

## 2024 Prior Authorization Criteria

Updated 12/01/2024

# ACITRETIN

### Products Affected

- acitretin

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Psoriasis: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to methotrexate or cyclosporine.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Prevention of non-melanoma skin cancers in high risk individuals, Lichen planus, Keratosis follicularis (Darier Disease)
Part B Prerequisite	No

# ACTEMRA SQ

## Products Affected

- Actemra ACTPen
- Actemra subcutaneous

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	Interstitial lung disease-18 years and older (initial and continuation)
<b>Prescriber Restrictions</b>	RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)
<b>Coverage Duration</b>	Approve through 12/31/24
<b>Other Criteria</b>	<p>RA initial - approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq, or Xeljanz/XR (Note: if the patient does not meet this requirement, previous trial(s) with the following drugs will be counted towards meeting the try TWO requirement: infliximab or another non-preferred adalimumab product will also count. Trials of multiple adalimumab products count as ONE preferred. OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial-approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, Rinvoq, Xeljanz or a preferred adalimumab product. (Note: if the patient does not meet this requirement, a previous trial with the drug infliximab or a non-preferred adalimumab product will be counted towards meeting the try TWO requirement. Trials of multiple adalimumab products counts as ONE Preferred Product.), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx, RA/PJIA - approve if the pt had a response as determined by the prescriber. Interstitial lung disease associated with systemic sclerosis initial-approve if the patient has elevated acute phase reactants AND the diagnosis is confirmed by high-resolution computed tomography. Interstitial lung disease assoc with systemic sclerosis, Cont tx-approve if the patient had adequate efficacy. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), Cyltezo, Idacio.</p>

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

# ACTIMMUNE

## Products Affected

- Actimmune

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Mycosis fungoides, Sezary syndrome.
Part B Prerequisite	No

## ADALIMUMAB OTHER

### Products Affected

- Cyltezo(CF)
- Cyltezo(CF) Pen
- Cyltezo(CF) Pen Crohn's-UC-HS
- Cyltezo(CF) Pen Psoriasis-UV
- Idacio(CF)
- Idacio(CF) Pen Crohn-UC Startr
- Idacio(CF) Pen Psoriasis Start
- Idacio(CF) Pen subcutaneous pen injector kit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried
<b>Age Restrictions</b>	CD, 6 or older (initial). UC, 5 or older (initial). PP-18 years and older (initial)
<b>Prescriber Restrictions</b>	Init tx only-RA/JIA/JRA/Ankylosing spondylitis, prescr/consult w/rheum. PsA, prescr/consult w/rheum or dermat. PP, prescr/consult w/dermat. UC/ CD, prescr/consult w/gastro. HS, prescr/consult w/dermat. UV, prescr/consult w/ophthalmologist.
<b>Coverage Duration</b>	Approve through 12/31/24

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. Plaque psoriasis (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. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ileocolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). cont tx - must respond to tx as determined by prescriber.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ADEMPAS

## Products Affected

- Adempas

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

# AIMOVIG

## Products Affected

- Aimovig Autoinjector

PA Criteria	Criteria Details
Exclusion Criteria	Combination therapy with Ajovy, Vyepti or Emgality
Required Medical Information	Diagnosis, number of migraine headaches per month
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Approve if the patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No



# AKEEGA

## Products Affected

- Akeega

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No

# ALDURAZYME

## Products Affected

- Aldurazyme

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For mucopolysaccharidosis I (MPS I): Diagnosis of MPS I was confirmed by an enzyme assay demonstrating a deficiency of alpha-L-iduronidase enzyme activity and/or by genetic testing. Patients with Scheie form (i.e., attenuated MPS I) must have moderate to severe symptoms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# ALECENSA

## Products Affected

- Alecensa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-small cell lung cancer-approve if the patient has both (A and B): A) either (i or ii): i) medication is used as adjuvant treatment following tumor resection (note: for tumors greater than or equal to 4 cm or node positive) or ii) advanced or metastatic disease and B) anaplastic lymphoma kinase (ALK)-positive disease as detected by an approved test. Anaplastic large cell lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease and (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor- pt has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) pt has advanced, recurrent or metastatic disease, or (ii) tumor is inoperable. Large B-Cell Lymphoma- pt has ALK-positive disease AND pt has relapsed or refractory disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma
Part B Prerequisite	No

# ALOSETRON

## Products Affected

- alosetron

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

# ALPHA 1 PROTEINASE INHIBITORS

## Products Affected

- Aralast NP
- Prolastin-C intravenous solution
- Zemaira

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# ALUNBRIG

## Products Affected

- Alunbrig

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	ALK status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT), Peripheral T-Cell Lymphoma
<b>Part B Prerequisite</b>	No

# AMPHETAMINES

## Products Affected

- dextroamphetamine-amphetamine oral capsule, extended release 24hr
- dextroamphetamine-amphetamine oral tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) OR 2) The patient has a diagnosis of narcolepsy confirmed by a sleep study.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

## ANTIFUNGALS (IV)

---

### Products Affected

- voriconazole

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



# APOKYN

## Products Affected

- APOKYN
- apomorphine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a serotonin 5-HT3 Antagonist
<b>Required Medical Information</b>	Diagnosis, other therapies
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Parkinson's disease (PD), new to therapy-approve if the patient meets the following criteria: 1. patient has advanced PD, 2. patient is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, 3. patient is currently receiving carbidopa/levodopa. Parkinson's disease (PD), patients currently receiving apokyn or apomorphine-approve if the patient meets the following criteria: 1. patient has advanced PD, 2. patient is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, 3. patient is currently receiving carbidopa/levodopa and 4. patient has previously tried one other treatment for off episodes and had significant intolerance or inadequate efficacy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ARCALYST

## Products Affected

- Arcalyst

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent biologic therapy
<b>Required Medical Information</b>	
<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>	CAPS renewal - approve if the patient has had a response as determined by the prescriber. DIRA initial-approve if the patient weighs at least 10 kg and genetic test confirms a mutation in the IL1RN gene. DIRA cont-approve if the patient has responded to therapy. Pericarditis initial-approve if the patient has recurrent pericarditis AND for the current episode, the patient is receiving standard treatment or standard treatment is contraindicated. Continuation-approve if the patient has had a clinical response.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ARIKAYCE

## Products Affected

- Arikayce

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	MAC Lung disease, initial-approve if the patient has a positive sputum culture for mycobacterium avium complex and the culture was collected within the past 3 months and was collected after the patient has completed a background multidrug regimen, the Mycobacterium avium complex isolate is susceptible to amikacin according to the laboratory report AND Arikayce will be used in conjunction to a background multidrug regimen. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin). MAC Lung Disease, continuation-approve if Arikayce will be used in conjunction with a background multidrug regimen AND i. Patient meets ONE of the following criteria (a or b):a)patient has not achieved negative sputum cultures for Mycobacterium avium complex OR b) patient has achieved negative sputum cultures for Mycobacterium avium complex for less than 12 months. Cystic fibrosis-patient has pseudomonas aeruginosa in culture of the airway.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Cystic fibrosis pseudomonas aeruginosa infection
<b>Part B Prerequisite</b>	No

