

## ABRYSVO

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### Products Affected

- ABRYSVO (PF)

<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>	Non-pregnant individuals: 60 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	The patient has not already received an RSV vaccine. For Pregnant Individuals: patient is between 32 through 36 weeks gestational age.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ACITRETIN

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## Products Affected

- *acitretin*

<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>	For initial therapy in the treatment of psoriasis: trial and failure, contraindication, or intolerance to methotrexate or cyclosporine is required. For continuation of therapy, approve if patient has already been started on Acitretin.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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>	Pending CMS Review
<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 mutation linked to chronic granulomatous disease. Malignant osteopetrosis, severe infantile - 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 mutation linked to severe, infantile malignant osteopetrosis.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</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

# AJOVY

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## Products Affected

- AJOVY AUTOINJECTOR
- AJOVY SYRINGE

<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 Ajovy, the pt has had significant clinical benefit from the medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</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- Approve if the patient meets the following (A, B, C, and D): A)Patient has metastatic castration-resistant prostate cancer, AND B)Patient has a BReast CAncer (BRCA) mutation, AND C)The medication is used in combination with prednisone, AND D)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

# 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 alpha-L-iduronidase gene mutation
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ALECENSA

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## Products Affected

- ALECENSA

<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>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma
<b>Part B Prerequisite</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>	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 FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ALPHA 1 PROTEINASE INHIBITORS

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## Products Affected

- GLASSIA

<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

# ALUNBRIG

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## Products Affected

- ALUNBRIG

<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 prior to approval of Alunbrig.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT)
<b>Part B Prerequisite</b>	No

# AMBRISENTAN

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## Products Affected

- *ambrisentan*

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

# ANKTIVA

## Products Affected

- ANKTIVA

PA Criteria	Criteria Details
<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 Bacillus Calmette-Guerin (BCG) unresponsive disease, AND ii) Patient has carcinoma in situ with or without papillary tumors, AND iii) Medication is used in combination with BCG. MAINTENANCE THERAPY-NON-MUSCLE INVASIVE BLADDER CANCER-all of (i and ii): i) Patient has an ongoing complete response defined as ONE of the following (a or b): a) Patient has negative cystoscopy and meets ONE of the following [(1) or (2)]: 1. Negative urine cytology, OR 2. Malignant urine cytology if cancer found in the upper tract or prostatic urethra and random bladder biopsies are negative, OR b) Patient has positive cystoscopy with biopsy-proven benign or low-grade Ta non-muscle invasive bladder cancer and negative urine cytology, AND ii) 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

# ANTIBIOTICS (INJECTABLE)

## Products Affected

- *amikacin injection solution 1,000 mg/4 ml, 500 mg/2 ml*
- *ampicillin sodium*
- *ampicillin-sulbactam*
- *azithromycin intravenous*
- *aztreonam*
- BICILLIN L-A
- CEFEPIME INTRAVENOUS
- *cefotetan injection*
- *cefoxitin*
- *cefoxitin in dextrose, iso-osm*
- *ceftazidime*
- *cefuroxime sodium injection recon soln 750 mg*
- *cefuroxime sodium intravenous*
- *ciprofloxacin in 5 % dextrose*
- CLINDAMYCIN IN 0.9 % SOD CHLOR
- CLINDAMYCIN IN 5 % DEXTROSE
- *clindamycin phosphate injection*
- *colistin (colistimethate na)*
- *doxy-100*
- *doxycycline hyclate intravenous*
- ERYTHROCIN INTRAVENOUS RECON SOLN 500 MG
- *erythromycin lactobionate*
- EXTENCILLINE
- *gentamicin in nacl (iso-osm) intravenous piggyback 100 mg/100 ml, 60 mg/50 ml, 80 mg/100 ml, 80 mg/50 ml*
- GENTAMICIN IN NACL (ISO-OSM) INTRAVENOUS PIGGYBACK 100 MG/50 ML, 120 MG/100 ML
- *gentamicin injection solution 40 mg/ml*
- *gentamicin sulfate (ped) (pf)*
- *levofloxacin in d5w*
- *lincomycin*
- *linezolid in dextrose 5%*
- LINEZOLID-0.9% SODIUM CHLORIDE
- *metro i.v.*
- *metronidazole in nacl (iso-os)*
- MOXIFLOXACIN-SOD.ACE,SUL-WATER
- *moxifloxacin-sod.chloride(iso)*
- *nafcillin in dextrose iso-osm intravenous piggyback 2 gram/100 ml*
- *nafcillin injection*
- *oxacillin*
- *penicillin g potassium*
- *pfizerpen-g*
- SIVEXTRO INTRAVENOUS
- STREPTOMYCIN
- *sulfamethoxazole-trimethoprim intravenous*
- *tazicef*
- TEFLARO
- *tigecycline*
- *tobramycin sulfate*

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

## ANTIFUNGALS (IV)

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### Products Affected

- *caspofungin*
- *fluconazole in nacl (iso-osm)*
- *voriconazole intravenous*

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



# ANTIFUNGALS, POLYENE

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## Products Affected

- ABELCET
- *amphotericin b*
- *amphotericin b liposome*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	B vs D coverage determination
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

# ANTINEOPLASTICS, MONOCLONAL ANTIBODIES

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## Products Affected

- ABRAXANE
- ADCETRIS
- ADSTILADRIN
- ALIQOPA
- BAVENCIO
- BESPONSA
- BORTEZOMIB INJECTION RECON SOLN 1 MG, 2.5 MG
- *bortezomib injection recon soln 3.5 mg*
- COLUMVI
- CYRAMZA
- DANYELZA
- DARZALEX
- DARZALEX FASPRO
- ELREXFIO
- ELZONRIS
- EPLICITI
- ENHERTU
- EPKINLY
- *eribulin*
- EVOMELA
- FYARRO
- GAZYVA
- HALAVEN
- IMFINZI
- IMJUDO
- JEMPERLI
- KADCYLA
- KANJINTI
- KEYTRUDA
- KIMMTRAK
- LIBTAYO
- LUNSUMIO
- MARGENZA
- MONJUVI
- MVASI
- MYLOTARG
- OGIVRI
- ONIVYDE
- OPDIVO
- OPDUALAG
- PACLITAXEL PROTEIN-BOUND
- PADCEV
- *pemetrexed disodium intravenous recon soln 1,000 mg, 100 mg, 500 mg*
- PEMETREXED DISODIUM INTRAVENOUS RECON SOLN 750 MG
- PERJETA
- PHESGO
- POLIVY
- POTELIGEO
- RUXIENCE
- RYBREVANT
- SARCLISA
- TALVEY
- TECENTRIQ
- TECVAYLI
- *thiotepa*
- TIVDAK
- TRAZIMERA
- TRODELVY
- TRUXIMA
- UNITUXIN
- VECTIBIX
- YERVOY
- YONDELIS
- ZEPZELCA
- ZIRABEV
- ZYNLONTA
- ZYNYZ

<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>	B vs D coverage determination
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# AREXVY

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## Products Affected

- AREXVY (PF)

<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>	60 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	The patient has not already received an RSV vaccine.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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. Cystic fibrosis-prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pending CMS Review
<b>Part B Prerequisite</b>	No

# ATYPICAL ANTIPSYCHOTIC

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## Products Affected

- FANAPT
- *paliperidone*

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>	1 year
<b>Other Criteria</b>	Approve if the patient has tried two of the following: olanzapine, quetiapine fumarate, risperidone, ziprasidone. Approve requests for paliperidone ER in Schizoaffective Disorder without the trial of other treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# AUGTYRO

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## Products Affected

- AUGTYRO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Pending CMS Review
<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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# AUSTEDO

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## Products Affected

- AUSTEDO
- AUSTEDO XR
- AUSTEDO XR TITRATION KT(WK1-4)

<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>	Chorea-prescribed by or in consult with a neuro. TD-Prescribed by or in consultation with a neurologist or a psychiatrist
<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

# AYVAKIT

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## Products Affected

- AYVAKIT

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>	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

# 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, previous therapies, test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# BENLYSTA

## Products Affected

- BENLYSTA INTRAVENOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with Other Biologics or Lupkynis
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 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

# 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 a hematologist or an oncologist
<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

# BETASERON

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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

# 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



# BOSULIF

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## Products Affected

- BOSULIF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	CML- 1 year and older. ALL, 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>	For Ph-positive CML-patients-approve. For Ph-positive ALL-approve. 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

# BRAFTOVI

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## Products Affected

- BRAFTOVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, BRAF V600 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>	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. In addition, patients new to therapy must have a trial of Zelboraf or Tafinlar prior to approval of Braftovi. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer. NSCLC- approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# BRUKINSA

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## Products Affected

- BRUKINSA

PA Criteria	Criteria Details
<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). Mantle Cell Lymphoma/CLL/SLL - for patients new to therapy, approve if the patient has tried Calquence. 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Hairy Cell Leukemia
<b>Part B Prerequisite</b>	No

# BUPRENORPHINE

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## Products Affected

- *buprenorphine hcl sublingual*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of opioid use disorder
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Induction therapy: 1 month. Pregnancy/intolerance to naloxone: 12 months
<b>Other Criteria</b>	For opioid dependence: The use of buprenorphine for maintenance therapy should be limited to patients who have experienced an intolerance to naloxone or require buprenorphine during pregnancy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CABOMETYX

## Products Affected

- CABOMETYX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, histology, RET gene rearrangement status for NSCLC
<b>Age Restrictions</b>	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. 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 a vascular endothelial growth factor receptor (VEGFR)-targeted therapy. 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.
<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
<b>Part B Prerequisite</b>	No

# CALQUENCE

## Products Affected

- CALQUENCE
- CALQUENCE (ACALABRUTINIB MAL)

