or a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility) AND C. patient has myasthenia gravis foundation of america classification of II to IV. CIDP (Vyvgart Hytrulo only), Cont therapy - pt has clinically significant improvement in neurologic symptoms (Examples include improvement in disability: nerve conduction study results improved or stabilized, physical examination shows improvement in neurological symptoms, strength, and sensation). Generalized myasthenia gravis, Continuation Therapy-Approve if patient is continuing to derive benefit from Vyvgart.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# WELIREG

## Products Affected

- WELIREG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Pheochromocytoma/paraganglioma-12 years and older, Other indications-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>Pheochromocytoma/paraganglioma- approve if pt has locally advanced, unresectable, or metastatic disease. Renal Cell Carcinoma- approve if patient meets the following (A, B, C and D): A) pt has advanced disease AND B) has clear cell histology AND C) has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND D) has tried at least one a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). [Note: Examples of PD-1 inhibitor or PD-L1 inhibitor include: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), and Bavencio (avelumab intravenous infusion). Examples of VEGF-TKI include Cabometyx (cabozantinib tablets), Lenvima (lenvatinib capsules), Inlyta (axitinib tablets), Fotivda (tivozanib capsules), pazopanib, sunitinib, and sorafenib.] Van Hippel-Lindau Disease-approve if the patient meets the following (A, B, and C): A) Patient has a von Hippel-Lindau (VHL) germline alteration as detected by genetic testing, B) Does not require immediate surgery and C) Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv): i. Central nervous system hemangioblastomas, OR ii. Pancreatic neuroendocrine tumors, OR iii. Renal cell carcinoma, OR iv. Retinal hemangioblastoma.</p>
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# WINREVAIR

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## Products Affected

- WINREVAIR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation)
<b>Coverage Duration</b>	Initial-6 months, Continuation-1 year
<b>Other Criteria</b>	INITIAL THERAPY-PULMONARY ARTERIAL HYPERTENSION (PAH) WHO GROUP 1-All of (A, B, C): A) right-heart catheterization to confirm the diagnosis, and B) Functional Class II or III or IV, and C) One of (a or b): a)currently receiving at least two other PAH therapies from the following different pharmacologic categories, each for greater than or equal to 60 days: phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), and prostacyclins or b) currently receiving at least one other PAH therapy for greater than or equal to 60 days and is intolerant to combination therapy with a phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), or prostacyclin. CONTINUATION THERAPY-PAH WHO GROUP 1-patient has had a right heart catheterization to confirm the diagnosis.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# XALKORI

## Products Affected

- XALKORI ORAL CAPSULE
- XALKORI ORAL PELLETT 150 MG, 20 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Anaplastic large cell lymphoma/IMT-patients greater than or equal to 1 year of age. All other diagnoses-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test and patients new to therapy must have a trial of Alecensa, Ensacove or Lorbrena prior to approval of Xalkori. Metastatic non-small cell lung cancer, approve if the patient has ROS1 rearrangement positive disease, as detected by an approved test. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Histiocytic neoplasm-approve if the patient has ALK rearrangement/fusion-positive disease and meets one of the following criteria (i, ii, or iii): (i. Patient has Langerhans cell histiocytosis, OR ii. Patient has Erdheim-Chester disease OR iii. Patient has Rosai-Dorfman disease. NSCLC with MET mutation-approve if the patient has high level MET amplification or MET exon 14 skipping mutation. Inflammatory Myofibroblastic Tumor-approve if the patient has ALK positive disease and the patient has advanced, recurrent or metastatic disease or the tumor is inoperable. Melanoma, cutaneous-approve if the patient has ALK fusion disease or ROS1 fusion disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# XDEMVY

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## Products Affected

- XDEMVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# XELJANZ

## Products Affected

- XELJANZ ORAL SOLUTION
- XELJANZ XR
- XELJANZ ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a Targeted Synthetic DMARD for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	AS/RA/UC-18 years and older (initial therapy), JIA/JRA/PsA-2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	RA, JIA/JRA/AS prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist. (all apply to initial therapy only)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	RA initial-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. PsA initial, approve Xeljanz immediate release tablets or oral solution (patients 2 years and older) or Xeljanz XR tablets (patients 18 years and older) if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. UC- Approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis or was unable to tolerate a 3-month trial. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthritis/active sacroiliac arthritis]-initial-approve Xeljanz immediate release tablets or solution if the patient meets the following: patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AS-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least

<b>PA Criteria</b>	<b>Criteria Details</b>
	one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# XERMELO

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## Products Affected

- XERMELO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapy, concomitant therapy
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial therapy - approve if the patient meets ALL of the following criteria: 1) patient has been on short-acting octreotide or long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]) AND 2) while on short-acting octreotide or long-acting SSA therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day, AND 3) Xermelo will be used concomitantly with short-acting octreotide or a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with short-acting octreotide or a long-acting SSA therapy for carcinoid syndrome diarrhea.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# XIAFLEX

## Products Affected

- XIAFLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Retreatment for Peyronie's Disease (i.e., treatment beyond eight injections).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Dupuytren's Contracture-administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture. Peyronie's Disease -administered by a healthcare provider experienced in the treatment of male urological diseases.
<b>Coverage Duration</b>	Dupuytren's Contracture-3 months, Peyronie's Disease-6 months
<b>Other Criteria</b>	Dupuytren's Contracture-approve if (A, B, C and D): A) pt has at least one palpable cord in the affected hand, and B) pt has contracture of a metacarpophalangeal or proximal interphalangeal joint that is associated with the palpable cord, and C) at baseline (prior to initial injection of Xiaflex), the contracture measures at least 20 degrees AND D) the patient will not be treated with more than a total of three injections (maximum) per affected cord as part of the current treatment course. Peyronie's Disease-approve if (A, B and C): A) pt has at least one palpable plaque in the penis, and B) the patient meets ONE of the following (i or ii): i) at baseline (prior to use of Xiaflex), the patient has a penile curvature deformity of at least 30 degrees OR ii) in a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees AND C) the patient has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Effective 05/01/2026

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# XIFAXAN

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## Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Traveler's diarrhea - 12 years of age or older. Hepatic encephalopathy, irritable bowel syndrome with diarrhea - 18 years of age or older.
<b>Prescriber Restrictions</b>	Pouchitis - prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	Enceph-6 mo, IBS w/diarrhea-14 days, TD-3 days, intest bact overgrowth-14 days, Pouchitis - 1 year
<b>Other Criteria</b>	Hepatic Encephalopathy-approve Xifaxan 550 mg tablets if the patient has previously had overt hepatic encephalopathy and the requested medication will be used concomitantly with lactulose, unless the patient has a contraindication or significant intolerance to treatment with lactulose. Irritable bowel syndrome with diarrhea-approve Xifaxan 550 mg tablets. Travelers Diarrhea-approve Xifaxan 200 mg tablets if the patient is afebrile and does not have blood in the stool. Small intestine bacterial overgrowth-approve Xifaxan 200mg or 550 mg tablets if the diagnosis has been confirmed by a glucose hydrogen breath test, lactulose hydrogen breath test, or small bowel aspiration and culture. Chronic antibiotic-dependent pouchitis- approve Xifaxan 200mg or 550mg tablets if patient meets all of (a, b, c and d): a) recurrent pouchitis (Note: recurrent pouchitis is typically considered history of at least 3 pouchitis episodes within a 12 month period), and b) episodes of pouchitis respond to antibiotic therapy but relapse shortly after antibiotic discontinuation, and c) alternative causes of recurrent pouchitis have been ruled out, and d) has tried long-term antibiotic therapy trials (at least 4 weeks) of BOTH ciprofloxacin and metronidazole for remission maintenance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Small intestine bacterial overgrowth, chronic antibiotic-dependent pouchitis
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# XOLAIR

## Products Affected

- XOLAIR SUBCUTANEOUS AUTO-INJECTOR 150 MG/ML, 300 MG/2 ML, 75 MG/0.5 ML
- XOLAIR SUBCUTANEOUS RECON SOLN
- XOLAIR SUBCUTANEOUS SYRINGE 150 MG/ML, 300 MG/2 ML, 75 MG/0.5 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another monoclonal antibody therapy.
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years and older. Food Allergy-1 yr and older
<b>Prescriber Restrictions</b>	Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist. Polyps-prescribed by or in consult with an allergist, immunologist, or otolaryngologist. Food allergy- allergist or immunologist
<b>Coverage Duration</b>	asthma-1 year, Polyps/CIU-initial-6 months, continued tx 12 months, Food allergy-1 yr
<b>Other Criteria</b>	<p>MODERATE TO SEVERE PERSISTENT ASTHMA (A, B, C and D):</p> <p>A)baseline IgE greater than or equal to 30 IU/mL, and B)baseline positive skin test or in vitro test for 1 or more perennial or seasonal aeroallergens</p> <p>C)received at least 3 months of combination therapy with an inhaled corticosteroid (ICS) and additional asthma controller/maintenance medication (e.g., LABA, LAMA, leukotriene receptor antagonist, monoclonal antibody) [see Exception 1 below] and D)asthma is uncontrolled or was uncontrolled prior to receiving Xolair or another monoclonal antibody and meets one of (a, b, c, d, or e): a) experienced two or more asthma exacerbations requiring systemic CSs in the past year, b) experienced one or more asthma exacerbation requiring hospitalization/urgent care visit/emergency department visit in the past year, c) FEV1 less than 80% predicted or less than 90% for pts less than 18, d) FEV1/forced vital capacity (FVC) less than 0.80 or 0.90 for pts less than 18, or e) asthma worsens upon tapering of oral CS. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRwNP) [all of A, B, C, D,</p>