# AUBAGIO

## Products Affected

- teriflunomide

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

# AUGTYRO

## Products Affected

- Augtyro

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	NSCLC - 18 years and older, Solid tumors - 12 years and older
<b>Prescriber Restrictions</b>	
<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. Solid tumors - approve if tumor is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND tumor is locally advanced or metastatic or surgical resection will likely result in severe morbidity AND disease has progressed following treatment or there are no satisfactory alternative therapies.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AUSTEDO

## Products Affected

- Austedo
- Austedo XR
- Austedo XR Titration Kt(Wk1-4)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Tourette's syndrome
Part B Prerequisite	No

# AUVELITY

## Products Affected

- Auvelity

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Major Depressive Disorder (MDD): The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: serotonin and norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs), mirtazapine, bupropion.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# AYVAKIT

## Products Affected

- Ayvakit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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

## Products Affected

- Balversa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies, test results
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy, other chemotherapy or checkpoint inhibitor therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# BENLYSTA

---

## Products Affected

- Benlysta

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent Use with Other Biologics or Lupkynis
Required Medical Information	Diagnosis, medications that will be used in combination, autoantibody status
Age Restrictions	Lupus Nephritis: 18 years and older (initial). SLE: 5 years and older (initial).
Prescriber Restrictions	SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)
Coverage Duration	SLE-Initial-4 months, cont-1 year. Lupus Nephritis-6 mo initial, 1 year cont

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 the requested medication. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA] 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, as determined by the prescribing physician. 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 be intolerant due to a significant toxicity, as determined by the prescribing physician AND The patient has responded to Benlysta as determined by the prescriber.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BERINERT

## Products Affected

- Berinert intravenous kit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hereditary angioedema (HAE): The requested drug is being used for the treatment of acute angioedema attacks. Patient has HAE with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR patient has HAE with normal C1 inhibitor confirmed by laboratory testing. For patients with HAE with normal C1 inhibitor, EITHER 1) Patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
<b>Age Restrictions</b>	5 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BESREMI

## Products Affected

- Besremi

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

# BETASERON/EXTAVIA

## Products Affected

- Betaseron subcutaneous kit

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

## BEXAROTENE (ORAL)

### Products Affected

- bexarotene

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

## BEXAROTENE (TOPICAL)

### Products Affected

- bexarotene

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	1 year
Other Criteria	Adult T-Cell Leukemia/Lymphoma- approve if the patient has chronic/smoldering subtype and this medication is used as first-line therapy.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Adult T-Cell Leukemia/Lymphoma
Part B Prerequisite	No



# BOSENTAN/AMBRISENTAN

## Products Affected

- ambrisentan
- bosentan

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

# BOSULIF

## Products Affected

- Bosulif

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis. For CML/ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies tried
<b>Age Restrictions</b>	CML- 1 year and older. ALL - 15 years and older. Myeloid/lymphoid neoplasms w eosinophilia- 18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For Ph-positive CML, patients new to therapy must have tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel. For Ph-positive ALL, patients new to therapy must have tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel.
<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

## Products Affected

- Braftovi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, BRAF V600 status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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. 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). Appendiceal adenocarcinoma-approve if (A and B): A) BRAF V600E mutation-positive, and B) used as subsequent therapy for advanced or metastatic disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Appendiceal adenocarcinoma
<b>Part B Prerequisite</b>	No

# BRIVIACT

## Products Affected

- Briviact

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant
Age Restrictions	1 month of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# BRUKINSA

## Products Affected

- Brukinsa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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 - approve if pt meets (i, ii, iii or iv): (i) the patient has tried at least one systemic regimen or (ii) patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail) or (iii) medication is being used in combination with rituximab as pre-treatment in order to limit the number of cycles of induction therapy with RHyperCVAD regimen (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) or (iv) pt has TP53 mutation and will use this in combination with Venclexta (venetoclax tablets) and Gazyva (obinutuzumab intravenous infusion). Chronic lymphocytic leukemia/small lymphocytic lymphoma-approve. 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, mantle cell lymphoma (not candidate for systemic tx, OR in combination with rituximab OR with TP53 mutation in combination with venetoclax)

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

# BUDESONIDE CAP

## Products Affected

- budesonide oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the maintenance of microscopic colitis: patient has had a clinical relapse after cessation of treatment (induction) therapy.
<b>Age Restrictions</b>	Crohn's, treatment: 8 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Microscopic colitis, maintenance: 12 months, all other indications: 3 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Treatment and maintenance of microscopic colitis in adults
<b>Part B Prerequisite</b>	No

# BUPRENORPHINE

## Products Affected

- buprenorphine HCl sublingual

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug is being prescribed for the treatment of opioid use disorder AND patient meets one of the following: 1) The patient is pregnant or breastfeeding, and the requested drug is being prescribed for induction therapy and/or subsequent maintenance therapy for treatment of opioid use disorder OR 2) The requested drug is being prescribed for induction therapy for transition from opioid use to treatment of opioid use disorder OR 3) The requested drug is being prescribed for maintenance therapy for treatment of opioid use disorder in in a patient who is intolerant to buprenorphine/naloxone.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# CABOMETYX

## Products Affected

- Cabometyx

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried Lenvima or sorafenib. Endometrial carcinoma-approve if the patient has tried one systemic regimen. GIST-approve if the patient has tried two of the following-imatinib, Ayvakit, sunitinib, dasatinib, Stivarga or Qinlock. NSCLC-approve if the patient has RET rearrangement positive tumor.
<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

# CALCIPOTRIENE

## Products Affected

- calcipotriene scalp
- calcipotriene topical ointment
- Enstilar

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Treatment of Psoriasis: The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to a topical steroid.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# CALQUENCE

## Products Affected

- Calquence
- Calquence (acalabrutinib mal)

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

# CAPRELSA

## Products Affected

- Caprelsa

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

# CARGLUMIC ACID

## Products Affected

- carglumic acid

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

# CAYSTON

## Products Affected

- Cayston

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

# CERDELGA

## Products Affected

- Cerdelga

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, lab test results
<b>Age Restrictions</b>	
<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 Gaucher disease or related disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient is a cytochrome P450(CYP) 2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an approved test and if the diagnosis has been established by 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>	
<b>Part B Prerequisite</b>	No

# CEREZYME

## Products Affected

- Cerezyme intravenous recon soln 400 unit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results
<b>Age Restrictions</b>	
<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>	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>	
<b>Part B Prerequisite</b>	No



# CLOBAZAM

## Products Affected

- clobazam
- Sympazan

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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