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>	1 year
<b>Other Criteria</b>	CLL and SLL-approve. Mantle Cell Lymphoma- approve if the patient 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). 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)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma.
<b>Part B Prerequisite</b>	No

# CAPRELSA

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## Products Affected

- CAPRELSA

<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

# 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-3 mo. Pt had genetic test-12 mo, 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 than 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.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</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>	Pending CMS Review
<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

# CEREZYME

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## Products Affected

- CEREZYME INTRAVENOUS RECON  
SOLN 400 UNIT

<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
<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 disorder
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	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

# CHORIONIC GONADOTROPIN

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## Products Affected

- CHORIONIC GONADOTROPIN,  
HUMAN INTRAMUSCULAR

<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

# CINRYZE

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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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# CLOBAZAM

## Products Affected

- *clobazam*
- 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

# COMETRIQ

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## Products Affected

- COMETRIQ

<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>	MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and oncocyctic) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy and patient has tried a Vascular Endothelial Growth Factor Receptor (VEGFR)-targeted therapy.
<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 oncocyctic) Thyroid Carcinoma
<b>Part B Prerequisite</b>	No

# 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 one systemic regimen (e.g., Imbruvica (ibrutinib capsules, tablets and oral solution), Venclexta (venetoclax tablets), rituximab, Gazyva (obinutuzumab intravenous infusion), chlorambucil, fludarabine, cyclophosphamide, bendamustine, high-dose methylprednisolone, Campath (alemtuzumab intravenous infusion), Calquence (acalabrutinib capsules), Brukinsa (zanubrutinib capsules), or Arzerra (ofatumumab intravenous infusion). 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



# CORLANOR

## Products Affected

- CORLANOR ORAL TABLET
- *ivabradine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	CHF: Previous use of a Beta-blocker, LVEF. IST: Previous use of a Beta-blocker
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Chronic HF, adults- must have LVEF of less than or equal 35 percent (currently or prior to initiation of Corlanor therapy) AND tried or is currently receiving a Beta-blocker for HF (e.g., metoprolol succinate sustained-release, carvedilol, bisoprolol, carvedilol ER) unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia). Heart failure due to dilated cardiomyopathy, children-approve. IST - tried or is currently receiving a Beta-blocker unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	inappropriate sinus tachycardia (IST)
<b>Part B Prerequisite</b>	No

# COSENTYX

## Products Affected

- COSENTYX
- COSENTYX (2 SYRINGES)
- COSENTYX PEN
- COSENTYX PEN (2 PENS)
- 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

# COTELLIC

## Products Affected

- COTELLIC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Melanoma initial - must have BRAF V600 mutation.
<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 (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf. 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) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma OR b) isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma 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 and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease AND C) Patient has BRAF V600 mutation-positive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Central Nervous System Cancer
<b>Part B Prerequisite</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

# 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>	Initial-4months, Continuation-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

# DAURISMO

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## Products Affected

- DAURISMO

<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

# DEFERASIROX

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## Products Affected

- *deferasirox oral tablet*

<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

# DERMATOLOGICAL WOUND CARE AGENTS

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## Products Affected

- REGRANEX

<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>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# DIABETIC SUPPLIES

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## Products Affected

- ADVOCATE PEN NEEDLE NEEDLE 32 GAUGE X 5/32"
- *alcohol pads*
- ALCOHOL PREP PADS
- ALCOHOL SWABS
- ALCOHOL WIPES
- ASSURE ID INSULIN SAFETY SYRINGE 1 ML 29 GAUGE X 1/2"
- BD ALCOHOL SWABS
- BD INSULIN SYRINGE ULTRA-FINE SYRINGE 0.5 ML 30 GAUGE X 1/2", 1 ML 31 GAUGE X 5/16
- BD SAFETYGLIDE INSULIN SYRINGE SYRINGE 1 ML 29 GAUGE X 1/2", 1 ML 31 GAUGE X 15/64"
- BD ULTRA-FINE MICRO PEN NEEDLE
- BD ULTRA-FINE MINI PEN NEEDLE
- BD ULTRA-FINE NANO PEN NEEDLE
- BD ULTRA-FINE SHORT PEN NEEDLE
- CARETOUCH ALCOHOL PREP PAD
- CURITY ALCOHOL SWABS
- CURITY GAUZE TOPICAL SPONGE 2 X 2 "
- DROPLET MICRON PEN NEEDLE
- DROPLET PEN NEEDLE NEEDLE 30 GAUGE X 5/16"
- DROPSAFE ALCOHOL PREP PADS
- DROPSAFE PEN NEEDLE NEEDLE 31 GAUGE X 3/16"
- EASY COMFORT ALCOHOL PAD
- EASY COMFORT SAFETY PEN NEEDLE NEEDLE 31 GAUGE X 3/16"
- EASY TOUCH ALCOHOL PREP PADS
- GAUZE PAD TOPICAL BANDAGE 2 X 2 "
- INCONTROL PEN NEEDLE NEEDLE 32 GAUGE X 5/32"
- INSULIN SYRINGE-NEEDLE U-100 SYRINGE 0.3 ML 29 GAUGE, 1 ML 29 GAUGE X 1/2", 1/2 ML 28 GAUGE
- IV PREP WIPES
- MAXICOMFORT SAFETY PEN NEEDLE NEEDLE 29 GAUGE X 5/16"
- NOVOFINE 32
- NOVOFINE PLUS
- PEN NEEDLE, DIABETIC NEEDLE 29 GAUGE X 1/2"
- PENTIPS
- PRO COMFORT ALCOHOL PADS
- PURE COMFORT ALCOHOL PADS
- TECHLITE INSULIN SYRINGE SYRINGE 1 ML 30 GAUGE X 1/2", 1 ML 31 GAUGE X 15/64", 1 ML 31 GAUGE X 5/16
- TECHLITE INSULN SYR(HALF UNIT) SYRINGE 0.3 ML 31 GAUGE X 15/64", 0.3 ML 31 GAUGE X 5/16", 0.5 ML 30 GAUGE X 1/2", 0.5 ML 31 GAUGE X 15/64", 0.5 ML 31 GAUGE X 5/16"
- TECHLITE PEN NEEDLE NEEDLE 29 GAUGE X 1/2", 31 GAUGE X 3/16", 31 GAUGE X 5/16", 32 GAUGE X 1/4", 32 GAUGE X 5/32"
- TRUE COMFORT ALCOHOL PADS
- TRUE COMFORT PRO ALCOHOL PADS
- TRUEPLUS INSULIN
- TRUEPLUS PEN NEEDLE
- UNIFINE PENTIPS MAXFLOW
- UNIFINE PENTIPS NEEDLE 29 GAUGE X 1/2", 31 GAUGE X 1/4", 31 GAUGE X 3/16", 31 GAUGE X 5/16", 32 GAUGE X 1/4", 32 GAUGE X 5/32", 33 GAUGE X 5/32"
- UNIFINE PENTIPS PLUS
- UNIFINE PENTIPS PLUS MAXFLOW
- UNIFINE SAFECONTROL
- UNIFINE ULTRA PEN NEEDLE
- VERIFINE PLUS PEN NEEDLE-SHARP

<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

# DICLOFENAC

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## Products Affected

- *diclofenac sodium topical drops*

<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>	Patients must try a generic oral NSAID or generic diclofenac 1 percent gel.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# DIHYDROERGOTAMINE MESYLATE

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## Products Affected

- *dihydroergotamine nasal*

<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>	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

# DIMETHYL FUMARATE PDP ASSURANCE

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## Products Affected

- *dimethyl fumarate*

<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

# 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>	18 years and older (for chronic ITP-initial therapy only)
<b>Prescriber Restrictions</b>	Chronic ITP-prescribed by or after consultation with a hematologist (initial therapy)
<b>Coverage Duration</b>	Thrombo w/chronic liver disease-5 days, chronic ITP-initial-3 months, cont-1 year
<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

# 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

# DUAVEE

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## Products Affected

- DUAVEE

<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>	For the prevention of postmenopausal osteoporosis, trial, failure, or intolerance of raloxifene is required prior to the use of Duavee.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# DUPIXENT

## Products Affected

- DUPIXENT PEN
- DUPIXENT SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody (i.e., Adbry, Cinqair, Fasentra, Nucala, Tezspire, or Xolair). Concurrent use with Janus Kinase Inhibitors (JAKis) [oral or topical].
<b>Required Medical Information</b>	Diagnosis, prescriber specialty, other medications tried and length of trials
<b>Age Restrictions</b>	AD-6 months and older, asthma-6 years of age and older, Esophagitis-1 yr and older, Chronic Rhinosinusitis/Prurigo nodularis-18 and older
<b>Prescriber Restrictions</b>	Atopic Dermatitis/prurigo nodularis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Esophagitis-presc/consult-allergist or gastro
<b>Coverage Duration</b>	AD-Init-4mo, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/prurigo nod-init-6 mo, cont 1 yr
<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

# 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, or plasma OR a molecular genetic test demonstrating iduronate-2-sulfatase gene mutation
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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>	PP-4 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Initial only-RA/AS/JIA/JRA,prescribed by or in consult w/ rheum. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist.PP, prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center. Uveitis, prescribed by or in consultation with an ophthalmologist. Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist.
<b>Coverage Duration</b>	End of the plan year
<b>Other Criteria</b>	RA/PsA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor for RA/PsA are not required to step back and try a conventional synthetic DMARD). JIA/JRA-initial-approve if the patient meets ONE of the following: patient has tried one other medication for this condition for at least 3 months (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor) OR patient has aggressive disease. PP initial, approve if the patient 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: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. Uveitis initial, tried one of the following: periocular, intraocular, or