PA Criteria	Criteria Details
	<p>and E]: A) diagnosis by direct exam, endoscopy, or sinus CT scan, B) baseline (prior to Xolair or another monoclonal antibody that may lower IgE) IgE at least 30 IU/ml, C) at least two of the following symptoms for 8 weeks: nasal congestion, obstruction, discharge, reduction/loss of smell, D) tried intranasal CS and will continue in combination with Xolair, and E) one of the following (a, b, or c): a) had systemic CS at least 5 days in past 2 years, b) contraindication to systemic CS, or c) had nasal polyp surgery.</p> <p>CHRONIC IDIOPATHIC URTICARIA (CIU): urticaria more than 6 weeks prior to treatment with Xolair with symptoms despite non-sedating H1-antihistamine therapy. IgE-MEDIATED FOOD ALLERGY (all of A, B, C and D): A) baseline IgE greater than or equal to 30 IU/mL, B) positive skin prick test or positive in vitro test for IgE to one or more foods, C) history of allergic reaction that met all of the following (a, b, and c): a) signs and symptoms of a significant systemic allergic reaction, b) reaction occurred within a short period of time following a known ingestion of the food, and c) prescriber deemed this reaction significant enough to require a prescription for injectable/nasal epinephrine, and D) patient has been prescribed injectable/nasal epinephrine. CONTINUATION THERAPY: ASTHMA: patient responded to therapy and continues to receive an ICS. CRwNP: patient responded after 6 months of therapy and continues intranasal CS. CIU: received at least 6 months of Xolair and experienced a beneficial clinical response, defined by decreased itch severity, decreased number of hives or decreased size of hives. Exception 1: an exception to the requirement of a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# XOSPATA

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## Products Affected

- XOSPATA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, FLT3-mutation status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	AML - approve if the disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Lymphoid, Myeloid Neoplasms
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# XPOVIO

## Products Affected

- XPOVIO ORAL TABLET 100 MG/WEEK (50 MG X 2), 40 MG/WEEK (10 MG X 4), 40MG TWICE WEEK (40 MG X 2), 60 MG/WEEK (60 MG X 1), 60MG TWICE WEEK (120 MG/WEEK), 80 MG/WEEK (40 MG X 2), 80 MG/WEEK (80 MG X 1), 80MG TWICE WEEK (160 MG/WEEK)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Multiple Myeloma-Approve if the patient meets the following (A and B):</p> <p>A) The medication will be taken in combination with dexamethasone AND</p> <p>B) Patient meets one of the following (i, ii, or iii): i. Patient has tried at least four prior regimens for multiple myeloma OR ii. Patient meets both of the following (a and b): a) Patient has tried at least two prior regimens for multiple myeloma AND b) The medication will be taken in combination with Pomalyst (pomalidomide) OR iii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib, Darzalex (daratumumb infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Kyprolis (carfilzomib intravenous infusion). Note: Examples of prior regimens include Darzalex (daratumumab intravenous infusion)/bortezomib/lenalidomide/dexamethasone, bortezomib/lenalidomide/dexamethasone, Kyprolis (carfilzomib infusion)/lenalidomide/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma Note:this</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	includes patients with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma)-approve if the patient has tried at least two prior therapies. B-Cell lymphoma-approve if (A and B): A) pt has high-grade B-cell lymphoma or HIV-related B-cell lymphoma or post-transplant lymphoproliferative disorders and B) has tried at least two prior therapies.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Treatment of multiple myeloma in combination with daratumumb or pomalidomide, B-cell lymphoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# XTANDI

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## Products Affected

- XTANDI ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Xtandi is being used.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Prostate cancer-castration-resistant [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy. Prostate cancer- Non-Metastatic, Castration-Sensitive - approve if pt has biochemical recurrence and is at high risk for metastasis. [Note: High-risk biochemical recurrence is defined as prostate-specific antigen (PSA) doubling time less than or equal to 9 months.]
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	No

# XYREM

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## Products Affected

- *sodium oxybate (preferred ndcs starting with 00054)*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with Xywav, Wakix or Sunosi
<b>Required Medical Information</b>	Medication history (as described in Other Criteria field)
<b>Age Restrictions</b>	7 years and older
<b>Prescriber Restrictions</b>	Prescribed by a sleep specialist physician or a Neurologist
<b>Coverage Duration</b>	12 months.
<b>Other Criteria</b>	For Excessive daytime sleepiness (EDS) in patients with narcolepsy - narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Patients requesting sodium oxybate who are 18 years or older-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil. Patients less than 18 years old requesting sodium oxybate-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextramphetamine) or modafinil. Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ZEJULA

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## Products Affected

- ZEJULA ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after platinum-based chemotherapy regimen and if the patient is new to therapy they must have a trial of Lynparza prior to approval of Zejula. Patients who have had a complete or partial response to first-line platinum based chemotherapy and do not have BRCA altered disease are not required to try Lynparza. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen. In addition, patients new to therapy must have a trial of Lynparza prior to approval of Zejula.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Uterine Leiomyosarcoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ZELBORAF

## Products Affected

- ZELBORAF

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	BRAFV600 mutation status required.
<b>Age Restrictions</b>	All diagnoses (except CNS cancer)-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. HCL - meets (A or B): A) must have tried at least one other systemic therapy for hairy cell leukemia OR B) meets (i and ii): i) is unable to tolerate purine analogs and ii) Zelboraf will be used in combination with rituximab or Gazyva (obinutuzumab intravenous infusion). Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. Erdheim-Chester disease, in patients with BRAF V600 mutation-approve. Central Nervous System Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, c or d): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Circumscribed ganglioglioma/neuroglioma/glioneuronal tumor OR d) pediatric diffuse high-grade glioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b or c): a) high grade glioma b) circumscribed glioma OR c) Glioblastoma OR iii. Melanoma with brain metastases AND the medication will be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis AND the patient has BRAF V600-mutation positive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or oncocytic carcinoma) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ZEPOSIA

## Products Affected

- ZEPOSIA
- ZEPOSIA STARTER KIT (28-DAY)
- ZEPOSIA STARTER PACK (7-DAY)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	MS-Concurrent use with other disease-modifying agents used for multiple sclerosis. UC- Concurrent Use with a Biologic or with a Targeted Synthetic Disease-modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	UC-18 years and older
<b>Prescriber Restrictions</b>	MS-Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. UC-Prescribed by or in consultation with a gastroenterologist
<b>Coverage Duration</b>	MS-1 year, UC initial, 6 months, cont-1 year
<b>Other Criteria</b>	MS-approve. Ulcerative Colitis, initial-approve if the patient has tried TWO of the following: a preferred adalimumab product, a preferred ustekinumab product, a preferred infliximab product, Rinvoq, Skyrizi, Tremfya. Note-a trial of Simponi SC, Entyvio IV/SC, Omvoh IV/SC, a non-preferred adalimumab product, a non-preferred ustekinumab product or a non-preferred infliximab would also count). Cont tx-approve if the patient has been established on Zeposia. Please Note: preferred adalimumab products include Hadlima, Simlandi. Preferred infliximab products include Remicade, infliximab IV (brand name product), Zymfentra. Preferred ustekinumab products include Otulfi, Pyzchiva, Selarsdi, Yesintek.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prerequisite Therapy Required</b>	Yes

# ZEPZELCA

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## Products Affected

- ZEPZELCA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Small cell lung cancer-approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ZIIHERA

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## Products Affected

- ZIIHERA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. BILIARY TRACT CANCER - (all of A, B, C, D and E): A. Patient has ONE of the following (i, ii, or iii): i. Gallbladder cancer, OR ii. Intrahepatic cholangiocarcinoma, OR iii. Extrahepatic cholangiocarcinoma, AND B. Patient has unresectable, resected gross residual, or metastatic disease, AND C. The tumor is human epidermal growth factor receptor 2 (HER2) positive with immunohistochemistry score of 3+ (IHC3+) as determined by an approved test, AND D. The medication is used for subsequent therapy, AND E. The medication is used as a single agent.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ZOLINZA

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## Products Affected

- ZOLINZA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Classic Hodgkin Lymphoma-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve. Classic Hodgkin Lymphoma- tried at least three systemic regimens AND used in combination with pembrolizumab.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Classic Hodgkin Lymphoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ZTALMY

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## Products Affected

- ZTALMY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	2 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder-approve if the patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ZURZUVAE