# CLOMIPRAMINE

## Products Affected

- clomipramine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The requested drug is being prescribed for one of the following: a) Obsessive-Compulsive Disorder (OCD), b) Panic Disorder AND 2) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to any of the following: a) a serotonin and norepinephrine reuptake inhibitor (SNRI), b) a selective serotonin reuptake inhibitor (SSRI) OR 3) The requested drug is being prescribed for Depression AND 4) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: a) serotonin and norepinephrine reuptake inhibitors (SNRIs), b) selective serotonin reuptake inhibitors (SSRIs), c) mirtazapine, d) bupropion
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Depression, Panic Disorder
Part B Prerequisite	No

# CLORAZEPATE

## Products Affected

- clorazepate dipotassium

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Short-term relief anxiety-1 month, Anxiety Disorders-4 months, All other Diagnoses-Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 65 years of age or older.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# COMETRIQ

## Products Affected

- Cometriq

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and Hurthle) 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 Hurthle) Thyroid Carcinoma
<b>Part B Prerequisite</b>	No

# COPIKTRA

## Products Affected

- Copiktra

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, previous therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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

# COTELLIC

## Products Affected

- Cotellic

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Melanoma initial - must have BRAF V600 mutation.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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/neuroglioma/glioneuronal tumor OR ii. Recurrent or progressive disease for one of the following conditions (a, b, c or d): a) glioma/circumscribed 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.
<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

## CRESEMBA (ORAL)

### Products Affected

- Cresemba oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Candidiasis of the esophagus - HIV infection, sepsis
Part B Prerequisite	No

## CYSTEAMINE (OPHTHALMIC)

### Products Affected

- Cystadrops
- Cystaran

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



# CYSTEAMINE (ORAL)

## Products Affected

- Cystagon

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

# DALFAMPRIDINE

## Products Affected

- dalfampridine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<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>	
<b>Part B Prerequisite</b>	No

# DAURISMO

## Products Affected

- Daurismo

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

# DEFERASIROX

## Products Affected

- deferasirox

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Serum ferritin level
<b>Age Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No

# DEXMETHYLPHENIDATE

## Products Affected

- dexmethylphenidate oral tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) OR 2) The requested drug is being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Cancer-related fatigue
<b>Part B Prerequisite</b>	No

# DHE NASAL

## Products Affected

- dihydroergotamine nasal

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin).
<b>Required Medical Information</b>	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least one triptan 5-HT <sub>1</sub> receptor agonist.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DIACOMIT

## Products Affected

- Diacomit

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

# DIAZEPAM

## Products Affected

- diazepam injection
- Diazepam Intensol
- diazepam oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Short-term relief anx-1 mo, skeletal muscle spasm-3 mo, Anx Disorders-4 mo, Other Diagnoses-PlanYR
<b>Other Criteria</b>	This Prior Authorization only applies to patients 65 years of age or older.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# DIMETHYL FUMARATE

## Products Affected

- Tecfidera

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

# DOPTELET

## Products Affected

- Doptelet (10 tab pack)
- Doptelet (15 tab pack)
- Doptelet (30 tab pack)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, platelet count, date of procedure (Thrombocytopenia with chronic liver disease)
<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>	Thrombocytopenia with chronic liver disease-Approve if the patient has a current platelet count less than 50 x 10 <sup>9</sup> /L AND the patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. Chronic ITP initial-approve if the patient has a platelet count less than 30,000 microliters or less than 50,000 microliters and is at an increased risk of bleeding and has tried one other therapy or if the patient has undergone splenectomy. Continuation-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DRIZALMA

## Products Affected

- Drizalma Sprinkle

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has tried duloxetine capsules OR 2) The patient is unable to take duloxetine capsules for any reason (e.g., difficulty swallowing capsules, requires nasogastric administration).
<b>Age Restrictions</b>	Generalized Anxiety Disorder - 7 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Cancer pain, chemotherapy-induced neuropathic pain
<b>Part B Prerequisite</b>	No

# DROXIDOPA

## Products Affected

- droxidopa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medication history (as described in Other Criteria field)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a neurologist
Coverage Duration	12 months
Other Criteria	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
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# DUPIXENT

---

## Products Affected

- Dupixent Pen
- Dupixent Syringe

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	No

# ELMIRON

## Products Affected

- Elmiron

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

# ELREXFIO

## Products Affected

- Elrexfio

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

# EMGALITY

## Products Affected

- Emgality Pen
- Emgality Syringe

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination therapy with Aimovig, Vyepti or Ajovy
<b>Required Medical Information</b>	Diagnosis, number of migraine or cluster headaches per month
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Cluster headache tx-6 months, migraine prevention-1 year
<b>Other Criteria</b>	Migraine headache prevention-Approve if the patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication). Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<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/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist.Plaque psoriasis (PP), prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center.Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist.
<b>Coverage Duration</b>	Approve through 12/31/24

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other systemic therapy for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID), biologic or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide. Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD-approve. Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Behcet's, GVHD-Cont-if the patient has had a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Graft versus host disease (GVHD), Behcet's disease
<b>Part B Prerequisite</b>	No

# ENDARI

## Products Affected

- Endari
- glutamine (sickle cell)

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

# EPCLUSA

## Products Affected

- Epclusa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin.
<b>Required Medical Information</b>	Genotype (including unknown), prescriber specialty, other medications tried or used in combination with requested medication
<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>	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

# EPIDIOLEX

## Products Affected

- Epidiolex

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

# EPOETIN ALFA

## Products Affected

- Procrit injection solution 10,000 unit/mL, 2,000 unit/mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL, 40,000 unit/mL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	CRF anemia in patients not on dialysis. Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start. Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa. Anemia w/myelosuppressive chemotx. pt must be currently receiving myelosuppressive chemo as a non-curative treatment, and Hb 10.0 g/dL or less to start. Hb less than or equal to 12.0 g/dL if previously on epoetin alfa. MDS, approve if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. Previously receiving EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV with zidovudine, Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 mU/mL or less at tx start. Previously on EA approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Hgb is less than or equal to 13, surgery is elective, nonvascular and non-cardiac and pt is unwilling or unable to donate autologous blood prior to surgery
<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>	Myelofibrosis-Initial-patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 Mu/mL. Cont-approve if according to the prescriber the patient has had a response. Anemia in patients with chronic renal failure on dialysis - 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

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

# ERGOTAMINE

## Products Affected

- ergotamine-caffeine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coverage will be denied when used in conjunction with potent CYP3A4 inhibitors (e.g., ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin).
<b>Required Medical Information</b>	The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least ONE triptan 5-HT <sub>1</sub> agonist.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# ERIVEDGE

## Products Affected

- Erivedge

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	BCC (La or Met) - must not have had disease progression while on Odomzo.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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

## Products Affected

- Erleada

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# ERLOTINIB

## Products Affected

- erlotinib

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Advanced or Metastatic NSCLC, approve if the patient has sensitizing EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of sensitizing EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. Advanced 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 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