<b>PA Criteria</b>	<b>Criteria Details</b>
	systemic corticosteroid, immunosuppressives or other biologic therapy. GVHD, approve. Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Continuation-approve if the patient has had a response as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Graft versus host disease (GVHD), Uveitis, Behcet's disease
<b>Part B Prerequisite</b>	No

# 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

# 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-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-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Tuberous Sclerosis Complex-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Continuation of therapy-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

# EPOETIN ALFA

## Products Affected

- 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>	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 -

<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



# ERIVEDGE

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## Products Affected

- ERIVEDGE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	BCC (La or Met) - must not have had disease progression while on Odomzo.
<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 the patient has tried Odomzo. 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Central nervous System Cancer
<b>Part B Prerequisite</b>	No

# ERLEADA

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## Products Affected

- ERLEADA

<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

# ERLOTINIB

## Products Affected

- *erlotinib*

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 has recurrent or advanced non-clear cell histology RCC or if the patient had hereditary leiomyomatosis and renal cell carcinoma and 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

# EVEROLIMUS

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## Products Affected

- *everolimus (antineoplastic)*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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
<b>Part B Prerequisite</b>	No

# EYLEA

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## Products Affected

- EYLEA

<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>	3 years
<b>Other Criteria</b>	BvsD Coverage Determination
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# FARYDAK

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## Products Affected

- FARYDAK

<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>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</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

# FORTEO

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## Products Affected

- FORTEO

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>	Treatment of PMO, approve if pt has tried one oral bisphosphonate 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 pt has severe renal impairment (creatinine clearance less than 35 mL/min) or CKD or pt has had an osteoporotic fracture or fragility fracture. Increase bone mass in men (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) with primary or hypogonadal osteoporosis/Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or 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 zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture. Patients who



<b>PA Criteria</b>	<b>Criteria Details</b>
	have already taken teriparatide for 2 years - approve if the patient is at high risk for fracture.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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

# FRUZAQLA

## Products Affected

- FRUZAQLA

PA Criteria	Criteria Details
<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>	Colon cancer, rectal cancer, or appendiceal cancer-Approve if the patient meets the following (A and B): A.Patient has advanced or metastatic disease, AND B.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 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

# 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

# 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 the disease is radioactive iodine-refractory. Anaplastic thyroid cancer or Medullary Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has RET fusion-positive or RET-mutation-positive disease.
<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

# 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>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# GILOTRIF

## Products Affected

- GILOTRIF

PA Criteria	Criteria Details
<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>	Pending CMS Review

# GLATIRAMER

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## Products Affected

- *glatiramer*
- *glatopa*

<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



# GLP-1 AGONISTS

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## Products Affected

- 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

# GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

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## Products Affected

- TRIPTODUR

<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 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

# GROWTH HORMONES - GENOTROPIN

## Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK

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 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, SBS 18 y/o or older
<b>Prescriber Restrictions</b>	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, 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 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, TBI or subarachnoid hemorrhage,

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>AND 3. meets one of the following - A. has known perinatal insults or congenital or genetic defects or structural hypothalamic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), 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 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 AND if a transitional adolescent must be off tx for at least one month before retesting. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 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 for age/gender. Cont tx - prescriber confirms response to therapy. CKD initial - CKD defined by abnormal CrCl. 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 for age/gender. SGA initial - baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy. Cont Tx for CKD, Noonan, PW in child/adolescents, SHOX, and TS - prescriber confirms response to therapy. SBS initial pt receiving specialized nutritional support. Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	SBS
<b>Part B Prerequisite</b>	No

# HETLIOZ

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## Products Affected

- *tasimelteon*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Non-24-patient is totally blind with no perception of light
<b>Age Restrictions</b>	Non-24-18 years or older (initial and continuation), SMS-3 years and older
<b>Prescriber Restrictions</b>	prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders (initial and continuation)
<b>Coverage Duration</b>	6 mos initial, 12 mos cont
<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

# HIGH RISK MEDICATIONS - BENZTROPINE

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## Products Affected

- *benztropine oral*

<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>	12 months
<b>Other Criteria</b>	For all medically-accepted indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing benztropine 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

# HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

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## Products Affected

- *cyclobenzaprine oral tablet 10 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>	Patients aged less than 65 years, approve.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	The physician 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

# HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

## Products Affected

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

<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>	Authorization will be for 12 months.
<b>Other Criteria</b>	For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. Approve hydroxyzine hydrochloride if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval of promethazine and hydroxyzine, approve if 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



# 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HRM - SKELETAL MUSCLE RELAXANTS

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## Products Affected

- *methocarbamol oral tablet 500 mg, 750 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The physician has documented the indication for the continued use of the HRM (high risk med) with an explanation of the specific benefit established with the medication and how that benefit outweighs the potential risk, AND the physician will continue to monitor for side effects. For patients concurrently taking multiple anticholinergic medications, the physician has assessed the risk.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior authorization required for age 65 or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	The physician 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. For patients concurrently taking multiple anticholinergic medications, the physician has assessed this risk as well.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# HUMIRA

## Products Affected

- HUMIRA PEN (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) PEN (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) PEN CROHNS-UC-HS (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) PEN PEDIATRIC UC (PREFERRED NDCS STARTING WITH 00074)
- HUMIRA(CF) PEN PSOR-UV-ADOL HS (PREFERRED NDCS STARTING WITH 00074)
- YUFLYMA(CF)
- YUFLYMA(CF) AI CROHN'S-UC-HS
- YUFLYMA(CF) AUTOINJECTOR

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>	Crohn's disease (CD), 6 or older (initial therapy). Ulcerative colitis (UC), 5 or older (initial therapy), PP-18 or older (initial therapy)
<b>Prescriber Restrictions</b>	Initial therapy only all dx-RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist.UV-ophthalmologist
<b>Coverage Duration</b>	End of the plan year
<b>Other Criteria</b>	RA/PsA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor for RA/PsA are not required to step back and try a conventional synthetic DMARD). JIA/JRA-initial-approve if the patient meets ONE of the following: patient has tried one other medication for this condition for at least 3 months (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor) OR patient

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>has aggressive disease. PP initial, approve if the patient 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: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial, approve if the patient has tried or is currently taking corticosteroids or patient has tried one other agent for CD for at least 3 months. UC initial, approve if the patient has had a trial of one systemic agent for at least 3 months (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, biologic, JAK inhibitor or a corticosteroid such as prednisone or methylprednisolone). Uveitis initial, tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives or other biologic therapy. HS initial, tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Continuation-approve if the patient has had a response as determined by the prescriber. Clinical criteria incorporated into the Humira 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# IBRANCE

## Products Affected

- IBRANCE

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>	3 years
<b>Other Criteria</b>	Breast cancer - approve 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 Ibrance will be used in combination with anastrozole, exemestane, or letrozole 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 meets one of the following conditions: Ibrance will be used in combination with anastrozole, exemestane, or letrozole or Ibrance will be used in combination with 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) who is receiving GnRH analog AND Ibrance will be used in combination with anastrozole, exemestane or letrozole or Ibrance will be used in combination with fulvestrant 4. Pt is postmenopausal and Ibrance will be used in combination with fulvestrant. In addition, patients new to therapy must have a trial of Kisqali, Kisqali Femara Co-Pack or Verzenio prior to approval of Ibrance. Liposarcoma-approve if the patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Liposarcoma

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

# ICATIBANT

## Products Affected

- *icatibant*
- *sajazir*

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>	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 percent 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</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>	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 chronic myeloid leukemia-approve. 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



# 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

# IMATINIB

## Products Affected

- *imatinib*

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/CML, must have Ph-positive for approval of imatinib. 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 according to the prescriber, the patient cannot take Turalio. 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 or PDGFRB rearrangement.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chordoma, desmoid tumors (aggressive fibromatosis), cKit positive metastatic or unresectable cutaneous melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic.

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

# IMBRUVICA

## Products Affected

- IMBRUVICA ORAL CAPSULE
- 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

# 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>	N/A
<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 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

# 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

# INCRELEX

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## Products Affected

- INCRELEX

<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 2 years of age or 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.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# INFLECTRA

## Products Affected

- INFLECTRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Biologic DMARD or Targeted Synthetic.
<b>Required Medical Information</b>	Diagnosis, concurrent medication, previous medications tried
<b>Age Restrictions</b>	CD and UC- Pts aged 6 years or more (initial therapy). PP-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	All dx Initial therapy only -prescribed by or in consultation with: RA/AS/Still's disease/JIA/JRA-rheumatologist, PP/Pyoderma gangrenosum/Hidradenitis suppurativa-dermatologist, Psoriatic Arthritis-rheum or derm, CD/UC-gastroenterologist, Uveitis ophthalmologist, GVHD-a physician affiliated with a transplant center, oncologist, or hematologist, Behcet's Disease- rheum, derm, ophthalmologist, gastroenterologist, or neurologist, Sarcoidosis-pulmonol, ophthalmol, cardio, neuro, or derm
<b>Coverage Duration</b>	GVHD intl-1 mo, cont-3 mo.Pyoderma Gangrenosum-intl 4 mo, cont 1 yr.all others-intl 6 mo, cont-12 mo
<b>Other Criteria</b>	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA-initial-approve if the patient meets ONE of the following: patient has tried one other medication for this condition for at least 3 months (Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID), biologic or JAK inhibitor OR Patient has aggressive disease. PP initial, approve if the patient 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: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. Uveitis initial, tried one of the following: periocular, intraocular, or