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Previous treatment with Zurzuvae during the current episode of postpartum depression
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a psychiatrist or an obstetrician-gynecologist
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	Postpartum depression-approve if the patient meets the following (A, B and C): A.Patient meets BOTH of the following (i and ii): i. Patient has been diagnosed with depression, AND ii. Symptom onset began during the third trimester of pregnancy or up to 4 weeks post-delivery, AND B. Patient is less than or equal to 12 months postpartum, AND C. Patient is not currently pregnant.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ZYDELIG

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## Products Affected

- ZYDELIG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	CLL/SLL-approve if the patient has tried at least one Bruton tyrosine kinase inhibitor (examples: ibrutinib, zanubrutinib, acalabrutinib, pirtobrutinib) and at least one Venclexta (venetoclax)-based regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	small lymphocytic lymphoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ZYKADIA

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## Products Affected

- ZYKADIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Erdheim-Chester Disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. NSCLC, ALK positive-approve if the patient has advanced or metastatic disease that is ALK positive as detected by an approved test and for patients new to therapy must have a trial of Alecensa, Ensacove or Lorbreña prior to approval of Zykadia. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Erdheim-Chester disease. Peripheral T-Cell Lymphoma.
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ZYMFENTRA

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## Products Affected

- ZYMFENTRA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic disease-modifying antirheumatic drug (DMARD).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist (initial therapy)
<b>Coverage Duration</b>	Approve through end of plan year
<b>Other Criteria</b>	Crohn's Disease, initial therapy-Approve if the patient is currently receiving infliximab intravenous maintenance therapy or will receive induction dosing with an infliximab intravenous product within 3 months of initiating therapy with Zymfentra. Crohn's Disease, continuation-approve if the patient has had a response to therapy. Ulcerative Colitis, initial therapy-Approve if the patient is currently receiving infliximab intravenous maintenance therapy or will receive induction dosing with an infliximab intravenous product within 3 months of initiating therapy with Zymfentra. Ulcerative Colitis, continuation-approve if the patient has had a response to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

# ZYNLONTA

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## Products Affected

- ZYNLONTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Large B-Cell Lymphoma, HIV-Related B-Cell Lymphoma and post-transplant lymphoproliferative disorder-approve if the patient has tried at least two systemic regimens.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	HIV-related B-Cell Lymphoma, Post-transplant lymphoproliferative disorders
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ZYNYZ

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## Products Affected

- ZYNYZ

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>Part B vs Part D determination will be made at time of prior authorization review per CMS guidance. Merkel Cell Carcinoma-approve if (A, B or C): A) pt has primary or recurrent locally advanced disease, if according to the prescriber curative surgery and curative radiation therapy are not feasible, or B) pt has primary or recurrent regional disease, if according to the prescriber curative surgery and curative radiation therapy are not feasible, or C) pt has metastatic disease. Anal carcinoma- approve if (A and B): A) pt has locally recurrent, progressive, or metastatic disease and, B) meets (i, ii, or iii): i) medication is used first-line and in combination with chemotherapy, or ii) pt progressed on or was intolerant to platinum-based chemotherapy, or iii) medication is administered before proceeding to abdominoperineal resection. Colon, rectal or appendiceal cancer- approve if (A and B): A) meets one of (i, ii or iii): i) locally unresectable or medically inoperable disease, or ii) advanced or metastatic disease, or iii) medication is used as neoadjuvant therapy, and B) meets (i or ii): i) pt has a deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or ii) pt has polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype. Small bowel adenocarcinoma- approve if (A and B): A) meets (i or ii): i) pt has locally unresectable or medically inoperable disease or ii) pt has advanced or metastatic disease, and B) meets (i or ii): i) pt has a deficient mismatch repair/microsatellite</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	instability-high (dMMR/MSI-H) or ii) pt has polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	colon/rectal/appendiceal cancer, small bowel adenocarcinoma
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	Yes

# ZYTIGA

## Products Affected

- *abiraterone oral tablet 250 mg, 500 mg*
- *abirtega*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year.
Other Criteria	<p>Prostate Cancer-Metastatic, Castration-Resistant (mCRPC)-Approve if abiraterone is being used in combination with prednisone or dexamethasone and the medication is used concurrently used with a gonadotropin-releasing hormone (GnRH) analog (see Note 1) or the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration-sensitive (mCSPC)- approve if the medication is used in combination with prednisone and the medication is concurrently used with a GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the patient meets all of the following criteria (A, B, and C): A) abiraterone is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii ): i. abiraterone with prednisone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer-very-high-risk-group-approve if according to the prescriber the patient is in the very-high-risk group, the medication will be used in combination with prednisone, the medication will be used in combination with external beam radiation therapy and the patient meets one of the following criteria (i or ii): i. abiraterone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer- radical prostatectomy or post radiation therapy-approve if patient meets (A, B, C and D): A) the medication is used in combination</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>with prednisone, B) meets (i or ii): i) the patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy or ii) PSA recurrence or positive digital rectal examination (DRE) after radiation therapy, C) patient has pelvic recurrence or positive regional lymph nodes, and D) the medication will be used concurrently with GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Salivary Gland Tumors- approve if (A, B and C): A) used in combination with prednisone, B) androgen receptor-positive (AR+) recurrent, unresectable or metastatic tumor, and C) used in combination with a GnRH analog (see Note 1). Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Prostate Cancer-Regional Risk Group, Prostate cancer-very-high-risk group, Prostate cancer- radical prostatectomy or post radiation, Salivary Gland Tumors
<b>Part B Prerequisite</b>	No
<b>Prerequisite Therapy Required</b>	No

## PART B VERSUS PART D

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### Products Affected

- *acetylcysteine*
- *acyclovir sodium intravenous solution*
- ADCETRIS
- *albuterol sulfate inhalation solution for nebulization 0.63 mg/3 ml, 1.25 mg/3 ml, 2.5 mg /3 ml (0.083 %), 2.5 mg/0.5 ml*
- *amphotericin b*
- *amphotericin b liposome*
- *aprepitant*
- *arformoterol*
- *arsenic trioxide*
- *azacitidine*
- *azathioprine oral tablet 50 mg*
- *azathioprine sodium*
- BAVENCIO
- BEIZRAY-ALBUMIN
- BELEODAQ
- *bendamustine intravenous recon soln*
- BENDEKA
- BESPONSA
- *bleomycin*
- BLINCYTO INTRAVENOUS KIT
- BOMYNTRA
- BORTEZOMIB INJECTION RECON SOLN 1 MG, 2.5 MG
- *bortezomib injection recon soln 3.5 mg*
- *budesonide inhalation suspension for nebulization 0.25 mg/2 ml, 0.5 mg/2 ml, 1 mg/2 ml*
- *busulfan*
- *carboplatin intravenous solution*
- *carmustine intravenous recon soln 100 mg*
- *cisplatin intravenous solution*
- *cladribine*
- CLINIMIX 5%/D15W SULFITE FREE
- CLINIMIX 4.25%/D10W SULF FREE
- CLINIMIX 4.25%/D5W SULFIT FREE
- CLINIMIX 5%-D20W(SULFITE-FREE)
- CLINIMIX 6%-D5W (SULFITE-FREE)
- CLINIMIX 8%-D10W(SULFITE-FREE)
- CLINIMIX 8%-D14W(SULFITE-FREE)
- *clofarabine*
- *cromolyn inhalation*
- *cyclophosphamide intravenous recon soln*
- *cyclophosphamide oral capsule*
- CYCLOPHOSPHAMIDE ORAL TABLET 50 MG
- *cyclosporine modified*
- *cyclosporine oral capsule*
- CYRAMZA
- *cytarabine*
- *cytarabine (pf)*
- *dacarbazine*
- *dactinomycin*
- DANYELZA
- DARZALEX
- *daunorubicin*
- *decitabine*
- *deferoxamine*
- *dexrazoxane hcl*
- *dobutamine*
- *dobutamine in d5w intravenous parenteral solution 1,000 mg/250 ml (4,000 mcg/ml), 250 mg/250 ml (1 mg/ml), 500 mg/250 ml (2,000 mcg/ml)*
- *docetaxel*
- *dopamine in 5 % dextrose*
- *dopamine intravenous solution 200 mg/5 ml (40 mg/ml), 400 mg/10 ml (40 mg/ml)*
- *doxorubicin*
- *doxorubicin, peg-liposomal*
- ELZONRIS
- EMLICITI
- ENGERIX-B (PF)
- ENGERIX-B PEDIATRIC (PF)
- ENVARSUS XR
- ERBITUX
- *eribulin*
- ETOPOPHOS
- *etoposide intravenous*
- *everolimus (immunosuppressive)*
- *floxuridine*
- *fludarabine*
- *fluorouracil intravenous*
- *formoterol fumarate*
- *fulvestrant*