---

## Products Affected

- everolimus (antineoplastic)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast Cancer-HER2 status, hormone receptor (HR) status.
Age Restrictions	All dx except TSC associated SEGA, renal angiomyolipoma or partial onset seizures-18 years and older.
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Breast Cancer-approve if pt meets ALL the following (A, B, C, D, E, and F):A)pt has recurrent or metastatic,HR+ disease AND B)pt has HER2-negative breast cancer AND C)pt has tried at least 1 prior endocrine therapy AND D)pt meets 1 of the following conditions (i or ii):i.pt is a postmenopausal woman or man OR ii.pt is pre/perimenopausal woman AND is receiving ovarian suppression/ablation with a GnRH agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND E)pt meets 1 of the following conditions (i or ii): i.Afinitor will be used in combo with exemestane and pt meets 1 of the following:pt is male and is receiving a GnRH analog or pt is a woman or ii. Afinitor will be used in combo with fulvestrant or tamoxifen AND F)pt has not had disease progression while on Afinitor. RCC, relapsed or Stage IV disease-approve if using for non-clear cell disease or if using for clear cell disease, pt has tried 1 prior systemic therapy (e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).TSC Associated SEGA-approve if pt requires therapeutic intervention but cannot be curatively resected. Thymomas and Thymic Carcinomas-approve if pt has tried chemotherapy or cannot tolerate chemotherapy.TSC associated renal angiomyolipoma -approve. WM/LPL - approve if pt has progressive or relapsed disease or if pt has not responded to primary therapy. Thyroid Carcinoma, differentiated-approve if pt is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if Afinitor will be used in combo with letrozole. GIST-approve if pt has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock or imatinib AND there is confirmation that Afinitor will be used in combo with 1 of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. TSC-associated partial-onset seizures-approve. NET tumors of the pancreas, GI Tract, Lung and Thymus (carcinoid tumors)-approve. Soft tissue sarcoma-approve if pt has perivascular epitheloid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangiomyomatosis. Classic hodgkin lymphoma-approve if pt has relapsed or refractory disease. Histiocytic neoplasm-approve if pt has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis. Patient must also have PIK3CA mutation. Meningioma- approve if pt has recurrent or progressive disease AND pt has surgically inaccessible disease and radiation therapy is not possible AND medication will be used in combination with a somatostatin analogue. Uterine Sarcoma-approve if the patient has advanced, recurrent, metastatic, or inoperable disease, AND has a</p>
	<p>perivascular epithelioid cell tumor (PEComa), AND has tried at least one systemic regimen. Note: Examples of systemic regimen include doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<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

# EXKIVITY

## Products Affected

- Exkivity

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Non-Small Cell Lung Cancer (NSCLC)-approve if the patient meets (A, B and C): A) Patient has locally advanced or metastatic NSCLC AND B) Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation, as determined by an approved test AND C) Patient has previously tried at least one platinum-based chemotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FABRAZYME

## Products Affected

- Fabrazyme

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



# FANAPT

## Products Affected

- Fanapt

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For treatment of schizophrenia: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: aripiprazole, asenapine, olanzapine, quetiapine, risperidone, ziprasidone AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following brand products: Latuda, Rexulti, Secuado, Vraylar.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FASENRA

---

## Products Affected

- Fasenra
- Fasenra Pen

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	No

# FINGOLIMOD

## Products Affected

- fingolimod

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

# FINTEPLA

## Products Affected

- Fintepla

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

# FIRMAGON

## Products Affected

- Firmagon kit w diluent syringe

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

# FLUCYTOSINE

## Products Affected

- flucytosine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# FOTIVDA

## Products Affected

- Fotivda

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, other therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No

# FRUZAQLA

## Products Affected

- Fruzaqla

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	
<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



# FYCOMPA

## Products Affected

- Fycompa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For treatment of partial-onset seizures: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) The patient has experienced an inadequate treatment response, intolerance, or contraindication to any of the following: Aptiom, Vimpat, Xcopri, Spritam. For adjunctive treatment of primary generalized tonic-clonic seizures: 1) The patient experienced an inadequate treatment response, intolerance, or contraindication to a generic anticonvulsant AND 2) The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following: Vimpat, Spritam.
<b>Age Restrictions</b>	Partial-onset seizures: 4 years of age or older. Primary generalized tonic-clonic seizures: 12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# GATTEX

## Products Affected

- Gattex 30-Vial
- Gattex One-Vial

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

# GAVRETO

## Products Affected

- Gavreto

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	NSCLC-approve if the patient has metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion-positive disease or RET-mutation positive disease and has anaplastic thyroid cancer or the patient has medullary thyroid cancer or the disease is radioactive iodine-refractory.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Medullary Thyroid Cancer
<b>Part B Prerequisite</b>	No

# GILOTRIF

## Products Affected

- Gilotrif

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<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>	Yes

# GLATIRAMER

## Products Affected

- glatiramer
- Glatopa

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

# GLUCAGON-LIKE PEPTIDE-1 AGONISTS

## Products Affected

- Bydureon BCise 5 mL), 1 mg/dose (4 mg/3 mL), 2 mg/dose (8 mg/3 mL)
- Mounjaro
- Ozempic subcutaneous pen injector 0.25 mg or 0.5 mg (2 mg/3 mL), 0.25 mg or 0.5 mg(2 mg/1. • Rybelsus
- Trulicity

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

# GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

## Products Affected

- Eligard
- Eligard (3 month)
- Eligard (4 month)
- Eligard (6 month)
- leuprolide subcutaneous kit
- Lupron Depot

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Premenstrual disorders - 18 years and older
<b>Prescriber Restrictions</b>	Prostate cancer-prescr/consult with oncologist or urologist. For the treatment of other cancer diagnosis must be prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	uterine leiomyomata approve 3months/all other dx 12 mo
<b>Other Criteria</b>	Premenstrual disorders including PMS and PMDD- approve if pt has severe refractory premenstrual symptoms AND pt has tried an SSRI or combined oral contraceptive.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Ovarian cancer including fallopian tube and primary peritoneal cancer, breast cancer, prophylaxis or treatment of uterine bleeding or menstrual suppression in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors, premenstrual disorders including premenstrual syndrome and premenstrual dysphoric disorder, uterine cancer
<b>Part B Prerequisite</b>	No