<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>systemic corticosteroid, immunosuppressives or other biologic therapy. GVHD, approve. CD initial, approve if the patient has tried or is currently taking corticosteroids or patient has tried one other agent for CD. UC initial, approve if the patient has had a trial of one systemic agent for at least 3 months (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, biologic, JAK inhibitor or a corticosteroid such as prednisone or methylprednisolone). HS initial, tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Behcet's initial, patient has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa) or at least one tumor necrosis factor for Behcet's disease OR has ophthalmic manifestations. Still's Disease initial, tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant. Prev trial of one biologic other than requested drug or biosimilar of the requested drug also counts. Sarcoidosis initial, tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG) initial, tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Continuation-approve if the patient has had a response as determined by the prescriber.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients already started on infliximab for a covered use, Behcet's disease, Still's disease, Uveitis, Pyoderma gangrenosum, Hidradenitis suppurativa,, Graft-versus-host disease, Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis
<b>Part B Prerequisite</b>	No

# INLYTA

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## Products Affected

- INLYTA

<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 patient is refractory to radioactive iodine therapy. Soft tissue sarcoma-approve if the patient has alveolar soft part sarcoma and the medication will be used in combination with Keytruda (pembrolizumab).
<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
<b>Part B Prerequisite</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/Myeloproliferative Neoplasm Overlap Neoplasms
<b>Part B Prerequisite</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 intermediate-2 or high-risk disease. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement.
<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

# IVERMECTIN

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## Products Affected

- *ivermectin 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>	1 month
<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

# 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

# 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-less than 21 years of age, GVHD-12 and older, MF/PV/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 T-cell prolymphocytic leukemia or T-cell large granular lymphocytic leukemia AND pt 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>	Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms, T-Cell lymphoma
<b>Part B Prerequisite</b>	No



# JAYPIRCA

## Products Affected

- JAYPIRCA

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 1 year
Other Criteria	<p>Mantle cell lymphoma-approve if the patient has tried at least one systemic regimen or patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail), 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, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, 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 meets (A or B): A) patient has resistance or intolerance to Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules) or B) patient has relapsed or refractory disease and has tried a Bruton tyrosine kinase (BTK) inhibitor and Venclexta (venetoclax tablet)-based regimen. 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.</p>

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

# JYLAMVO

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## Products Affected

- JYLAMVO

<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>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# KALYDECO

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## Products Affected

- KALYDECO ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with Orkambi, Trikafta or Symdeko
<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 CFTR 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 CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR 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

# KERENDIA

## Products Affected

- KERENDIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with spironolactone or eplerenone
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older (initial and continuation therapy)
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Diabetic kidney disease, initial-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 labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b)According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy. 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 labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b. According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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

# KISQALI

## Products Affected

- KISQALI
- KISQALI FEMARA CO-PACK

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	<p>Breast cancer - approve 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</p> <ol style="list-style-type: none"> <li>1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole</li> <li>2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, or letrozole</li> <li>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.</li> <li>4. Patient 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 Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole.</li> </ol> <p>Endometrial cancer - approve if pt meets all of (A, B and C): A) pt has recurrent or metastatic disease, and B) has estrogen receptor (ER)-positive tumors, and C) if request is for Kisqali (not Co-Pack), Kisqali will be used in combination with letrozole.</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pending CMS Review
<b>Part B Prerequisite</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, prior surgeries
<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>	Endogenous Cushing's Synd-1 yr. Pt awaiting surgery or response after radiotherapy-4 months
<b>Other Criteria</b>	Endogenous Cushing's Syndrome-Approve if, according to the prescribing physician, the patient is not a candidate for surgery or surgery has not been curative AND if mifepristone is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Endogenous Cushing's Syndrome, awaiting surgery. Patients with Endogenous Cushing's syndrome, awaiting a response after radiotherapy
<b>Part B Prerequisite</b>	No

# KOSELUGO

## Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	<p>Neurofibromatosis Type 1-approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas and if the patient is 2 to 18 years old OR if the patient is 19 years or older if the patient started on therapy with Koselugo prior to becoming 19. Circumscribed Glioma-approve if the patient has recurrent, refractory or progressive disease AND the tumor is BRAF fusion positive OR BRAF V600E activating mutation positive OR patient has neurofibromatosis type 1 mutated glioma AND this medication will be used as a single agent AND the patient is 3-21 years of age OR is greater 21 and has been previously started on therapy with Koselugo prior to becoming 21 years of age. Langerhans Cell Histiocytosis- approve if the patient meets the following criteria (A and B):</p> <p>A) Patient meets one of the following (i, ii, iii, or iv): i. Patient meets both of the following (a and b): a) Patient has multisystem Langerhans cell histiocytosis, AND b) Patient has symptomatic disease or impending organ dysfunction, OR ii. Patient has single system lung Langerhans cell histiocytosis, OR iii. Patient meets all of the following (a, b, and c): a) Patient has single system bone disease, AND b) Patient has not responded to treatment with a bisphosphonate, AND c) Patient has more than 2 bone lesions, OR iv. Patient has central nervous system disease, AND B) The medication is used as a single agent.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Circumscribed Glioma, Langerhans Cell Histiocytosis
<b>Part B Prerequisite</b>	No

# KRAZATI

## Products Affected

- KRAZATI

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>	Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND has been previously treated with at least one systemic regimen. Note: 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. 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 previously received a chemotherapy regimen for colon or rectal cancer.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pending CMS Review
<b>Part B Prerequisite</b>	No

# LAPATINIB

## Products Affected

- *lapatinib*

PA Criteria	Criteria Details
<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 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 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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	Pending CMS Review

# LENALIDOMIDE

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## Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis and previous therapies or drug regimens tried.
<b>Age Restrictions</b>	18 years and older (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma)
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Follicular lymphoma-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one prior therapy. MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one other therapy or therapeutic 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]). B-cell-lymphoma (other)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia and the pt has serum erythropoietin levels greater than or equal to 500 mU/mL or according to the prescriber the patient has anemia, has serum erythropoietin levels less than 500 mU/mL and patient has experienced no response or loss of response to erythropoietic stimulating agents. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried at least one other therapy or regimen. CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-approve if the patient has tried at least three other I222 regimens.

<b>PA Criteria</b>	<b>Criteria Details</b>
	Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi's 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system lymphoma, Kaposi's sarcoma.
<b>Part B Prerequisite</b>	No



# LENVIMA

## Products Affected

- LENVIMA

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>	3 years
<b>Other Criteria</b>	<p>DTC - must be refractory to radioactive iodine treatment for approval.</p> <p>RCC, advanced disease- approve if the pt meets i or ii: i. Lenvima is being used in combination with pembrolizumab OR ii. Lenvima is used in combination with everolimus 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. New starts for all RCC must have tried Cabometyx. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND B) The medication is used in combination with Keytruda (pembrolizumab for intravenous injection) AND C)the disease has progressed on at least one prior systemic therapy AND D) The patient is not a candidate for curative surgery or radiation.</p> <p>Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. New starts for Hepacocellular Carnicoma: For first line systemic therapy, sorafenib must be tried first. For subsequent-line system therapy if disease progression, Cabometyx must be tried first.</p> <p>Melanoma - approve if the patient has unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	progression on anti-programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Renal cell carcinoma with non-clear cell histology and Melanoma
<b>Part B Prerequisite</b>	No

# LIBERVANT

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## Products Affected

- LIBERVANT

<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 to 5 years of age
<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.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LIDOCAINE PATCH

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## Products Affected

- *lidocaine topical adhesive patch, medicated 5 %*

<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

# 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
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center.
<b>Coverage Duration</b>	2 months
<b>Other Criteria</b>	Cytomegalovirus Infection, Treatment-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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LONSURF

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## Products Affected

- LONSURF

<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>	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. Colon and rectal cancer-approve per labeling if the patient has been previously treated with a fluopyrimidine, oxaliplatin, irinotecan and if the patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type) they must also try Erbitux or Vectibix.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LOQTORZI

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## Products Affected

- LOQTORZI

<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>	Nasopharyngeal carcinoma-approve if the patient has recurrent, unresectable, oligometastatic, or metastatic disease AND the patient meets ONE of the following (i or ii): i. Patient meets BOTH of the following (a and b): a) Loqtorzi is used for first-line treatment AND b) Loqtorzi is used in combination with cisplatin and gemcitabine, OR ii. Patient meets both of the following (a and b): a) Loqtorzi is used for subsequent treatment AND b) Loqtorzi 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

# LORBRENA

## Products Affected

- LORBRENA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, ALK status, ROS1 status, 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>	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 IMT with ALK translocation. NSCLC - Approve if the patient has ALK-positive advanced or metastatic NSCLC, as detected by an approved test. In addition, patients new to therapy must also have a trial of Alecensa prior to approval of Lorbrena. NSCLC-ROS1 Rearrangement-Positive, advanced or metastatic NSCLC-approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib.
<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)
<b>Part B Prerequisite</b>	No



# LUMAKRAS

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## Products Affected

- LUMAKRAS

<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 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. 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pancreatic Adenocarcinoma
<b>Part B Prerequisite</b>	No

# 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 acid alpha-glucosidase gene mutation
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# LUPRON DEPOT

## Products Affected

- LEUPROLIDE (3 MONTH)
- *leuprolide subcutaneous kit*
- LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)
- LUPRON DEPOT (6 MONTH)
- LUPRON DEPOT-PED
- LUPRON DEPOT-PED (3 MONTH)

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 Orgovyx or 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

<b>PA Criteria</b>	<b>Criteria Details</b>
	disorders including premenstrual syndrome and premenstrual dysphoric disorder, prophylaxis or treatment of uterine bleeding or menstrual 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

# LYNPARZA

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## Products Affected

- LYNPARZA

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>	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 germline BRCA 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 or the pateint has had a bilateral orchiectomy, and the

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>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 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