- *ganciclovir sodium*
- GAZYVA
- *gemcitabine intravenous recon soln*
- *gemcitabine intravenous solution 1 gram/26.3 ml (38 mg/ml), 2 gram/52.6 ml (38 mg/ml), 200 mg/5.26 ml (38 mg/ml)*
- GEMCITABINE INTRAVENOUS SOLUTION 100 MG/ML
- *gengraf oral capsule*
- GRAFAPEX
- *granisetron hcl oral*
- HEPLISAV-B (PF)
- *idarubicin*
- *ifosfamide*
- IMFINZI
- IMOVAX RABIES VACCINE (PF)
- *intralipid intravenous emulsion 20 %*
- *ipratropium bromide inhalation solution*
- *ipratropium-albuterol*
- *irinotecan*
- ISTODAX
- IXEMPRA
- JEVTANA
- JYLAMVO
- JYNNEOS (PF)
- KHAPZORY INTRAVENOUS RECON SOLN 175 MG
- KIMMTRAK
- KYPROLIS
- *levoleucovorin calcium intravenous solution*
- LIORESAL
- *melphalan hcl*
- *mesna intravenous*
- *methotrexate sodium*
- *methotrexate sodium (pf)*
- *methylprednisolone oral tablet*
- *milrinone*
- *milrinone in 5 % dextrose*
- *mitomycin intravenous*
- *mitoxantrone*
- *mycophenolate mofetil*
- *mycophenolate mofetil (hcl)*
- *mycophenolate sodium*
- MYHIBBIN
- MYLOTARG
- NELARABINE
- NULOJIX
- ONCASPAR
- *ondansetron hcl oral solution*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet, disintegrating 4 mg, 8 mg*
- ONIVYDE
- *oxaliplatin*
- *paclitaxel*
- *paclitaxel protein-bound*
- *pemetrexed disodium intravenous recon soln*
- *pentamidine inhalation*
- PERJETA
- PLENAMINE
- *plerixafor*
- *pralatrexate intravenous solution 20 mg/ml (1 ml)*
- PRALATREXATE INTRAVENOUS SOLUTION 40 MG/2 ML (20 MG/ML)
- *premasol 10 %*
- PROGRAF INTRAVENOUS
- PROGRAF ORAL GRANULES IN PACKET
- PULMOZYME
- RABAVERT (PF)
- RECOMBIVAX HB (PF)
- *romidepsin intravenous recon soln*
- RYLAZE
- SIMULECT
- *sirolimus*
- SYLVANT
- *tacrolimus oral capsule*
- TECENTRIQ
- TECENTRIQ HYBREZA
- TEMODAR
- *temsirolimus*
- *thiotepa*
- TICE BCG
- *topotecan*
- *travasol 10 %*
- TRAZIMERA
- TROPHAMINE 10 %
- TYVASO

- TYVASO INSTITUTIONAL START KIT
- TYVASO REFILL KIT
- TYVASO STARTER KIT
- UNITUXIN
- *valrubicin*
- VARUBI
- VECTIBIX
- *veletri*
- *vinblastine*
- *vincristine*
- *vinorelbine*
- VYXEOS
- WYOST
- XEMBIFY
- YERVOY
- YONDELIS
- ZALTRAP
- ZIRABEV
- *zoledronic acid intravenous solution*

### **Details**

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

## Index

### A

abiraterone oral tablet 250 mg, 500 mg . 523, 524  
abirtega..... 523, 524  
acetylcysteine..... 525  
ACTEMRA ACTPEN ..... 3, 4  
ACTEMRA INTRAVENOUS..... 1, 2  
ACTEMRA SUBCUTANEOUS ..... 3, 4  
ACTIMMUNE..... 5  
acyclovir sodium intravenous solution ... 525  
acyclovir topical ointment..... 6  
ADBRY..... 9  
ADCETRIS ..... 525  
ADEMPAS ..... 10  
ADSTILADRIN..... 11  
AIMOVIG AUTOINJECTOR..... 12  
AKEEGA ..... 13  
albuterol sulfate inhalation solution for nebulization 0.63 mg/3 ml, 1.25 mg/3 ml, 2.5 mg /3 ml (0.083 %), 2.5 mg/0.5 ml525  
alcohol pads ..... 94  
ALDURAZYME..... 14  
ALECENSA..... 15, 16  
alosetron..... 17  
ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG..... 19  
ALUNBRIG ORAL TABLETS,DOSE PACK..... 19  
alyq..... 326  
ambrisentan ..... 48  
amikacin injection solution 1,000 mg/4 ml, 500 mg/2 ml ..... 21, 22  
amphotericin b ..... 525  
amphotericin b liposome..... 525  
ampicillin sodium injection recon soln 1 gram, 10 gram, 2 gram, 250 mg, 500 mg ..... 21, 22  
ampicillin sodium intravenous ..... 21, 22  
ampicillin-sulbactam..... 21, 22  
ANKTIVA ..... 20  
aprepitant..... 525  
ARCALYST ..... 24  
arformoterol ..... 525  
ARIKAYCE..... 25, 26

armodafinil..... 264  
arsenic trioxide..... 525  
ASPARLAS ..... 27  
ASSURE ID INSULIN SAFETY SYRINGE 1 ML 29 GAUGE X 1/2 ..... 96  
AUGTYRO ORAL CAPSULE 160 MG, 40 MG ..... 29, 30  
AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG ..... 31  
AUSTEDO XR ..... 31  
AUSTEDO XR TITRATION KT(WK1-4) ORAL TABLET, EXT REL 24HR DOSE PACK 12-18-24-30 MG ..... 31  
AVMAPKI-FAKZYNJA ..... 32  
AVONEX INTRAMUSCULAR PEN INJECTOR KIT ..... 33  
AVONEX INTRAMUSCULAR SYRINGE KIT ..... 33  
AYVAKIT ..... 34  
azacitidine ..... 525  
azathioprine oral tablet 50 mg..... 525  
azathioprine sodium ..... 525  
azithromycin intravenous..... 21, 22  
aztreonam ..... 21, 22  
**B**  
BALVERSA ..... 35  
BAVENCIO..... 525  
BEIZRAY-ALBUMIN ..... 525  
BELBUCA..... 234, 235  
BELEODAQ..... 525  
BELSOMRA..... 103  
bendamustine intravenous recon soln ..... 525  
BENDEKA ..... 525  
BENLYSTA..... 36, 37, 38, 39  
benztropine oral ..... 152  
BESPONSA ..... 525  
BESREMI ..... 40  
BETASERON SUBCUTANEOUS KIT .. 41  
bexarotene ..... 42, 43  
BICILLIN L-A..... 21, 22  
BIZENGR..... 44  
BLENREP ..... 45  
bleomycin..... 525  
BLINCYTO INTRAVENOUS KIT ..... 525

BOMYNTRA.....	525	CINRYZE .....	56
BONSITY .....	419, 420	ciprofloxacin in 5 % dextrose .....	21, 22
BORTEZOMIB INJECTION RECON SOLN 1 MG, 2.5 MG .....	525	cisplatin intravenous solution .....	525
bortezomib injection recon soln 3.5 mg..	525	cladribine.....	525
bosentan oral tablet .....	48	clindamycin in 5 % dextrose.....	21, 22
BOSULIF ORAL CAPSULE 100 MG, 50 MG .....	49	clindamycin phosphate injection.....	21, 22
BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG.....	49	CLINIMIX 5%/D15W SULFITE FREE	525
BRAFTOVI.....	50, 51	CLINIMIX 4.25%/D10W SULF FREE .	525
BRIUMVI .....	52	CLINIMIX 4.25%/D5W SULFIT FREE	525
BRUKINSA ORAL TABLET .....	53, 54	CLINIMIX 5%-D20W(SULFITE-FREE) .....	525
budesonide inhalation suspension for nebulization 0.25 mg/2 ml, 0.5 mg/2 ml, 1 mg/2 ml .....	525	CLINIMIX 6%-D5W (SULFITE-FREE)	525
buprenorphine transdermal patch....	234, 235	CLINIMIX 8%-D10W(SULFITE-FREE) .....	525
busulfan.....	525	CLINIMIX 8%-D14W(SULFITE-FREE) .....	525
BYOOVIZ.....	55	clobazam oral suspension .....	72
<b>C</b>		clobazam oral tablet .....	72
CABLIVI INJECTION KIT .....	57	clofarabine.....	525
CABOMETYX .....	58, 59	clomid .....	73
calcium acetate(phosphat bind).....	325	clomiphene citrate.....	73
CALQUENCE (ACALABRUTINIB MAL) .....	60, 61	clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg .....	153, 154
CAMZYOS.....	62, 63	colistin (colistimethate na).....	21, 22
CAPRELSA ORAL TABLET 100 MG, 300 MG .....	64	COLUMVI.....	74, 75
carboplatin intravenous solution.....	525	COMETRIQ ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X1), 140 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY (20 MG X 3/DAY).....	76
carglumic acid.....	65	COPIKTRA.....	77
carmustine intravenous recon soln 100 mg .....	525	COSENTYX (2 SYRINGES).....	78, 79
CAYSTON.....	66	COSENTYX INTRAVENOUS.....	80
cefoxitin .....	21, 22	COSENTYX PEN.....	78, 79
cefoxitin in dextrose, iso-osm.....	21, 22	COSENTYX PEN (2 PENS) .....	78, 79
ceftazidime .....	21, 22	COSENTYX SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.5 ML .....	78, 79
cefuroxime sodium injection recon soln 750 mg .....	21, 22	COSENTYX UNOREADY PEN .....	78, 79
cefuroxime sodium intravenous .....	21, 22	COTELLIC .....	81, 82
CEPROTIN (BLUE BAR).....	67	CRESEMBA ORAL .....	83
CEPROTIN (GREEN BAR).....	67	cromolyn inhalation .....	525
CHEMET .....	68	CRYSVITA.....	84, 85
CIMZIA .....	69, 70	cyclobenzaprine oral tablet 10 mg, 5 mg	157
CIMZIA POWDER FOR RECONST	69, 70	cyclophosphamide intravenous recon soln .....	525
CIMZIA STARTER KIT .....	69, 70	cyclophosphamide oral capsule .....	525
cinacalcet.....	71		