# GRALISE

## Products Affected

- Gralise oral tablet extended release 24 hr

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



# GROWTH HORMONE

## Products Affected

- Genotropin
- Genotropin MiniQuick

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pediatric patients with closed epiphyses
<b>Required Medical Information</b>	Pediatric growth hormone deficiency (GHD): Patient (pt) is a neonate or was diagnosed with GHD as a neonate OR meets any of the following: 1) younger than 2.5 years old (yo) with pre-treatment (pre-tx) height (ht) more than 2 standard deviations (SD) below mean and slow growth velocity OR 2) 2.5 yo or older AND one of the following: a) pre-tx 1-year ht velocity more than 2 SD below mean OR b) pre-tx ht more than 2 SD below mean and 1-year ht velocity more than 1 SD below mean, AND patient meets any of the following: 1) failed 2 pre-tx growth hormone (GH) stimulation tests (peak below 10 ng/mL), OR 2) pituitary/central nervous system (CNS) disorder (e.g., genetic defects, acquired structural abnormalities, congenital structural abnormalities) and pre-tx insulin-like growth factor-1 (IGF-1) more than 2 SD below mean. Turner syndrome: 1) Confirmed by karyotyping AND 2) pre-tx ht is less than the 5th percentile for age. Small for gestational age (SGA): 1) Birth weight (wt) less than 2500g at gestational age (GA) greater than 37 weeks, OR birth wt or length below 3rd percentile for GA or at least 2 SD below mean for GA, AND 2) did not manifest catch-up growth by age 2.
<b>Age Restrictions</b>	SGA: 2 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist, pediatric endocrinologist, nephrologist, infectious disease specialist, gastroenterologist/nutritional support specialist, or geneticist.
<b>Coverage Duration</b>	Plan Year

PA Criteria	Criteria Details
Other Criteria	Adult GHD: Pt meets any of the following: 1) failed 2 pre-tx GH stimulation tests, OR 2) pre-tx IGF-1 more than 2 SD below mean AND failed 1 pre-tx GH stimulation test. (Note: Stimulation tests include: a) insulin tolerance test [ITT] [peak GH less than or equal to 5 ng/ml], or b) Macrilen-stimulation test [peak GH level less than 2.8ng/ml], or c) glucagon-stimulation test [GST] [peak GH level less than or equal to 3 ng/ml] for pt with a body mass index [BMI] 25-30 kg/m2 and high pretest probability of GHD [e.g., acquired structural abnormalities] or BMI less than 25 kg/m2, or d) GST [peak GH level less than or equal to 1 ng/ml] in pt with BMI 25-30 kg/m2 and low pretest probability of GHD or BMI greater than 30 kg/m2), OR 3) organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with 3 or more pituitary hormone deficiencies AND pre-tx IGF-1 more than 2 SD below mean, OR 4) genetic or structural hypothalamic-pituitary defects, OR 5) childhood-onset GHD with congenital (genetic or structural) abnormality of the hypothalamus/pituitary/CNS. Renewal for pediatric GHD, TS, SGA, and adult GHD: Patient is experiencing improvement.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# HAEGARDA

## Products Affected

- Haegarda

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hereditary angioedema: The requested drug is being used for the prevention of acute angioedema attacks. Patient has hereditary angioedema (HAE) with C1 inhibitor deficiency or dysfunction confirmed by laboratory testing OR patient has hereditary angioedema with normal C1 inhibitor confirmed by laboratory testing. For patients with HAE with normal C1 inhibitor, EITHER 1) Patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month.
<b>Age Restrictions</b>	6 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HARVONI

## Products Affected

- Harvoni

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	3 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
<b>Coverage Duration</b>	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

# HRM-ANTICONSULSANTS

## Products Affected

- phenobarbital
- phenobarbital sodium injection solution

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization requirement only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Epilepsy
<b>Part B Prerequisite</b>	No

# HRM-ANTIPARKINSON

## Products Affected

- benztropine oral
- trihexyphenidyl oral tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. EPS (extrapyramidal symptoms): 1) The patient has not tried the non-HRM alternative drug amantadine AND 2) The patient has a contraindication to the non-HRM alternative drug amantadine OR 3) The patient has tried the non-HRM alternative drug amantadine AND 4) The patient experienced an inadequate treatment response OR intolerance to the non-HRM alternative drug amantadine.</p> <p>Parkinson's: 1) The patient has tried two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HRM-CYPROHEPTADINE

## Products Affected

- cyproheptadine oral tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Pruritus, spasticity due to spinal cord injury
<b>Part B Prerequisite</b>	No

# HRM-DIPYRIDAMOLE

## Products Affected

- dipyridamole oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# HRM-GUANFACINE ER

## Products Affected

- guanfacine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HRM-GUANFACINE IR

## Products Affected

- guanfacine

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# HRM-HYDROXYZINE

## Products Affected

- hydroxyzine HCl oral tablet
- hydroxyzine pamoate oral capsule 25 mg, 50 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For anxiety: 1) The patient has tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline, or venlafaxine extended-release OR 3) The patient has not tried two of the following alternative drugs: buspirone, duloxetine, escitalopram, sertraline or venlafaxine extended-release AND 4) The patient has acute anxiety. For all indications: 1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. AND 2) If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, cyclobenzaprine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# HRM-HYPNOTICS

## Products Affected

- zolpidem oral tablet

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For insomnia: 1) The patient meets one of the following: a) the patient has a contraindication to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) OR b) The non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) has been tried AND the patient experienced an inadequate treatment response OR intolerance to the non-HRM (non-High Risk Medication) alternative drug doxepin (3 mg or 6 mg) AND 2) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient AND 3) If the patient is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, quetiapine, sertraline, clonazepam, escitalopram, alprazolam) with the requested drug, the prescriber has determined that taking multiple central nervous system (CNS) active medications is medically necessary for the patient [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls.].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) APPLIES TO GREATER THAN CUMULATIVE 90 DAYS OF THERAPY PER YEAR.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# HRM-PROMETHAZINE

## Products Affected

- promethazine injection solution
- promethazine oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. For rhinitis: 1) The patient has tried two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal AND 2) The patient experienced an inadequate treatment response OR intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HRM-SCOPOLAMINE

## Products Affected

- scopolamine base

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Excessive salivation
Part B Prerequisite	No



# HRM-SKELETAL MUSCLE RELAXANTS

## Products Affected

- cyclobenzaprine oral tablet 10 mg, 5 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) Prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for this patient. AND 2) If the patient is using one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, hydroxyzine) with the requested drug, the prescriber has determined that taking multiple anticholinergic medications is medically necessary for the patient [Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline.].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	This Prior Authorization only applies to patients 70 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HUMIRA

## Products Affected

- Humira Pen
- Humira subcutaneous syringe kit 40 mg/0.8 mL
- Humira(CF)
- Humira(CF) Pedi Crohns Starter
- Humira(CF) Pen
- Humira(CF) Pen Crohns-UC-HS
- Humira(CF) Pen Pediatric UC
- Humira(CF) Pen Psor-Uv-Adol HS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another biologic DMARD 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 only). Ulcerative colitis (UC) 5 or older (initial therapy only), PP-18 or older (initial therapy only)
<b>Prescriber Restrictions</b>	Initial therapy only for 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>	Approve through 12/31/24

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt 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. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ileocolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. FDA approve indications cont tx - must respond to tx as determined by prescriber. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). 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>	
<b>Part B Prerequisite</b>	No

# IBRANCE

## Products Affected

- Ibrance

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
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 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 with 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).</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Liposarcoma