# 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

# MAVYRET

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## Products Affected

- MAVYRET

<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>	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



# MEGESTROL

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## Products Affected

- *megestrol oral suspension 400 mg/10 ml (10 ml), 400 mg/10 ml (40 mg/ml), 800 mg/20 ml (20 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

# MEKINIST

## Products Affected

- MEKINIST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations
<b>Age Restrictions</b>	1 year and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Melanoma must be used in patients 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. For NSCLC requires BRAF V600E Mutation and 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, unless intolerant AND the patient has BRAF V600-positive disease. Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for low-grade serous carcinoma or the patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafenlar. Central Nervous System Cancer-approve if the 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) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma OR b) Isocitrate dehydrogenase-2 (IDH2)-mutant astrocytoma OR c) Glioblastoma or d) Oligodendroglioma OR iii. Melanoma with brain

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Tafinlar (dabrafenib).  Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR patient has Erdheim Chester disease or Rosai-Dorfman disease. Metastatic or Solid Tumors-Approve if the patient meets the following (A, B, and C): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafinlar (dabrafenib capsules), AND C) Patient has no satisfactory alternative treatment options.  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
<b>Part B Prerequisite</b>	No

# MEKTOVI

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## Products Affected

- MEKTOVI

PA Criteria	Criteria Details
<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 has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. Histiocytic neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. multisystem disease OR, ii. pulmonary disease or, iii. central nervous system lesions. NSCLC-approve if pt has BRAF V600E mutation-positive 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
<b>Part B Prerequisite</b>	No

# MODAFINIL

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## Products Affected

- *modafinil*

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 if the patient is working at least 5 overnight shifts per month. 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).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Excessive daytime sleepiness (EDS) associated with myotonic dystrophy. Adjunctive/augmentation for treatment of depression in adults.
<b>Part B Prerequisite</b>	No

# MRESVIA

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## Products Affected

- MRESVIA (PF)

<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>	60 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	The patient has not already received an RSV vaccine
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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 arylsulfatase B gene mutation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</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



# NERLYNX

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## Products Affected

- NERLYNX

<b>PA Criteria</b>	<b>Criteria Details</b>
<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-Approve for 1 year (total), advanced or metastatic disease-1 year
<b>Other Criteria</b>	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-approve if the patient has HER-2 positive breast cancer, Nerlynx will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NEXLETOL

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## Products Affected

- NEXLETOL

<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>	Patient has tried and failed or has a contraindication to a statin or the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of two statins and during both trials the skeletal-related symptoms resolved during discontinuation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NEXLIZET

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## Products Affected

- NEXLIZET

<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>	Patient has tried and failed or has a contraindication to a statin or the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of two statins and during both trials the skeletal-related symptoms resolved during discontinuation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NINLARO

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## Products Affected

- NINLARO

<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>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma
<b>Part B Prerequisite</b>	Pending CMS Review

# NIVESTYM

## Products Affected

- NIVESTYM

<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/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>	Pending CMS Review
<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

# NMDA RECEPTOR ANTAGONIST

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## Products Affected

- *memantine oral solution*
- *memantine oral tablet*
- MEMANTINE ORAL TABLETS,DOSE PACK
- NAMZARIC

<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>	Automatic approval if member is greater than 26 years of age. Prior Authorization is required for age 26 or younger.
<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

# NON-INJECTABLE TESTOSTERONE PRODUCTS

## Products Affected

- *testosterone transdermal gel*
- *testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %)*
- *testosterone transdermal gel in packet 1 % (25 mg/2.5gram)*
- TESTOSTERONE TRANSDERMAL GEL IN PACKET 1 % (50 MG/5 GRAM)

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



# 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) agonist or if the patient has had a bilateral orchiectomy or if the medication is used concurrently with Firmagon. Prostate cancer-metastatic, castration sensitive-approve if (A and B): A) the medication is used in combination with docetaxel or patient has completed docetaxel therapy, and B) the medication will be used in combination with a GnRH agonist or in combination with Firmagon or if the patient had a bilateral orchiectomy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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

# 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

# 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# NYVEPRIA

## Products Affected

- NYVEPRIA

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 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 or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, or 3) patient has had a neutropenic complication from prior chemotherapy 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
<b>Part B Prerequisite</b>	No

# OCALIVA

## Products Affected

- OCALIVA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prescriber specialty, lab values, prior medications used for diagnosis and length of trials
<b>Age Restrictions</b>	18 years and older (initial)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)
<b>Coverage Duration</b>	6 months initial, 1 year cont.
<b>Other Criteria</b>	Initial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following:a)Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b)Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative c)Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)). Patients new to therapy and continuing therapy must not have cirrhosis or must have compensated cirrhosis without evidence of portal hypertension.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OCTREOTIDE INJECTABLE

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## Products Affected

- *octreotide acetate*

<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>	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-prescr/consult with oncologist
<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, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma
<b>Part B Prerequisite</b>	No

# 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.)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Metastatic BCC
<b>Part B Prerequisite</b>	No



# OFEV

## Products Affected

- OFEV

PA Criteria	Criteria Details
<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) [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. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (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 (all of A, B and C): A) FVC greater than or equal to 45 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OJEMDA

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## Products Affected

- OJEMDA

<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

# 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 intermediate-risk or high-risk disease and (a or b): a) the patient has anemia, defined as hemoglobin less than 10g/dL and has symptomatic splenomegaly and/or constitutional symptoms, or b) the patient has platelet count greater than or equal to 50x10 <sup>9</sup> /L.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</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 the patient has intermediate or poor-risk cytogenetics AND allogeneic hematopoietic stem cell transplant is not planned.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ORENCIA PDP

## Products Affected

- ORENCIA
- ORENCIA CLICKJECT

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>	N/A
<b>Prescriber Restrictions</b>	Initial therapy only-RA and JIA/JRA prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist.
<b>Coverage Duration</b>	End of the plan year
<b>Other Criteria</b>	RA, approve if the patient has tried one of the following: Enbrel, a preferred adalimumab product, Rinvoq, Xeljanz. PsA, approve if the patient meets one of the following (i or ii): i. patient is 2 to 5 years of age OR ii. patient is 6 years of age or older and has tried one of the following: Enbrel, a preferred adalimumab product, Rinvoq, Stelara, Skyrizi, Xeljanz. JIA/JRA, approve if the patient has tried one of the following: Enbrel, a preferred adalimumab product, or Xeljanz. Continuation- approve if the patient has had a response as determined by the prescriber. Please Note: preferred adalimumab products include Humira (NDCs starting with - 00074), adalimumab-aaty and Yuflyma.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ORENITRAM

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## Products Affected

- ORENITRAM
- ORENITRAM MONTH 1 TITRATION KT
- ORENITRAM MONTH 2 TITRATION KT
- ORENITRAM MONTH 3 TITRATION KT

<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>	Diagnosis, results of right heart cath
<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>	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

# 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

# ORKAMBI

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## Products Affected

- ORKAMBI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with Kalydeco, Trikafta or Symdeko.
<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 CFTR 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 CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR 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



# ORSERDU

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## Products Affected

- ORSERDU

<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 in postmenopausal women or Men-approve if the patient meets the following criteria (A, B, C, D, and E): A) Patient has recurrent or metastatic disease, AND B) Patient has estrogen receptor positive (ER+) 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# OTEZLA

## Products Affected

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

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, previous drugs tried
<b>Age Restrictions</b>	PP- 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>	End of the plan year
<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

# 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

# PEGASYS

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## Products Affected

- PEGASYS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pending CMS Review
<b>Age Restrictions</b>	HCV - patients 5 years of age or older, HBV - patients 3 years of age or 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.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</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>	Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease and the tumor has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen. 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 and the cancer is in chronic phase or blast phase.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# PHENYL BUTYRATE

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## Products Affected

- *sodium phenylbutyrate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant therapy with more than one phenylbutyrate product
<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 testing confirmed a mutation resulting in 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

# 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

# PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

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## Products Affected

- *sildenafil (pulm.hypertension) oral tablet*

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) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets require confirmation that the indication is PAH (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>Part B Prerequisite</b>	No



# PIQRAY

## Products Affected

- PIQRAY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	N/A
<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) 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pending CMS Review
<b>Part B Prerequisite</b>	No

# PIRFENIDONE

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## Products Affected

- *pirfenidone oral tablet 267 mg, 801 mg*
- PIRFENIDONE ORAL TABLET 534 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 - must have FVC greater than or equal to 40 percent of the predicted value 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# POMALYST

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## Products Affected

- POMALYST

<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-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	CNS Lymphoma-approve if the patient has relapsed or refractory disease. 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 received at least one other Revlimid (lenalidomide tablets)-containing regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma
<b>Part B Prerequisite</b>	No

# PROMACTA

## Products Affected

- PROMACTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Imm Thrombo/MDS init-3mo,cont 1yr,AA-init-4mo,cont-1yr,Thrombo/HepC-1yr,Transplant-init 3mo,cont 6mo
<b>Other Criteria</b>	Pending CMS Review
<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

# 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>	Patient's immune status (Toxoplasma gondii Encephalitis, chronic maintenance and prophylaxis, primary)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis
<b>Part B Prerequisite</b>	No

# QINLOCK

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## Products Affected

- QINLOCK

PA Criteria	Criteria Details
<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

# QUININE SULFATE

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## Products Affected

- *quinine sulfate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Excluded if used for treatment or prevention of nocturnal leg cramps.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Babesiosis, uncomplicated Plasmodium vivax malaria.
<b>Part B Prerequisite</b>	No

# RADICAVA IV

## Products Affected

- *edaravone intravenous solution 30 mg/100 ml* • RADICAVA

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>	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 2. The 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. The patient has a percent predicted FVC greater than or equal to 80% (ie, has normal respiratory function), AND 4. The Patient has been diagnosed with ALS for less than or equal to 2 years 5. 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