CYCLOPHOSPHAMIDE ORAL TABLET  
 50 MG ..... 525  
 cyclosporine modified..... 525  
 cyclosporine oral capsule..... 525  
 CYRAMZA..... 525  
 CYSTAGON..... 87  
 CYSTARAN..... 86  
 cytarabine..... 525  
 cytarabine (pf)..... 525  
**D**  
 dacarbazine ..... 525  
 dactinomycin..... 525  
 dalfampridine ..... 88  
 DANYELZA..... 525  
 DANZITEN ..... 279, 280  
 DARZALEX..... 525  
 dasatinib oral tablet 100 mg, 140 mg, 20 mg,  
 50 mg, 70 mg, 80 mg ..... 395  
 DATROWAY ..... 89, 90  
 daunorubicin ..... 525  
 DAURISMO ORAL TABLET 100 MG, 25  
 MG ..... 91  
 decitabine ..... 525  
 deferasirox..... 92  
 deferiprone ..... 93  
 deferoxamine..... 525  
 dermacinrx lidocan..... 229  
 dexrazoxane hcl ..... 525  
 DIACOMIT..... 98  
 diazepam injection ..... 153, 154  
 diazepam intensol..... 153, 154  
 diazepam oral concentrate..... 153, 154  
 diazepam oral solution ..... 153, 154  
 diazepam oral tablet ..... 153, 154  
 diclofenac sodium topical gel 3 %..... 389  
 dimethyl fumarate oral capsule, delayed  
 release(dr/ec) 120 mg, 120 mg (14)- 240  
 mg (46), 240 mg..... 99  
 dobutamine..... 525  
 dobutamine in d5w intravenous parenteral  
 solution 1,000 mg/250 ml (4,000  
 mcg/ml), 250 mg/250 ml (1 mg/ml), 500  
 mg/250 ml (2,000 mcg/ml) ..... 525  
 docetaxel ..... 525  
 dopamine in 5 % dextrose..... 525

dopamine intravenous solution 200 mg/5 ml  
 (40 mg/ml), 400 mg/10 ml (40 mg/ml)525  
 DOPTelet (10 TAB PACK)..... 100  
 DOPTelet (15 TAB PACK)..... 100  
 DOPTelet (30 TAB PACK)..... 100  
 doxorubicin ..... 525  
 doxorubicin, peg-liposomal ..... 525  
 doxy-100 ..... 21, 22  
 doxycycline hyclate intravenous..... 21, 22  
 dronabinol ..... 101  
 DROPSAFE ALCOHOL PREP PADS .... 94  
 droxidopa ..... 102  
 DUPIXENT PEN SUBCUTANEOUS PEN  
 INJECTOR 200 MG/1.14 ML, 300 MG/2  
 ML..... 104, 105, 106  
 DUPIXENT SYRINGE SUBCUTANEOUS  
 SYRINGE 200 MG/1.14 ML, 300 MG/2  
 ML..... 104, 105, 106  
**E**  
 ELAHERE ..... 107  
 ELAPRASE ..... 108  
 ELIGARD ..... 146  
 ELIGARD (3 MONTH)..... 146  
 ELIGARD (4 MONTH)..... 146  
 ELIGARD (6 MONTH)..... 146  
 ELREXFIO ..... 109  
 eltrombopag olamine ..... 336, 337  
 ELZONRIS ..... 525  
 EMGALITY PEN ..... 110  
 EMGALITY SYRINGE  
 SUBCUTANEOUS SYRINGE 120  
 MG/ML..... 110  
 EMLICITI..... 525  
 EMRELIS ..... 111  
 ENBREL MINI..... 112, 113  
 ENBREL SUBCUTANEOUS SOLUTION  
 ..... 112, 113  
 ENBREL SUBCUTANEOUS SYRINGE  
 ..... 112, 113  
 ENBREL SURECLICK..... 112, 113  
 ENGERIX-B (PF)..... 525  
 ENGERIX-B PEDIATRIC (PF)..... 525  
 ENSACOVE ..... 115  
 ENVARUSUS XR..... 525  
 EPIDIOLEX..... 116  
 EPKINLY ..... 117

ERBITUX ..... 525  
eribulin ..... 525  
ERIVEDGE..... 120  
ERLEADA ORAL TABLET 240 MG, 60  
MG ..... 121  
erlotinib oral tablet 100 mg, 150 mg, 25 mg  
..... 122, 123  
ertapenem ..... 21, 22  
ETOPOPHOS ..... 525  
etoposide intravenous..... 525  
EUCRISA ..... 430  
everolimus (antineoplastic) oral tablet... 124,  
125  
everolimus (antineoplastic) oral tablet for  
suspension 2 mg, 3 mg, 5 mg..... 124, 125  
everolimus (immunosuppressive) ..... 525  
exenatide subcutaneous pen injector 10  
mcg/dose(250 mcg/ml) 2.4 ml, 5  
mcg/dose (250 mcg/ml) 1.2 ml ..... 143

**F**  
FABRAZYME ..... 126  
FASENRA PEN..... 127, 128  
FASENRA SUBCUTANEOUS SYRINGE  
10 MG/0.5 ML, 30 MG/ML ..... 127, 128  
fentanyl transdermal patch 72 hour 100  
mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr,  
75 mcg/hr ..... 433, 434  
fingolimod..... 129  
FINTEPLA..... 130  
FIRMAGON KIT W DILUENT SYRINGE  
..... 131  
floxuridine..... 525  
fluconazole in nacl (iso-osm) intravenous  
piggyback 200 mg/100 ml, 400 mg/200  
ml ..... 23  
fludarabine ..... 525  
fluorouracil intravenous ..... 525  
formoterol fumarate ..... 525  
FOTIVDA ..... 132  
FRUZAQLA ORAL CAPSULE 1 MG, 5  
MG ..... 133, 134  
FULPHILA ..... 135, 136  
fulvestrant ..... 525  
FYARRO ..... 137

**G**  
gabapentin oral tablet extended release 24 hr  
300 mg, 450 mg, 600 mg, 750 mg, 900  
mg ..... 147  
GAMUNEX-C ..... 191  
ganciclovir sodium..... 526  
GATTEX 30-VIAL..... 138  
GATTEX ONE-VIAL ..... 138  
GAUZE PAD TOPICAL BANDAGE 2 X 2  
..... 95  
GAVRETO ..... 139  
GAZYVA..... 526  
gefitinib ..... 140  
gemcitabine intravenous recon soln..... 526  
gemcitabine intravenous solution 1  
gram/26.3 ml (38 mg/ml), 2 gram/52.6 ml  
(38 mg/ml), 200 mg/5.26 ml (38 mg/ml)  
..... 526  
GEMCITABINE INTRAVENOUS  
SOLUTION 100 MG/ML ..... 526  
gengraf oral capsule ..... 526  
gentamicin in nacl (iso-osm) intravenous  
piggyback 100 mg/100 ml, 60 mg/50 ml,  
80 mg/100 ml, 80 mg/50 ml..... 21, 22  
gentamicin injection..... 21, 22  
gentamicin sulfate (ped) (pf)..... 21, 22  
GILOTRIF ..... 141  
glatiramer subcutaneous syringe 20 mg/ml,  
40 mg/ml ..... 142  
glatopa subcutaneous syringe 20 mg/ml, 40  
mg/ml ..... 142  
glutamine (sickle cell)..... 114  
GOMEKLI ORAL CAPSULE 1 MG, 2 MG  
..... 145  
GOMEKLI ORAL TABLET FOR  
SUSPENSION ..... 145  
GRAFAPEX ..... 526  
granisetron hcl oral ..... 526