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

# ICATIBANT

## Products Affected

- icatibant
- Sajazir

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No

# ICLUSIG

## Products Affected

- Iclusig

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Patients new to therapy with Acute lymphoblastic leukemia, Philadelphia chromosome positive or chronic myeloid leukemia-approve if the patient has tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel. GIST - approve if the patient tried all of the FDA-approved 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

## Products Affected

- Idhifa

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



# IMATINIB

## Products Affected

- imatinib

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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-18 years and older
<b>Prescriber Restrictions</b>	
<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). Metastatic melanoma-approve if the patient has c-Kit-positive advanced/recurrent or metastatic melanoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement or an FIP1L1-PDGFRα or PDGFRβ rearrangement.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Chordoma, advanced, aggressive or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic.
<b>Part B Prerequisite</b>	No

# IMBRUVICA

## Products Affected

- Imbruvica oral capsule
- Imbruvica oral suspension
- Imbruvica oral tablet 420 mg, 560 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	GVHD-1 year and older, other-18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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]). Mantle Cell Lymphoma - approve if the patient has tried one systemic regimen or is not a candidate for a systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, cytarabine, carboplatin, cisplatin, oxaliplatin, or lenalidomide) or if Imbruvica is being used in combination with rituximab prior to induction therapy (e.g., rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) or if Imbruvica is being used as induction or maintenance therapy in combination with chemotherapy. Marginal Zone Lymphoma - approve if the patient has tried at least one systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, or lenalidomide). 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, thiotepe, 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]).</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>	Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma, Marginal Zone Lymphoma, Mantle Cell Lymphoma
<b>Part B Prerequisite</b>	No

# INBRIJA

## Products Affected

- Inbrija inhalation capsule, w/inhalation device

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

# INCRELEX

## Products Affected

- Increlex

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pediatric patients with closed epiphyses
<b>Required Medical Information</b>	For growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency or growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH, patient meets all of the following prior to beginning therapy with the requested drug (new starts only): 1) height 3 or more standard deviations (SD) below the mean for children of the same age and gender AND 2) basal IGF-1 level 3 or more SD below the mean for children of the same age and gender AND 3) provocative growth hormone test showing a normal or elevated growth hormone level. For growth failure due to severe primary IGF-1 deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH, continuation of therapy: patient is experiencing improvement.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# INLYTA

## Products Affected

- Inlyta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	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).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma, Soft tissue sarcoma
Part B Prerequisite	No

# INQOVI

## Products Affected

- Inqovi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Neoplasms
Part B Prerequisite	No

# INREBIC

## Products Affected

- Inrebic

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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



# IRESSA

## Products Affected

- gefitinib

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

# ITRACONAZOLE

## Products Affected

- itraconazole oral capsule

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug will be used orally. For the treatment of onychomycosis due to dermatophytes ( <i>Tinea unguium</i> ), the diagnosis has been confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Disseminated/CNS histoplasmosis, Histoplasmosis/Coccidioidomycosis/CGD ppx: 12 mths. Others: 6 mths
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Coccidioidomycosis, Coccidioidomycosis prophylaxis in HIV infection, Cryptococcosis, Microsporidiosis, Talaromycosis (formerly Penicilliosis), Histoplasmosis prophylaxis in HIV infection, Invasive fungal infection prophylaxis in liver transplant, chronic granulomatous disease (CGD), and hematologic malignancy, Sporotrichosis, Pityriasis versicolor, Tinea versicolor, Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis.
<b>Part B Prerequisite</b>	No

# IVERMECTIN (ORAL)

## Products Affected

- ivermectin oral

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

# IVIG

## Products Affected

- Bivigam
- Flebogamma DIF intravenous solution 10 %
- Gammagard Liquid
- Gammagard S-D (IgA < 1 mcg/mL)
- Gammaked
- Gammaplex
- Gammaplex (with sorbitol)
- Gamunex-C
- Octagam
- Panzyga
- Privigen

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

# IWILFIN

## Products Affected

- Iwifin

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# JAKAFI

## Products Affected

- Jakafi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<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>	
<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>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

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

# JAYPIRCA

## Products Affected

- Jaypirca

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	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. Marginal Zone Lymphoma - approve if pt has tried at least one Bruton tyrosine kinase inhibitor.</p>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.



PA Criteria	Criteria Details
<b>Off Label Uses</b>	Richter's Transformation to Diffuse Large B-Cell Lymphoma, Marginal Zone Lymphoma
<b>Part B Prerequisite</b>	No

# KALYDECO

## Products Affected

- Kalydeco

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with Orkambi, Trikafta or Symdeko
Required Medical Information	
Age Restrictions	1 month of age and older
Prescriber Restrictions	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year
Other Criteria	CF - must have one mutation in the CFTR gene that is responsive to the requested medication.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# KETOCONAZOLE

## Products Affected

- ketoconazole oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute or chronic liver disease. Concurrent use with drugs that are contraindicated with ketoconazole tablets: dofetilide, quinidine, pimozone, cisapride, methadone, disopyramide, dronedarone, ranolazine, ergot alkaloids, irinotecan, lurasidone, oral midazolam, alprazolam, triazolam, felodipine, nisoldipine, tolvaptan, eplerenone, lovastatin, simvastatin, or colchicine.
<b>Required Medical Information</b>	The potential benefits outweigh the risks of treatment with oral ketoconazole. For systemic fungal infections, the patient has any of the following diagnoses: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis. For Cushing's syndrome: the requested drug is being prescribed for a patient who cannot tolerate surgery or where surgery has not been curative.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Cushing's syndrome
<b>Part B Prerequisite</b>	No

# KEYTRUDA

## Products Affected

- Keytruda

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Melanoma - 12 and older, Glioma-less than 18 years old, All others - 18 and older (except Merkel cell, MSI-H/dMMR tumors, large B-cell lymph, TMB-H)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Adjuvant treatment of melanoma/RCC-approve up to 1 year total, all other dx-1 year
<b>Other Criteria</b>	Part B vs Part D determination will be made at time of prior authorization review per CMS guidance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	adrenal gland tumor, anal carcinoma, extranodal NK/T-Cell Lymphoma (nasal type), Gestational trophoblastic neoplasia, mycosis fungoides/Sezary syndrome, soft tissue sarcoma, squamous cell skin cancer, thymic carcinoma, Vulvar cancer, primary cutaneous anaplastic large cell lymphoma, small cell lung cancer tumor, glioma, Kaposi sarcoma
<b>Part B Prerequisite</b>	No

# KISQALI

## Products Affected

- Kisqali
- Kisqali Femara Co-Pack

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	<p>Breast cancer - approve for hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative early (stage II or III), recurrent, or metastatic breast cancer [for early breast cancer must be adjuvant treatment and high risk of recurrence] when the pt meets ONE of the following</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 will 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>	Endometrial cancer
<b>Part B Prerequisite</b>	No