# RELISTOR

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## Products Affected

- RELISTOR SUBCUTANEOUS SOLUTION
- RELISTOR SUBCUTANEOUS 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>	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.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# REPATHA

## Products Affected

- REPATHA PUSHTRONEX
- REPATHA SYRINGE
- 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>	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Hyperlipidemia with HeFH - approve if: 1) diagnosis of HeFH AND 2) tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the symptoms resolved upon discontinuation. Hyperlipidemia with ASCVD -approve if: 1) has one of the following conditions: prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, CAD, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) tried ONE high intensity statin (defined above) and LDL remains 70 mg/dL or higher unless pt is statin intolerant (defined above). HoFH - approve if: 1) has one of the following: a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha or Juxtapid), OR d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity statin (defined above) for 8 weeks or longer and

<b>PA Criteria</b>	<b>Criteria Details</b>
	LDL remains 70 mg/dL or higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)- approve if all of the following are met: 1) coronary artery calcium or calcification (CAC) score 300 Agatston units or higher, AND 2) the patient has tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RETEVMO

## Products Affected

- RETEVMO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Pending CMS Review
<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 AND the patient meets i or ii: i. patient has anaplastic thyroid cancer OR ii. the disease requires treatment with systemic therapy and patient has medullary thyroid cancer or the disease is radioactive iodine-refractory. 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

# REZDIFFRA

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## Products Affected

- REZDIFFRA

<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 an endocrinologist, gastroenterologist, or hepatologist (initial/continuation)
<b>Coverage Duration</b>	1 year
<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

# 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

# REZUROK

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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
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Graft-versus-host disease-approve if the patient has chronic graft-versus-host disease and has tried at least two conventional systemic treatments (e.g., ibrutinib, cyclosporine) for chronic graft-versus-host disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# RINVOQ

## Products Affected

- RINVOQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Pending CMS Review
<b>Prescriber Restrictions</b>	RA/AS/Non-Radiographic Spondy/JIA, 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 derm. UC/CD-prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	End of the plan year
<b>Other Criteria</b>	RA/PsA/UC/AS/CD/JIA initial - patient has tried a TNF blocker for at least 3 months. AD - patient has tried at one systemic agent for at least 3 months. Examples of traditional systemic therapies include azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis. Non-Radiographic Axial Spondyloarthritis-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 sacroiliitis reported on MRI and patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3- month trial. Continuation-approve if the patient has had a response as determined by the prescriber.
<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

# 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

# ROFLUMILAST (ORAL)

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## Products Affected

- *roflumilast*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
<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>	COPD, approve in patients who meet all of the following conditions: Patients has severe COPD or very severe COPD, AND Patient has a history of exacerbations, AND Patient has tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, indacaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ROMIDEPSIN

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## Products Affected

- *romidepsin intravenous recon soln*
- ROMIDEPSIN INTRAVENOUS SOLUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis and past medication history.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Use of romidepsin is considered medically necessary for the treatment of cutaneous T-cell lymphoma in patients that have tried and failed at least 1 prior therapy. B vs D coverage determination.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ROZLYTREK

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## Products Affected

- ROZLYTREK

PA Criteria	Criteria Details
<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 patients 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

# 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>	Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient is in complete or partial response after a platinum-based chemotherapy regimen and the patient is in complete or partial response to first-line primary treatment or if the patient has recurrent disease and has a BRCA mutation. 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) The patient meets one of the following criteria (i or ii): i. The patient has been previously treated with at least one taxane-based chemotherapy OR ii. The patient is not a candidate or is intolerant to taxane-based chemotherapy. 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. 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>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma
<b>Part B Prerequisite</b>	No

# 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



# 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myeloid or lymphoid Neoplasms with eosinophilia
<b>Part B Prerequisite</b>	No

# SABRIL

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## Products Affected

- *vigabatrin*
- *vigadrone*
- VIGAFYDE
- *vigpoder*

<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/West Syndrome - patients 1 month to 2 years of age
<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.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SCSEMBLIX

## Products Affected

- SCSEMBLIX

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>	Chronic Myeloid Leukemia (CML)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i or ii): i. The chronic myeloid leukemia is T315I-positive, OR ii. Patient has tried at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia. Note: Examples of tyrosine kinase inhibitors include imatinib tablets, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), Sprycel (dasatinib tablets), and Tasisga (nilotinib capsules). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has an ABL1 rearrangement.
<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

# 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

# SIRTURO

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## Products Affected

- SIRTURO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients weighing less than 15 kg
<b>Required Medical Information</b>	Diagnosis, concomitant therapy
<b>Age Restrictions</b>	Patients 5 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with an infectious diseases specialist
<b>Coverage Duration</b>	9 months
<b>Other Criteria</b>	Tuberculosis (Pulmonary) - Approve if the patient has multidrug-resistant tuberculosis 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

# SKYRIZI

## Products Affected

- SKYRIZI INTRAVENOUS
- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR

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>	PP-18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	PP-Prescribed by or in consultation with a dermatologist (initial therapy). Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD, prescribed by or in consultation with a gastroenterologist (initial therapy).
<b>Coverage Duration</b>	End of the plan year
<b>Other Criteria</b>	PP initial, approve if the patient 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: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. PsA initial - peripheral disease, patient has tried one conventional synthetic DMARD for at least 3 months, unless intolerant. (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor are not required to step back and try a conventional synthetic DMARD) PsA initial - axial disease (sacroiliitis), patient has tried one conventional synthetic DMARD or NSAID for at least 3 months, unless intolerant. (note: patients who have already had a 3-month trial of a biologic or JAK inhibitor are not required to step back and try a conventional synthetic DMARD or NSAID). CD initial, approve if the patient has tried or is currently taking corticosteroids, or patient has tried one other agent for at least 3 months. Continuation-approve if the patient has had a response as determined by the prescriber.

<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



# SOMATULINE

## Products Affected

- SOMATULINE DEPOT

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 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-approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pheochromocytoma/paraganglioma, Neuroendocrine tumors of the gastrointestinal tract, lung, thymus (carcinoid tumor) and pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</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

# SORAFENIB

## Products Affected

- *sorafenib*

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 1 year.
Other Criteria	<p>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 (ie, papillary, follicular, oncocytic) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. 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 for all diagnoses: Part B before Part D Step Therapy applies only to beneficiaries enrolled in an MA-PD plan</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Pending CMS Review

# SPRAVATO

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## Products Affected

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

PA Criteria	Criteria Details
<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>	Psychiatrist
<b>Coverage Duration</b>	MDD with Acute Suicidal Ideation or Behavior: 2 mo. Treatment-Resistant Depression: 6 mo
<b>Other Criteria</b>	Major Depressive Disorder with Acute Suicidal Ideation or Behavior-approve if the patient meets the following criteria (A, B and C): A) Patient has major depressive disorder that is considered to be severe, according to the prescriber, AND B) Patient is concomitantly receiving at least one oral antidepressant (Note: Antidepressants may include, but are not limited to, selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), mirtazapine, and bupropion), AND C) Patient has one of the following (i or ii): i. No history of psychosis, OR ii. History of psychosis and the prescriber believes that the benefits of Spravato outweigh the risks. Treatment-Resistant Depression-approve if the patient meets the following criteria (A, B, C and D): A) Patient meets both of the following (i and ii): i. 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, according to the prescriber (Note: Different pharmacologic classes of antidepressants include selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), bupropion, mirtazapine, etc.) AND ii. Each antidepressant was used at therapeutic dosages for at least 6 weeks in the current episode of depression, according

<b>PA Criteria</b>	<b>Criteria Details</b>
	to the prescriber, AND C) Patient is concomitantly receiving at least one oral antidepressant, AND D) Patient has one of the following (i or ii): i. No history of psychosis, OR ii. History of psychosis and the prescriber believes that the benefits of Spravato outweigh the risks, AND E) The patient history of controlled substance prescriptions has been checked using the state prescription drug monitoring program (PDMP), according to the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# SPRYCEL

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## Products Affected

- SPRYCEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Sprycel 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 CML. For ALL, patient must have Ph-positive ALL. 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



# STELARA

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## Products Affected

- STELARA SUBCUTANEOUS

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	18 years and older CD/UC (initial therapy). PP/PsA-6 years and older (initial therapy).
<b>Prescriber Restrictions</b>	PP-Prescr/consult w/derm (initial therapy).PsA-prescr/consult w/rheum or derm (initial therapy).CD/UC-prescr/consult w/gastro (initial therapy).
<b>Coverage Duration</b>	End of the plan year
<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

# 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, patient must have previously been treated with imatinib or Ayvakit and sunitinib or Sprycel. 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). Glioblastoma-approve if the patient has recurrent or progressive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Soft tissue Sarcoma, Bone Cancer, Glioblastoma, Appendiceal cancer

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

# SUCRAID

## 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 to normal isomaltase (palatinase) [normal reference: greater than 5 U/g protein], c) Decreased maltase (normal reference: greater than 100 U/g protein), d) Decreased to 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

# SUNITINIB

## 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 Ayvakit or if the patient has succinate dehydrogenase (SDH)-deficient GIST. Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. 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. 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), differentiated (ie, papillary, follicular, and oncocytic carcinoma) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma, pheochromocytoma/paraganglioma, myeloid/lymphoid neoplasms with eosinophilia, GIST-unresectable succinate dehydrogenase (SDH)-deficient GIST, or use after avapritinib.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</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