**H**  
HADLIMA..... 7, 8  
HADLIMA PUSHTOUCH..... 7, 8  
HADLIMA(CF) ..... 7, 8  
HADLIMA(CF) PUSHTOUCH ..... 7, 8  
HEPLISAV-B (PF) ..... 526  
HERNEXEOS..... 151

hydromorphone oral tablet extended release  
 24 hr ..... 234, 235  
 hydroxyzine hcl oral tablet..... 155  
 HYRNUO ..... 158  
**I**  
 ibandronate intravenous ..... 46, 47  
 IBRANCE ..... 159, 160  
 IBTROZI..... 161  
 icatibant..... 162, 163  
 ICLUSIG..... 164, 165  
 idarubicin ..... 526  
 IDHIFA ..... 166  
 ifosfamide ..... 526  
 ILARIS (PF)..... 167, 168  
 imatinib oral tablet 100 mg, 400 mg 169, 170  
 IMBRUVICA ORAL CAPSULE 140 MG,  
 70 MG ..... 171, 172  
 IMBRUVICA ORAL SUSPENSION.... 171,  
 172  
 IMBRUVICA ORAL TABLET 140 MG,  
 280 MG, 420 MG..... 171, 172  
 IMDELLTRA ..... 173  
 IMFINZI ..... 526  
 imipenem-cilastatin..... 21, 22  
 IMJUDO ..... 174, 175  
 IMKELDI..... 169, 170  
 IMOVAX RABIES VACCINE (PF) ..... 526  
 IMPAVIDO..... 176  
 INBRIJA INHALATION CAPSULE,  
 W/INHALATION DEVICE ..... 177  
 INFLIXIMAB ..... 346, 347  
 INGREZZA..... 178  
 INGREZZA INITIATION PK(TARDIV)  
 ..... 178  
 INGREZZA SPRINKLE ..... 178  
 INLEXZO ..... 181  
 INLURIYO ..... 182, 183  
 INLYTA ORAL TABLET 1 MG, 5 MG 184  
 INPEFA..... 185  
 INQOVI ..... 186  
 INREBIC..... 187  
 INSULIN SYRINGE-NEEDLE U-100  
 SYRINGE 0.3 ML 29 GAUGE, 1 ML 29  
 GAUGE X 1/2..... 97  
 intralipid intravenous emulsion 20 % ..... 526  
 ipratropium bromide inhalation solution 526

ipratropium-albuterol ..... 526  
 irinotecan..... 526  
 ISTODAX ..... 526  
 ITOVEBI ORAL TABLET 3 MG, 9 MG  
 ..... 188, 189  
 ivermectin oral tablet 3 mg, 6 mg ..... 190  
 IWILFIN ..... 192  
 IXEMPRA..... 526  
**J**  
 JAKAFI..... 193, 194  
 JAYPIRCA ORAL TABLET 100 MG, 50  
 MG ..... 195, 196  
 JEMPERLI ..... 197, 198  
 JEVTANA..... 526  
 JYLAMVO ..... 526  
 JYNNEOS (PF)..... 526  
**K**  
 KADCYLA ..... 200  
 KALYDECO..... 201  
 KANUMA..... 202  
 KERENDIA ..... 203, 204  
 KESIMPTA PEN ..... 205  
 KEYTRUDA..... 206  
 KEYTRUDA QLEX..... 207  
 KHAPZORY INTRAVENOUS RECON  
 SOLN 175 MG..... 526  
 KIMMTRAK ..... 526  
 KINERET ..... 208, 209  
 KISQALI ORAL TABLET 200 MG/DAY  
 (200 MG X 1), 400 MG/DAY (200 MG X  
 2), 600 MG/DAY (200 MG X 3) 210, 211  
 KOMZIFTI ..... 212  
 KOSELUGO ..... 214  
 KRAZATI..... 215, 216  
 KYPROLIS ..... 526  
**L**  
 lanreotide subcutaneous syringe 120 mg/0.5  
 ml ..... 217, 218  
 lapatinib..... 219, 220  
 LAZCLUZE ORAL TABLET 240 MG, 80  
 MG ..... 221  
 LEDIPASVIR-SOFOSBUVIR..... 222  
 lenalidomide..... 223, 224  
 LENVIMA ORAL CAPSULE 10 MG/DAY  
 (10 MG X 1), 12 MG/DAY (4 MG X 3),  
 14 MG/DAY(10 MG X 1-4 MG X 1), 18

MG/DAY (10 MG X 1-4 MG X2), 20  
 MG/DAY (10 MG X 2), 24 MG/DAY(10  
 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY  
 (4 MG X 2)..... 225, 226  
 leuprolide subcutaneous kit..... 146  
 levofloxacin in d5w..... 21, 22  
 levofloxacin intravenous..... 21, 22  
 levoleucovorin calcium intravenous solution  
 ..... 526  
 LIBTAYO ..... 227, 228  
 lidocaine topical adhesive patch,medicated 5  
 % ..... 229  
 lidocan iii ..... 229  
 lidocan iv..... 229  
 lidocan v..... 229  
 lincomycin..... 21, 22  
 linezolid in dextrose 5%..... 21, 22  
 linezolid-0.9% sodium chloride ..... 21, 22  
 LIORESAL ..... 526  
 liraglutide ..... 143  
 LIVDELZI ..... 230, 231  
 LIVTENCITY ..... 232, 233  
 LONSURF ..... 236, 237  
 LOQTORZI..... 238, 239  
 lorazepam injection..... 153, 154  
 lorazepam intensol ..... 153, 154  
 lorazepam oral concentrate ..... 153, 154  
 lorazepam oral tablet 0.5 mg, 1 mg, 2 mg  
 ..... 153, 154  
 LORBRENA ORAL TABLET 100 MG, 25  
 MG ..... 240, 241  
 LUMAKRAS ORAL TABLET 120 MG,  
 240 MG, 320 MG..... 242, 243  
 LUMIZYME ..... 244  
 LUNSUMIO ..... 245, 246  
 LUNSUMIO VELO..... 247, 248  
 LUPRON DEPOT..... 249, 250  
 LYNOZYFIC..... 251, 252  
 LYNPARZA ..... 253, 254  
 LYTGObI ORAL TABLET 12 MG/DAY  
 (4 MG X 3), 16 MG/DAY (4 MG X 4),  
 20 MG/DAY (4 MG X 5) ..... 255  
**M**  
 MAVYRET ORAL PELLETS IN PACKET  
 ..... 256  
 MAVYRET ORAL TABLET..... 256

megestrol oral suspension 400 mg/10 ml (10  
 ml), 400 mg/10 ml (40 mg/ml), 625 mg/5  
 ml (125 mg/ml) ..... 257  
 megestrol oral tablet..... 257  
 MEKINIST ORAL RECON SOLN 258, 259  
 MEKINIST ORAL TABLET 0.5 MG, 2  
 MG ..... 258, 259  
 MEKTOVI ..... 260  
 melphalan hcl ..... 526  
 memantine oral capsule,sprinkle,er 24hr 261  
 memantine oral solution..... 261  
 memantine oral tablet..... 261  
 memantine-donepezil ..... 261  
 MEPSEVII ..... 262  
 meropenem intravenous recon soln 1 gram,  
 2 gram, 500 mg ..... 21, 22  
 mesna intravenous..... 526  
 methadone intensol ..... 234, 235  
 methadone oral concentrate ..... 234, 235  
 methadone oral solution 10 mg/5 ml, 5 mg/5  
 ml ..... 234, 235  
 methadone oral tablet 10 mg, 5 mg. 234, 235  
 methadose oral concentrate..... 234, 235  
 methotrexate sodium ..... 526  
 methotrexate sodium (pf)..... 526  
 methylergonovine oral ..... 263  
 methylprednisolone oral tablet..... 526  
 metro i.v. .... 21, 22  
 metronidazole in nacl (iso-os)..... 21, 22  
 metyrosine..... 324  
 mifepristone oral tablet 300 mg ..... 213  
 milophene..... 73  
 milrinone ..... 526  
 milrinone in 5 % dextrose ..... 526  
 mitomycin intravenous..... 526  
 mitoxantrone ..... 526  
 modafinil oral tablet 100 mg, 200 mg.... 264  
 MODEYSO..... 265  
 MONJUVI..... 266  
 morphine oral tablet extended release.... 234,  
 235  
 MOUNJARO ..... 143  
 moxifloxacin-sod.chloride(iso)..... 21, 22  
 mycophenolate mofetil..... 526  
 mycophenolate mofetil (hcl)..... 526  
 mycophenolate sodium ..... 526