# KORLYM

## Products Affected

- Korlym
- mifepristone oral tablet 300 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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. Patients 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	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
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): 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.
Off Label Uses	Circumscribed Glioma, Langerhans Cell Histiocytosis



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

# KRAZATI

## Products Affected

- Krazati

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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>	Colon or Rectal cancer
<b>Part B Prerequisite</b>	No

# LAPATINIB

## Products Affected

- lapatinib

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<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/peri-menopausal women and men

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

# LAZCLUZE

## Products Affected

- Lazcluze

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

# LENALIDOMIDE

## Products Affected

- lenalidomide

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	<p>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. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve. 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 regimens. 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. Histiocytic neoplasms-approve if the patient has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman disease.</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>	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, histiocytic neoplasms.
<b>Part B Prerequisite</b>	No

# LENVIMA

## Products Affected

- Lenvima

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	<p>DTC - must be refractory to radioactive iodine treatment for approval. RCC - approve if the pt meets ALL of the following criteria: 1) pt has advanced disease AND if the patient meets i or ii-i. Lenvima is is being used in combination with Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b-a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that is mismatch repair proficient (pMMR) or 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. HCC-approve if the patient has unresectable or metastatic disease. Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. Melanoma - approve if the patient has unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy. Anaplastic thyroid carcinoma-approve if the medication is used in combination with Keytruda (pembrolizumab intravenous infusion).</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>	Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Melanoma, Anaplastic thyroid carcinoma
<b>Part B Prerequisite</b>	No

# LIBERVANT

## Products Affected

- Libervant

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	2 to 5 years of age
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# LIDOCAINE PATCH

## Products Affected

- DermacinRx Lidocan
- lidocaine topical adhesive patch,medicated 5 %
- Lidocan III
- Lidocan IV
- Lidocan V
- Tridacaine II

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

# LONG ACTING OPIOIDS

## Products Affected

- Hysingla ER
- Methadone IntenSol
- methadone oral concentrate
- methadone oral solution
- methadone oral tablet
- morphine oral tablet extended release

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute (ie, non-chronic) pain
<b>Required Medical Information</b>	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, in hospice, sickle cell disease or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LONSURF

## Products Affected

- Lonsurf

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	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 fluoropyrimidine, oxaliplatin, irinotecan and if the patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# LORBRENA

## Products Affected

- Lorbrena

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, ALK status, ROS1 status, previous therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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

## Products Affected

- Lumakras

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	<p>Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Ampullary adenocarcinoma - approve if pt has KRAS G12C-mutated disease as determined by an approved test AND this is used as subsequent therapy. Colon or rectal cancer - approve if pt meets all (A, B, C and D): A) unresectable, advanced, or metastatic disease, and B) KRAS G12C mutation-positive disease, and C) medication is prescribed as part of a combination regimen for colon or rectal cancer [Ex: Lumakras plus cetuximab or panitumumab] or patient is unable to tolerate combination therapy, and D) previously received a chemotherapy regimen for colon or rectal cancer. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease, as determined by an approved test AND either (i or ii): (i) patient has locally advanced or metastatic disease and has been previously treated with at least one systemic regimen OR (ii) patient has recurrent disease after resection.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Colon or Rectal Cancer
<b>Part B Prerequisite</b>	No

# LUMIZYME

## Products Affected

- Lumizyme

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No



# LUPRON DEPOT 7.5MG

## Products Affected

- Lupron Depot

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Premenstrual disorders - 18 years and older
<b>Prescriber Restrictions</b>	Prostate cancer-prescr/consult with oncologist or urologist. For the treatment of other cancer diagnosis must be prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	uterine leiomyomata 3 mo.All other=12 mo
<b>Other Criteria</b>	For a diagnosis of prostate cancer, patients are required to try Orgovyx or Eligard prior to approval. Premenstrual disorders including PMS and PMDD- approve if pt has severe refractory premenstrual symptoms AND pt has tried an SSRI or combined oral contraceptive.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Ovarian cancer including fallopian tube and primary peritoneal cancer, breast cancer, prophylaxis or treatment of uterine bleeding or menstrual suppression in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors, premenstrual disorders including premenstrual syndrome and premenstrual dysphoric disorder, uterine cancer
<b>Part B Prerequisite</b>	No

# LYNPARZA

---

## Products Affected

- Lynparza

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient meets one of the following criteria (A or B): A) The patient meets both of the following criteria for first-line maintenance therapy (i and ii): i. The patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND ii. The patient is in complete or partial response to first-line platinum-based chemotherapy regimen (e.g., carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin) OR B) The patient is in complete or partial response after at least two platinum-based chemotherapy regimens (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 patient has had a bilateral orchiectomy, and the patient meets either (i or ii): i) the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test and the patient has been previously treated with at least one androgen receptor directed therapy or ii) the patient has a BRCA mutation and the medication is used in combination with abiraterone plus one of prednisone or prednisolone. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried 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

# LYRICA CR

## Products Affected

- Lyrica CR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Approve if patient is already taking pregabalin CR (brand or generic) OR the patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to gabapentin
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LYTGOBI

## 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)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# MEGESTROL

## Products Affected

- megestrol oral suspension 625 mg/5 mL (125 mg/mL)

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

# MEKINIST

---

## Products Affected

- Mekinist

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations
Age Restrictions	1 year and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Tafenlar (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 Tafenlar (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 Tafenlar.</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

## Products Affected

- Mektovi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, BRAF V600 status, concomitant medications
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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

# MEMANTINE

## Products Affected

- memantine oral capsule, sprinkle, ER 24hr
- memantine oral solution
- memantine oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Indication for which memantine is being prescribed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	This Prior Authorization requirement only applies to patients 25 years of age and younger
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with mild to moderate vascular dementia.
Part B Prerequisite	No

# METHYLPHENIDATE

## Products Affected

- methylphenidate HCl oral solution
- methylphenidate HCl oral tablet
- methylphenidate HCl oral tablet extended release
- methylphenidate HCl oral tablet, chewable

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) OR 2) The patient has a diagnosis of narcolepsy confirmed by a sleep study OR 3) The requested drug is being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# MODAFINIL/ARMODAFINIL

## Products Affected

- armodafinil
- modafinil

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<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 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 (modafinil only). Adjunctive/augmentation for treatment of depression in adults (modafinil only).
<b>Part B Prerequisite</b>	No

# MONJUVI

## Products Affected

- Monjuvi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 Year
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Diffuse large B-Cell Lymphoma - Approve if the patient meets the following criteria: Patient has been treated with at least one prior chemotherapy regimen AND the patient is not eligible for autologous stem cell transplant AND Monjuvi will be used in combination with Revlimid (lenalidomide) OR Patient has already received 12 cycles of Monjuvi. B-cell lymphoma - Approve if the patient meets the following criteria: Patient has been treated with at least one prior chemotherapy regimen AND the patient is not eligible for autologous stem cell transplant AND Monjuvi will be used in combination with Revlimid (lenalidomide) OR Patient has already received 12 cycles of Monjuvi.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	B-Cell lymphoma
<b>Part B Prerequisite</b>	No