# 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>	N/A
<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



# TAFAMIDIS

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## Products Affected

- VYNDAQEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with Onpattro or Tegsedi or Wainua. Concurrent use of Vyndaqel and Vyndamax.
<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 the diagnosis was confirmed by one of the following (i, ii or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy),ii. Amyloid deposits are identified on cardiac biopsy OR iii. patient had genetic testing which, according to the prescriber, identified a TTR mutation AND Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TAFINLAR

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## Products Affected

- TAFINLAR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Tafinlar is being used. BRAF V600 mutations
<b>Age Restrictions</b>	1 year and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Pending CMS Review
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Differentiated Thyroid Cancer, Biliary tract cancer, central nervous system cancer, histiocytic neoplasm, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, hairy cell leukemia
<b>Part B Prerequisite</b>	No

# TAGRISSO

## 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 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.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TALZENNA

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## Products Affected

- TALZENNA

<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>	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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TARGRETIN 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>	Adult T-Cell Leukemia/Lymphoma- approve if the patient has chronic/smoldering subtype and this medication is used as first-line therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Adult T-Cell Leukemia/Lymphoma
<b>Part B Prerequisite</b>	No

# TASIGNA

## Products Affected

- TASIGNA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and melanoma, cutaneous, prior therapies tried. For melanoma, cutaneous, KIT mutation status.
<b>Age Restrictions</b>	ALL/GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 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 or 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 cannot take Turalio, 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

# TAZAROTENE

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## Products Affected

- *tazarotene topical cream 0.1 %*
- *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

# 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



# 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

# TETRABENAZINE

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## Products Affected

- *tetrabenazine*

<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

# THALOMID

## Products Affected

- THALOMID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	MM, myelofibrosis-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	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]). Myelofibrosis, approve if according to the prescriber the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/mL or if the patient has serum erythropoietin level less than 500 mU/mL and experienced no response or loss of response to erythropoietic stimulating agents. 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's Sarcoma-approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease. Castleman's disease-approve if the patient has multicentric Castleman's disease, is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi's Sarcoma, Castleman's Disease.
<b>Part B Prerequisite</b>	No

# TIBSOVO

## 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 recurrent or progressive disease, AND patient has World Health Organization (WHO) grade 2 or 3 oligodendroglioma, OR Patient has WHO grade 2 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>	Pending CMS Review

# TOLVAPTAN

## Products Affected

- *tolvaptan*

PA Criteria	Criteria Details
<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

# TOPICAL AGENTS FOR ATOPIC DERMATITIS

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## Products Affected

- *pimecrolimus*
- *tacrolimus topical*

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 12 months.
<b>Other Criteria</b>	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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TOPICAL RETINOID PRODUCTS

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## Products Affected

- *tretinoin*
- *tretinoin microspheres topical gel 0.1 %*
- *tretinoin microspheres topical gel with pump 0.1 %*

<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



# TOPIRAMATE/ZONISAMIDE

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## Products Affected

- EPRONTIA
- *topiramate oral capsule, sprinkle*
- *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

# TRANSMUCOSAL FENTANYL DRUGS

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## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

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 12 months.
<b>Other Criteria</b>	For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer 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>Part B Prerequisite</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>	Prescribed by or in consultation with a 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TRIENTINE

## Products Affected

- CUVRIOR
- *trientine oral capsule 250 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medication history, pregnancy status, disease manifestations (all as described in Other Criteria)
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	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.
<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

# TRIKAFTA

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## Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko.
<b>Required Medical Information</b>	Diagnosis, specific CFTR gene mutations, concurrent medications
<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 CFTR gene that is considered to be pathogenic or likely pathogenic, 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 CFTR function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two CFTR 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

# TRUQAP

## Products Affected

- TRUQAP

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>	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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# TUKYSA

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## Products Affected

- TUKYSA

<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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# TURALIO

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## Products Affected

- TURALIO ORAL CAPSULE 125 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>	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

# TYMLOS

## 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. 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

# TZIELD

## Products Affected

- TZIELD

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Diagnosis of clinical type 1 diabetes (i.e., Stage 3 type 1 diabetes) or type 2 diabetes
<b>Required Medical Information</b>	Patient meets ALL of the following (A, B, C and D): A) has tested positive for at least TWO of the following type 1 diabetes-related autoantibodies on two separate occasions: anti-glutamic acid decarboxylase 65 (anti-GAD65), anti-islet antigen-2 (anti-IA-2), islet-cell autoantibody (ICA), micro insulin, or anti-zinc transporter 8 (anti-ZnT8). B) Patient meets both of the following (i and ii): i. Patient has taken an oral glucose tolerance test within the preceding 2 months AND ii. The results of the oral glucose tolerance test indicated dysglycemia by meeting at least one of the following (a, b, or c): a) Fasting plasma glucose level greater than or equal to 110 to less than 126 mg/dL OR b) 2-hour postprandial plasma glucose level greater than or equal to 140 to less than 200 mg/dL OR c) Intervening postprandial glucose level at 30, 60, or 90 minutes greater than 200 mg/dL. C) At baseline (prior to the initiation of Tzield), patient does NOT have evidence of hematologic compromise, as defined by meeting the following (i, ii, iii, and iv): i. Lymphocyte count greater than or equal to 1,000 lymphocytes/mcL AND ii. Hemoglobin greater than or equal to 10 g/dL AND iii. Platelet count greater than or equal to 150,000 platelets/mcL AND iv. Absolute neutrophil count greater than or equal to 1,500 neutrophils/mcL AND D) At baseline (prior to the initiation of Tzield), patient does NOT have evidence of hepatic compromise, as defined by meeting the following (i, ii, and iii): i. Alanine aminotransferase (ALT) greater than or equal to 2 times the upper limit of normal (ULN) AND ii. Aspartate aminotransferase (AST) greater than or equal to 2 times the ULN AND iii. Bilirubin greater than or equal to 1.5 times the ULN.
<b>Age Restrictions</b>	8 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	14 days

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	Patient meets all the following (A, B and C): A) has at least one biological relative with a diagnosis of type 1 diabetes B) According to the prescriber, the patient does NOT have any of the following (i, ii, or iii): i. Laboratory or clinical evidence of acute infection with Epstein-Barr Virus or cytomegalovirus OR ii. Active serious infection OR iii. Chronic active infection (other than localized skin infection) AND C) Patient has NOT received Tzield in the past
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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 chronic/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

# 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

# VANCOMYCIN

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## Products Affected

- *vancomycin oral capsule*

<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

# 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 and this medication is being used for induction, re-induction, consolidation, or maintenance treatment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# VENCLEXTA

## Products Affected

- VENCLEXTA
- 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
<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. Mantle Cell Lymphoma- approve if the patient has tried at least one systemic regimen. 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>Off-Label Uses</b>	Mantle Cell Lymphoma, waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, multiple myeloma, systemic light chain amyloidosis
<b>Part B Prerequisite</b>	No

# VENTAVIS

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## Products Affected

- VENTAVIS

<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>	B vs D coverage determination
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VERQUVO

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## Products Affected

- VERQUVO

<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>	Patient has symptomatic chronic heart failure, an ejection fraction less than 45% and for new starts, has had either a hospitalization for heart failure within the last six months or has needed outpatient IV diuretics within the last three months.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# VERZENIO

## 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-Approve if pt meets (A,B,C and D): A)Pt has HR+disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt has node-positive disease at high risk of recurrence AND D)Pt meets ONE 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 a postmenopausal woman, OR b)Pt is a pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, OR 2-Pt has had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is a man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets one of the following (a or b): a)Pt is a postmenopausal woman or man OR b)Pt is a pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Patient has had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Recurrent or Metastatic in Women-Approve if pt meets (A, B, C and D): A) Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i or ii): i.Pt is a postmenopausal woman, OR ii.Pt is a pre/perimenopausal woman and meets one of the following (a or b): a)Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt has had surgical bilateral oophorectomy or ovarian irradiation, AND D)Pt meets ONE of the</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>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 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 one prior endocrine therapy, AND c)Pt has tried chemotherapy for metastatic breast cancer.Breast Cancer-Recurrent or Metastatic in Men-Approve if pt meets the following criteria (A,B and C): A)Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)Pt is 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 one prior endocrine therapy, AND c)Pt has tried chemotherapy for metastatic breast cancer. Endometrial cancer- approve if pt meets all of (A, B, And C): A) pt has recurrent or metastatic disease, and B) pt has estrogen receptor (ER)-positive tumors, and C) pt 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

# VITRAKVI

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## Products Affected

- VITRAKVI

<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>	N/A
<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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</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

# VONJO

## Products Affected

- VONJO

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>	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) the patient has a platelet count of less than 50 X 10 <sup>9</sup> /L (less than 50,000/mcL) and meets one of the following criteria (a or b):a) Patient has intermediate-risk or high-risk disease and is not a candidate for transplant, or b) Patient has lower-risk disease OR (B) Patient has a platelet count of greater than or equal to 50 X 10 <sup>9</sup> /L (greater than or equal to 50,000/mcL) and meets all of the following criteria (a, b and c): a) Patient has high-risk disease, AND b) Patient is not a candidate for transplant, AND c) Patient has tried Jakafi (ruxolitinib tablets) or Inrebic (fedratinib capsules) OR (C) patient has myelofibrosis-associated anemia with symptomatic splenomegaly and/or constitutional symptoms.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</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

# VOTRIENT

## Products Affected

- *pazopanib*

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>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, desmoid tumors (aggressive fibromatosis, dermatofibrosarcoma protuberans with fibrosarcomatous transformation, non-adipocytic sarcoma or pleomorphic rhabdomyosarcoma.</p> <p>Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has recurrent or metastatic disease. 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.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Differentiated (ie, papillary, follicular, oncocytic carcinoma) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or