MYFEMBREE.....	267, 268	OJJAARA .....	305
MYHIBBIN .....	526	OMNITROPE .....	148, 149, 150
MYLOTARG .....	526	ONCASPAR .....	526
<b>N</b>		ondansetron hcl oral solution .....	526
nafcillin in dextrose iso-osm intravenous		ondansetron hcl oral tablet 4 mg, 8 mg... 526	
piggyback 2 gram/100 ml .....	21, 22	ondansetron oral tablet,disintegrating 4 mg,	
nafcillin injection .....	21, 22	8 mg .....	526
NAGLAZYME .....	269	ONIVYDE .....	526
NANO PEN NEEDLE .....	96	ONUREG .....	306
NAYZILAM .....	270	OPDIVO .....	307
NELARABINE .....	526	OPDIVO QVANTIG .....	308
NEMLUVIO .....	271, 272	OPDUALAG.....	309
NERLYNX .....	273, 274	OPSUMIT .....	310
NEXLETOL.....	275, 276	OPSYNVI .....	311
NEXLIZET .....	277, 278	ORGOVYX.....	312
nilotinib hcl oral capsule 150 mg, 200 mg,		ORKAMBI ORAL GRANULES IN	
50 mg .....	279, 280	PACKET.....	313
nilutamide .....	281	ORKAMBI ORAL TABLET .....	313
NINLARO.....	282, 283	ORSERDU ORAL TABLET 345 MG, 86	
nitisinone.....	284	MG .....	314, 315
NIVESTYM.....	285, 286	OTEZLA.....	316
NUBEQA.....	289	OTEZLA STARTER ORAL	
NUCALA SUBCUTANEOUS AUTO-		TABLETS,DOSE PACK 10 MG (4)- 20	
INJECTOR.....	290, 291, 292	MG (51), 10 MG (4)-20 MG (4)-30 MG	
NUCALA SUBCUTANEOUS RECON		(47).....	316
SOLN .....	290, 291, 292	OTEZLA XR .....	316
NUCALA SUBCUTANEOUS SYRINGE		OTEZLA XR INITIATION.....	316
100 MG/ML, 40 MG/0.4 ML ....	290, 291,	OTULFI INTRAVENOUS.....	457
292		OTULFI SUBCUTANEOUS SOLUTION	
NUEDEXTA.....	293	.....	458, 459
NULOJIX.....	526	OTULFI SUBCUTANEOUS SYRINGE 45	
NUPLAZID.....	294	MG/0.5 ML, 90 MG/ML .....	458, 459
NURTEC ODT .....	295	oxacillin.....	21, 22
NYVEPRIA .....	296, 297	oxacillin in dextrose(iso-osm) intravenous	
<b>O</b>		piggyback 2 gram/50 ml .....	21, 22
octreotide acetate .....	298, 299	oxaliplatin .....	526
octreotide,microspheres .....	377, 378	OXERVATE.....	317
ODOMZO .....	300	OZEMPIC SUBCUTANEOUS PEN	
OFEV .....	301, 302	INJECTOR 0.25 MG OR 0.5 MG (2	
OGSIVEO ORAL TABLET 100 MG, 150		MG/3 ML), 1 MG/DOSE (4 MG/3 ML),	
MG .....	303	2 MG/DOSE (8 MG/3 ML) .....	143
OJEMDA ORAL SUSPENSION FOR		<b>P</b>	
RECONSTITUTION .....	304	paclitaxel .....	526
OJEMDA ORAL TABLET 400 MG/WEEK		paclitaxel protein-bound .....	526
(100 MG X 4), 500 MG/WEEK (100 MG		PADCEV.....	318
X 5), 600 MG/WEEK (100 MG X 6) .	304	PANRETIN.....	319

PAVBLU.....	320	PREVYMIS ORAL TABLET 240 MG, 480	
pazopanib oral tablet 200 mg.....	477, 478	MG .....	335
PEMAZYRE .....	321	PROCRIT.....	118, 119
pemetrexed disodium intravenous recon soln		PROGRAF INTRAVENOUS.....	526
.....	526	PROGRAF ORAL GRANULES IN	
PEN NEEDLE, DIABETIC NEEDLE 29		PACKET .....	526
GAUGE X 1/2.....	96	PROLASTIN-C INTRAVENOUS	
penicillamine oral tablet.....	322	SOLUTION.....	18
PENICILLIN G POT IN DEXTROSE		promethazine oral.....	155
INTRAVENOUS PIGGYBACK 2		PULMOZYME .....	526
MILLION UNIT/50 ML, 3 MILLION		pyrimethamine .....	338
UNIT/50 ML.....	21, 22	PYZCHIVA (ONLY NDCS STARTING	
penicillin g potassium .....	21, 22	WITH 61314) INTRAVENOUS	
penicillin g sodium.....	21, 22	SOLUTION 130 MG/26 ML .....	457
pentamidine inhalation.....	526	PYZCHIVA (ONLY NDCS STARTING	
PERJETA.....	526	WITH 61314) SUBCUTANEOUS	
pfizerpen-g .....	21, 22	SOLUTION 45 MG/0.5 ML .....	458, 459
phenobarbital.....	156	PYZCHIVA (ONLY NDCS STARTING	
pimecrolimus.....	430	WITH 61314) SUBCUTANEOUS	
PIQRAY ORAL TABLET 200 MG/DAY		SYRINGE 45 MG/0.5 ML, 90 MG/ML	
(200 MG X 1), 250 MG/DAY (200 MG		.....	458, 459
X1-50 MG X1), 300 MG/DAY (150 MG		<b>Q</b>	
X 2) .....	327, 328	QINLOCK.....	339
pirfenidone oral capsule.....	329	QULIPTA .....	340
pirfenidone oral tablet 267 mg, 801 mg..	329	<b>R</b>	
PLEGRIDY INTRAMUSCULAR .....	330	RABAVERT (PF).....	526
PLEGRIDY SUBCUTANEOUS PEN		RADICAVA ORS.....	341
INJECTOR 125 MCG/0.5 ML, 63		RADICAVA ORS STARTER KIT SUSP	
MCG/0.5 ML- 94 MCG/0.5 ML.....	330	.....	341
PLEGRIDY SUBCUTANEOUS SYRINGE		RECOMBIVAX HB (PF).....	526
125 MCG/0.5 ML, 63 MCG/0.5 ML- 94		RELEUKO SUBCUTANEOUS.....	344, 345
MCG/0.5 ML .....	330	REMICADE.....	346, 347
PLENAMINE .....	526	REPATHA .....	350, 351
plerixafor.....	526	REPATHA SURECLICK.....	350, 351
POLIVY .....	331	RETACRIT.....	118, 119
pomalidomide .....	332	RETEVMO ORAL TABLET 120 MG, 160	
posaconazole oral tablet, delayed release		MG, 40 MG, 80 MG .....	352, 353
(dr/ec).....	333	REVCOVI.....	354
POTELIGEO.....	334	REVUFORJ ORAL TABLET 110 MG, 160	
pralatrexate intravenous solution 20 mg/ml		MG, 25 MG.....	355
(1 ml).....	526	REZDIFFRA.....	356, 357
PRALATREXATE INTRAVENOUS		REZLIDHIA .....	358
SOLUTION 40 MG/2 ML (20 MG/ML)		REZUROCK.....	359
.....	526	riluzole .....	360
premasol 10 %.....	526	RINVOQ LQ.....	363
PREVYMIS INTRAVENOUS.....	335		

RINVOQ ORAL TABLET EXTENDED RELEASE 24 HR 15 MG, 30 MG, 45 MG .....	361, 362	SIRTURO .....	384
roflumilast .....	364, 365	SKYRIZI INTRAVENOUS .....	387
romidepsin intravenous recon soln .....	526	SKYRIZI SUBCUTANEOUS PEN INJECTOR.....	385, 386
ROMVIMZA .....	366	SKYRIZI SUBCUTANEOUS SYRINGE .....	385, 386
ROZLYTREK ORAL CAPSULE 100 MG, 200 MG .....	367	SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR 180 MG/1.2 ML (150 MG/ML), 360 MG/2.4 ML (150 MG/ML) .....	385, 386
ROZLYTREK ORAL PELLETS IN PACKET .....	367	sodium oxybate (preferred ndcs starting with 00054) .....	506
RUBRACA .....	368, 369	sodium phenylbutyrate.....	323
rufinamide .....	370	SOFOSBUVIR-VELPATASVIR.....	388
RUXIENCE .....	371	SOMATULINE DEPOT SUBCUTANEOUS SYRINGE 60 MG/0.2 ML, 90 MG/0.3 ML .....	217, 218
RYBELSUS .....	143	SOMAVERT.....	390
RYBREVANT .....	372	sorafenib.....	391, 392
RYBREVANT FASPRO .....	373	SPRAVATO NASAL SPRAY, NON- AEROSOL 56 MG (28 MG X 2), 84 MG (28 MG X 3).....	393, 394
RYDAPT.....	374	STELARA INTRAVENOUS .....	457
RYLAZE.....	526	STELARA SUBCUTANEOUS SOLUTION.....	458, 459
RYTELO.....	375, 376	STIVARGA .....	396, 397
<b>S</b>		STRENSIQ .....	398, 399
sajazir .....	162, 163	STREPTOMYCIN.....	21, 22
SANDOSTATIN LAR DEPOT INTRAMUSCULAR SUSPENSION, EXTENDED REL RECON 10 MG.....	377, 378	SUCRAID .....	400, 401
sapropterin.....	379	sulfamethoxazole-trimethoprim intravenous .....	21, 22
SARCLISA .....	380	sunitinib malate.....	402, 403
SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG.....	381, 382	SYLVANT .....	526
SELARSDI INTRAVENOUS .....	457	SYMDEKO.....	404
SELARSDI SUBCUTANEOUS SOLUTION.....	458, 459	SYMPAZAN.....	72
SELARSDI SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML .....	458, 459	<b>T</b>	
sevelamer carbonate oral tablet.....	325	TABRECTA .....	405
SIGNIFOR .....	383	tacrolimus oral capsule .....	526
sildenafil (pulmonary arterial hypertension) oral tablet 20 mg .....	326	tacrolimus topical.....	430
SIMLANDI(CF) AUTOINJECTOR SUBCUTANEOUS AUTO-INJECTOR, KIT 40 MG/0.4 ML, 80 MG/0.8 ML..	7, 8	tadalafil (pulm. hypertension).....	326
SIMLANDI(CF) SUBCUTANEOUS SYRINGE KIT 20 MG/0.2 ML, 40 MG/0.4 ML .....	7, 8	tadalafil oral tablet 2.5 mg, 5 mg .....	406
SIMULECT.....	526	TAFINLAR ORAL CAPSULE .....	409, 410
sirolimus.....	526	TAFINLAR ORAL TABLET FOR SUSPENSION .....	409, 410
		TAGRISO .....	411, 412
		TALVEY.....	413