<b>PA Criteria</b>	<b>Criteria Details</b>
	Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma, bone cancer.
<b>Part B Prerequisite</b>	No

# 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, 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

# WELIREG

## Products Affected

- WELIREG

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>	Renal Cell Carcinoma- approve if pt has advanced disease AND has tried at least one programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XALKORI

## Products Affected

- XALKORI

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 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

# XATMEP

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## Products Affected

- XATMEP

<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>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No



# XCOPRI

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## Products Affected

- XCOPRI
- XCOPRI MAINTENANCE PACK
- XCOPRI TITRATION PACK

<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 patient has tried one other anticonvulsant therapy (eg, carbamazepine, divalproex sodium, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, topiramate, valproic acid).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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

# 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 long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]) AND 2) while on 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 a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with 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

# XGEVA

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## Products Affected

- XGEVA

<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>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# XIAFLEX

## Products Affected

- XIAFLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Retreatment (i.e., treatment beyond eight injections for Peyronie's Disease).
<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-at baseline (prior to initial injection of Xiaflex), the patient had contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint of at least 20 degrees AND 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-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 in a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees AND 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

# XIFAXAN

## Products Affected

- XIFAXAN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Hepatic encephalopathy, irritable bowel syndrome - 18 years of age or older. Traveler's diarrhea - 12 years of age or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Hep Enceph-6mo, IBS/diarrhea-14days, Traveler's diarr-3 days, Sm intest bacterial overgrowth-14days
<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. (For IBS with diarrhea - customers are limited to 3 courses) 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Small intestine bacterial overgrowth
<b>Part B Prerequisite</b>	No

# XOLAIR

## Products Affected

- XOLAIR

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/CIU-Initial tx 4 months, Polyps-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): 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 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 the following (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) forced expiratory volume in 1 second (FEV1) less than 80% predicted, d) FEV1/forced vital capacity (FVC) less than 0.80, or e) asthma worsens upon tapering of oral CS. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRwNP) [all of A, B, C, D, 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)</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>at least two of the following symptoms for 6 months: 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. CHRONIC IDIOPATHIC URTICARIA (CIU): urticaria more than 6 weeks prior to treatment with Xolair with symptoms present more than 3 days per week despite daily 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 and 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 an epinephrine auto-injector, and D) patient has been prescribed an epinephrine auto-injector.</p> <p>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: patient responded to therapy.</p> <p>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



# 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 patient has relapsed or refractory disease AND 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

# XPOVIO

## Products Affected

- XPOVIO

PA Criteria	Criteria Details
<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>	Multiple Myeloma-Approve if the patient meets the following (A and B): A) The medication will be taken in combination with dexamethasone AND 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 one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib 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 Darzalex (daratumumab infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Kyprolis (carfilzomib infusion)/Revlimid/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 includes patients with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma)-approve if the patient has been treated with at least two prior systemic therapies.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Treatment of multiple myeloma in combination with daratumumb or pomalidomide
<b>Part B Prerequisite</b>	No

# XTANDI

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## Products Affected

- XTANDI

<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

# XYREM

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## Products Affected

- SODIUM OXYBATE

<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, 18 years and older - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). For EDS in patients with narcolepsy, less than 18 years old-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextramphetamine) or modafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). 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

# 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 in complete or partial response to first-line primary treatment or if the patient has recurrent disease and a BRCA mutation. 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, Ovarian, fallopian tube or primary peritoneal cancer-treatment
<b>Part B Prerequisite</b>	No

# 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 - must have tried at least one other systemic therapy for hairy cell leukemia OR is unable to tolerate purine analogs and Zelboraf will be used in combination with Gazyva (obinutuzumab intravenous infusion) as initial therapy. 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, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma OR ii. Recurrent or progressive disease for one of the following conditions (a or b): a) glioma OR b) Glioblastoma OR iii. Melanoma with brain metastases AND the medication with be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. Multisystem disease OR ii. Pulmonary disease OR iii. Central nervous system lesions 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



# 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>	N/A
<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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# 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 and patient has tried or is concomitantly receiving two other antiepileptic drugs.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

# ZTLIDO

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## Products Affected

- ZTLIDO

<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

# ZURZUVAE

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## Products Affected

- ZURZUVAE

<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 severe 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

# 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 1 year
<b>Other Criteria</b>	CLL/SLL-approve if 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>	small lymphocytic lymphoma
<b>Part B Prerequisite</b>	No

# 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 prior to approval of Zykadia. NSCLC, ROS1 Rearrangement-approve if the patient has advanced or metastatic disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement. Erdheim-Chester disease.
<b>Part B Prerequisite</b>	No

# ZYPREXA RELPREVV

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## Products Affected

- ZYPREXA RELPREVV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Dementia-related psychosis
<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>	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

# ZYTIGA

## Products Affected

- *abiraterone*

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>	Authorization will be for 1 year.
<b>Other Criteria</b>	<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) agonist, or the medication is concurrently used with Firmagon 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 gonadotropin-releasing hormone agonist or concurrently used with Firmagon 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, ii or iii): i. abiraterone with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) agonist OR ii. Patient has had a bilateral orchiectomy OR iii. the medication is used in combination with Firmagon. 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, ii or iii): i. abiraterone is used in combination with gonadotropin-releasing hormone (GnRH) agonist OR</p>



<b>PA Criteria</b>	<b>Criteria Details</b>
	ii. Patient has had a bilateral orchiectomy OR iii. the medication is used in combination with Firmagon. Prostate cancer-radical prostatectomy-approve if the medication is used in combination with prednisone, the patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy, patient has pelvic recurrence, the medication will be used concurrently with GnRH agonist, Firmagon or the patient has had a bilateral orchiectomy.
<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
<b>Part B Prerequisite</b>	No

## PART B VERSUS PART D

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### Products Affected

- *acetylcysteine*
- *acyclovir sodium intravenous solution*
- *albuterol sulfate inhalation solution for nebulization*
- *amiodarone intravenous solution*
- *aprepitant*
- *arformoterol*
- *arsenic trioxide*
- ATGAM
- *azacitidine*
- *azathioprine oral tablet 50 mg*
- *azathioprine sodium*
- BELEODAQ
- *bendamustine intravenous recon soln*
- BENDAMUSTINE INTRAVENOUS SOLUTION
- BENDEKA
- *bleomycin*
- BLINCYTO INTRAVENOUS KIT
- *budesonide inhalation*
- *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)
- CLINISOL SF 15 %
- *clofarabine*
- *cromolyn inhalation*
- *cyclophosphamide intravenous recon soln*
- CYCLOPHOSPHAMIDE INTRAVENOUS SOLUTION
- *cyclophosphamide oral capsule*
- CYCLOPHOSPHAMIDE ORAL TABLET
- *cyclosporine modified*
- *cyclosporine oral capsule*
- *cytarabine*
- *cytarabine (pf)*
- *dacarbazine*
- *dactinomycin*
- *daunorubicin*
- *decitabine*
- *docetaxel*
- *doxorubicin intravenous recon soln 50 mg*
- *doxorubicin intravenous solution*
- *doxorubicin, peg-liposomal*
- *dronabinol*
- ENGERIX-B (PF)
- ENGERIX-B PEDIATRIC (PF)
- ENVARSUS XR
- *epirubicin intravenous solution*
- ERBITUX
- ETOPOPHOS
- *etoposide intravenous*
- *everolimus (immunosuppressive)*
- FIRMAGON KIT W DILUENT SYRINGE
- *floxuridine*
- *fludarabine*
- *fluorouracil intravenous*
- FOLOTYN
- *fulvestrant*
- *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*
- *granisetron hcl oral*
- HEPLISAV-B (PF)
- *idarubicin*
- *ifosfamide*
- INFUMORPH P/F
- *intralipid intravenous emulsion 20 %*
- INTRALIPID INTRAVENOUS EMULSION 30 %
- *ipratropium bromide inhalation*
- *ipratropium-albuterol*

- *irinotecan*
- IXEMPRA
- JEVTANA
- KABIVEN
- KYPROLIS
- *melphalan hcl*
- *mesna*
- *methotrexate sodium (pf)*
- *methotrexate sodium injection*
- *mitomycin intravenous*
- *mitoxantrone*
- *mycophenolate mofetil*
- *mycophenolate mofetil (hcl)*
- *mycophenolate sodium*
- *nelarabine*
- NIPENT
- *nitroglycerin intravenous*
- NULOJIX
- ONCASPAR
- *ondansetron hcl oral solution*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet, disintegrating 4 mg, 8 mg*
- *oxaliplatin*
- *paclitaxel*
- PANZYGA
- *pentamidine inhalation*
- PERIKABIVEN
- PLENAMINE
- *plerixafor*
- PORTRAZZA
- PRALATREXATE
- PREHEVBRIO (PF)
- *premasol 10 %*
- PROGRAF INTRAVENOUS
- PROGRAF ORAL GRANULES IN PACKET
- PROSOL 20 %
- PULMOZYME
- RECOMBIVAX HB (PF)
- RYLAZE
- SIMULECT
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- *tacrolimus oral capsule*
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- *temsirolimus*
- TICE BCG
- *tobramycin in 0.225 % nacl*
- *topotecan*
- *travasol 10 %*
- TROPHAMINE 10 %
- TYVASO
- TYVASO INSTITUTIONAL START KIT
- TYVASO REFILL KIT
- TYVASO STARTER KIT
- *valrubicin*
- *vinblastine*
- *vincristine*
- *vinorelbine*
- VYXEOS
- XEMBIFY
- ZALTRAP
- ZANOSAR
- ZOLADEX
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- *zoledronic acid-mannitol-water*
- ZOLEDRONIC AC-MANNITOL-0.9NACL

### **Details**

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

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