TALZENNA .....	414	topiramate oral tablet .....	432
tazarotene topical cream .....	415	topotecan .....	526
tazarotene topical gel .....	415	torpenz.....	124, 125
tazicef.....	21, 22	travasol 10 %.....	526
TAZVERIK.....	416	TRAZIMERA .....	526
TECENTRIQ .....	526	TRELSTAR INTRAMUSCULAR	
TECENTRIQ HYBREZA .....	526	SUSPENSION FOR	
TECVAYLI.....	417	RECONSTITUTION .....	435
TEFLARO.....	21, 22	TREMFYA INTRAVENOUS .....	436
TEMODAR.....	526	TREMFYA ONE-PRESS .....	437, 438
temsirolimus.....	526	TREMFYA PEN.....	437, 438
TEPMETKO .....	418	TREMFYA PEN INDUCTION PK(2PEN)	
teriflunomide.....	28	.....	437, 438
teriparatide subcutaneous pen injector 20		TREMFYA SUBCUTANEOUS SYRINGE	
mcg/dose (560mcg/2.24ml) .....	419, 420	.....	437, 438
testosterone cypionate .....	179, 180	treprostinil sodium .....	348, 349
testosterone enanthate .....	179, 180	tretinoin topical .....	431
testosterone transdermal gel.....	287, 288	tridacaine ii.....	229
testosterone transdermal gel in metered-dose		trientine oral capsule 250 mg.....	439, 440
pump 12.5 mg/ 1.25 gram (1 %), 20.25		TRIKAFTA ORAL GRANULES IN	
mg/1.25 gram (1.62 %) .....	287, 288	PACKET, SEQUENTIAL .....	441
testosterone transdermal gel in packet 1 %		TRIKAFTA ORAL TABLETS,	
(25 mg/2.5gram), 1 % (50 mg/5 gram),		SEQUENTIAL.....	441
1.62 % (20.25 mg/1.25 gram), 1.62 %		TRODELVY .....	442, 443
(40.5 mg/2.5 gram) .....	287, 288	TROPHAMINE 10 %.....	526
testosterone transdermal solution in metered		TRULICITY .....	143
pump w/app.....	287, 288	TRUQAP.....	444, 445
tetrabenazine oral tablet 12.5 mg, 25 mg	421	TUKYSA ORAL TABLET 150 MG, 50	
TEVIMBRA.....	422, 423	MG .....	446, 447
THALOMID ORAL CAPSULE 100 MG,		TURALIO .....	448
50 MG .....	424, 425	TYENNE AUTOINJECTOR.....	451, 452
thiotepa.....	526	TYENNE INTRAVENOUS .....	449, 450
TIBSOVO .....	426	TYENNE SUBCUTANEOUS.....	451, 452
TICE BCG .....	526	TYMLOS .....	453, 454
tigecycline.....	21, 22	TYVASO .....	526
TIVDAK .....	427	TYVASO INSTITUTIONAL START KIT	
tobramycin in 0.225 % nacl .....	428	.....	527
tobramycin inhalation .....	428	TYVASO REFILL KIT .....	527
tobramycin sulfate injection recon soln ...	21,	TYVASO STARTER KIT .....	527
22		U	
tobramycin sulfate injection solution..	21, 22	UBRELVY .....	455
tolvaptan.....	429	ULTRA-FINE INSULIN SYRINGE	
tolvaptan (polycys kidney dis).....	199	SYRINGE 1/2 ML 31 GAUGE X 15/64	
topiramate oral capsule, sprinkle 15 mg, 25		.....	97
mg .....	432	UNITUXIN.....	527
topiramate oral solution .....	432	UPTRAVI ORAL TABLET .....	456

UPTRAVI ORAL TABLETS,DOSE PACK	456	VYVGART HYTRULO.....	483, 484
.....	456	VYXEOS .....	527
USTEKINUMAB INTRAVENOUS .....	457	<b>W</b>	
USTEKINUMAB SUBCUTANEOUS		WELIREG.....	485, 486
SOLUTION.....	458, 459	WINREVAIR.....	487, 488
USTEKINUMAB-AEKN		WYOST .....	527
SUBCUTANEOUS SYRINGE 45		<b>X</b>	
MG/0.5 ML, 90 MG/ML .....	458, 459	XALKORI ORAL CAPSULE .....	489, 490
<b>V</b>		XALKORI ORAL PELLETT 150 MG, 20	
VALCHLOR.....	460	MG, 50 MG.....	489, 490
valrubicin .....	527	XDEMVY .....	491
VALTOCO .....	461	XELJANZ ORAL SOLUTION .....	492, 493
vancomycin oral capsule 125 mg, 250 mg		XELJANZ ORAL TABLET .....	492, 493
.....	462	XELJANZ XR .....	492, 493
VANFLYTA.....	463	XEMBIFY.....	527
VARUBI.....	527	XERMELO .....	494
VECTIBIX.....	527	XIAFLEX .....	495, 496
veletri .....	527	XIFAXAN ORAL TABLET 200 MG, 550	
VENCLEXTA ORAL TABLET 10 MG,		MG .....	497, 498
100 MG, 50 MG.....	464, 465	XOLAIR SUBCUTANEOUS AUTO-	
VENCLEXTA STARTING PACK	464, 465	INJECTOR 150 MG/ML, 300 MG/2 ML,	
VERZENIO.....	466, 467	75 MG/0.5 ML.....	499, 500
VIBATIV INTRAVENOUS RECON SOLN		XOLAIR SUBCUTANEOUS RECON	
750 MG .....	21, 22	SOLN .....	499, 500
vigabatrin .....	468	XOLAIR SUBCUTANEOUS SYRINGE	
vigadrone.....	468	150 MG/ML, 300 MG/2 ML, 75 MG/0.5	
VIMIZIM .....	469	ML.....	499, 500
vinblastine.....	527	XOSPATA .....	501
vincristine.....	527	XPOVIO ORAL TABLET 100 MG/WEEK	
vinorelbine .....	527	(50 MG X 2), 40 MG/WEEK (10 MG X	
VITRAKVI ORAL CAPSULE 100 MG, 25		4), 40MG TWICE WEEK (40 MG X 2),	
MG .....	470	60 MG/WEEK (60 MG X 1), 60MG	
VITRAKVI ORAL SOLUTION .....	470	TWICE WEEK (120 MG/WEEK), 80	
VIZIMPRO .....	471	MG/WEEK (40 MG X 2), 80 MG/WEEK	
VONJO .....	472, 473	(80 MG X 1), 80MG TWICE WEEK (160	
VORANIGO ORAL TABLET 10 MG, 40		MG/WEEK) .....	502, 503
MG .....	474	XTANDI ORAL CAPSULE.....	504, 505
voriconazole.....	23, 475	XTANDI ORAL TABLET 40 MG, 80 MG	
voriconazole-hpbc	23	.....	504, 505
VOSEVI.....	476	<b>Y</b>	
VOWST .....	479	YERVOY .....	527
VUMERITY .....	480	YESINTEK INTRAVENOUS.....	457
VYLOY.....	481, 482	YESINTEK SUBCUTANEOUS	
VYNDAMAX.....	407, 408	SOLUTION.....	458, 459
VYNDAQEL .....	407, 408	YESINTEK SUBCUTANEOUS SYRINGE	
VYVGART .....	483, 484	45 MG/0.5 ML, 90 MG/ML .....	458, 459

YONDELIS.....	527	zoledronic acid intravenous solution .....	527
<b>Z</b>		zoledronic acid-mannitol-water intravenous	
ZALTRAP.....	527	piggyback 5 mg/100 ml .....	342, 343
ZEJULA ORAL TABLET.....	507	ZOLINZA .....	514
ZELBORAF.....	508, 509	ZONISADE.....	432
ZEPOSIA .....	510, 511	zonisamide .....	432
ZEPOSIA STARTER KIT (28-DAY)...	510,	ZTALMY .....	515
511		ZURZUVAE ORAL CAPSULE 20 MG, 25	
ZEPOSIA STARTER PACK (7-DAY). 510,		MG, 30 MG.....	516
511		ZYDELIG .....	517
ZEPZELCA.....	512	ZYKADIA .....	518
ZIIHERA.....	513	ZYMFENTRA .....	519
ZIRABEV .....	527	ZYNLONTA.....	520
ZOLADEX.....	144	ZYNYZ.....	521, 522