# NAGLAZYME

## Products Affected

- Naglazyme

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No

# NERLYNX

## Products Affected

- Nerlynx

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<b>Coverage Duration</b>	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>	
<b>Part B Prerequisite</b>	No

# NINLARO

## Products Affected

- Ninlaro

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	MM - be used in combination with lenalidomide or cyclophosphamide OR pt had received at least ONE previous therapy for multiple myeloma OR the agent will be used following autologous stem cell transplantation (ASCT). Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma-approve if used in combination with a rituximab product and dexamethasone (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan).
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma
Part B Prerequisite	No



# NITISINONE

## Products Affected

- nitisinone

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant therapy with nitisinone products
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	HereditaryTyrosinemia, Type 1-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the FAH gene OR elevated levels of succinylacetone.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<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 %), 20.25 mg/1.25 gram (1.62 %)
- testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<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-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>PA Criteria</b>	<b>Criteria Details</b>
<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

# NOXAFIL SUSP

## Products Affected

- Noxafil oral suspension
- posaconazole oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	The requested drug will be used orally. For treatment of oropharyngeal candidiasis: patient has experienced an inadequate treatment response, intolerance, or has a contraindication to fluconazole.
<b>Age Restrictions</b>	13 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Oropharyngeal candidiasis: 1 month. All other indications: 6 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NUBEQA

## Products Affected

- Nubeqa

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

# NUEDEXTA

## Products Affected

- Nuedexta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# NUPLAZID

## Products Affected

- Nuplazid

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

# NURTEC

## Products Affected

- Nurtec ODT

PA Criteria	Criteria Details
<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>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Migraine, Acute treatment-approve. 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>	
<b>Part B Prerequisite</b>	No



# OCALIVA

## Products Affected

- Ocaliva

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

# OCREVUS

## Products Affected

- Ocrevus

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other Disease-Modifying Agents used for MS
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age and older (initial/continuation)
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a physician who specializes in the treatment of MS and/or a neurologist (initial/continuation)
<b>Coverage Duration</b>	1 Year
<b>Other Criteria</b>	Relapsing forms of MS-Patients new to therapy-approve if the patient had a trial with generic dimethyl fumarate prior to approval of Ocrevus. (Note: Prior treatment with Tecfidera, Bafiertam or Vumerity also counts. Also, a patient who has previously tried a glatiramer product (Copaxone, Glatopa, generic) or Lemtrada, Tysabri or Kesimpta can bypass the requirement of a trial of generic dimethyl fumarate). Continuation-approve if the patient has responded to therapy. Primary progressive MS-approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# OCTREOTIDE INJECTABLE

## Products Affected

- octreotide acetate

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-presc/consult with oncologist
<b>Coverage Duration</b>	Enterocutaneous fistula - 3 months, all others - 1 year
<b>Other Criteria</b>	Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. Patient has had an inadequate response to surgery and/or radiotherapy OR ii. Patient is NOT an appropriate candidate for surgery and/or radiotherapy OR iii. Patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND Patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma, enterocutaneous fistulas
<b>Part B Prerequisite</b>	No

# ODOMZO

## Products Affected

- Odomzo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<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
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age and older
Prescriber Restrictions	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.
Coverage Duration	1 year
Other Criteria	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. Interstitial lung disease associated with systemic sclerosis-approve if the FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography. Chronic fibrosing interstitial lung disease-approve if the forced vital capacity is greater than or equal to 45 percent of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10 percent of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# OGSIVEO

## Products Affected

- Ogsiveo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Desmoid tumors (aggressive fibromatosis)-approve if the patient has progressing desmoid tumors, the desmoid tumors are not amenable to surgery or radiotherapy and if the patient requires systemic treatment. Note: Progressing desmoid tumors are defined as greater than or equal to 20 percent progression within 12 months
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# OJEMDA

## Products Affected

- Ojemda

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	6 months of age and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# OJJAARA

## Products Affected

- Ojjaara

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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 or b) the patient has platelet count greater than or equal to 50x10 <sup>9</sup> /L.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No



# OMNIPOD

## Products Affected

- Omnipod 5 G6-G7 Intro Kit(Gen5)
- Omnipod 5 G6-G7 Pods (Gen 5)
- Omnipod Classic PDM Kit(Gen 3)
- Omnipod Classic Pods (Gen 3)
- Omnipod Dash Intro Kit (Gen 4)
- Omnipod Dash Pods (Gen 4)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: 1) The patient has diabetes requiring insulin management with multiple daily injections AND 2) The patient is self-testing glucose levels 2 or more times per day OR the patient is using a continuous glucose monitor AND 3) For patients with Type 2 diabetes: The patient has a history of problematic hypoglycemia defined as 1) Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan OR 2) A history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia. Continuation: the patient has stable or improved glycemic control.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# OMNIPOD-GO

## Products Affected

- Omnipod Go Pods
- Omnipod Go Pods 10 units/day
- Omnipod Go Pods 15 units/day
- Omnipod Go Pods 20 units/day
- Omnipod Go Pods 25 units/day
- Omnipod Go Pods 30 units/day

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial- The patient has Type 2 diabetes requiring basal insulin management. Continuation- The patient has stable or improved glycemic control
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# ONUREG

## Products Affected

- Onureg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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 declined or is not fit or eligible for allogeneic hematopoietic stem cell transplant. Peripheral T-cell lymphoma - all of (A, B, and C): A) relapsed or refractory disease, and B) pt has one of the following (i, ii or iii): i) angioimmunoblastic T-cell lymphoma, or ii) nodal peripheral T-cell lymphoma with T-follicular helper (TFH) phenotype, or iii) follicular T-cell lymphoma, and C) medication is used as a single agent.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Peripheral T-cell lymphoma
<b>Part B Prerequisite</b>	No

# OPSUMIT

## Products Affected

- Opsumit

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

# ORGOVYX

## Products Affected

- Orgovyx

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Prostate Cancer-approve.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# ORKAMBI

## Products Affected

- Orkambi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with Kalydeco, Trikafta or Symdeko.
<b>Required Medical Information</b>	
<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 - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation)
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORSERDU

## Products Affected

- Orserdu

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No

# OTEZLA

## Products Affected

- Otezla
- Otezla Starter oral tablets,dose pack 10 mg (4)-20 mg (51), 10 mg (4)-20 mg (4)-30 mg (47)

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>	Approve through 12/31/24
<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-approve. Behcet's-patient has oral ulcers or other mucocutaneous involvement AND patient has tried at least ONE other systemic therapy. PsA/PP/Behcet's cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# PANRETIN

## Products Affected

- Panretin

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

# PEGASYS

## Products Affected

- Pegasys

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For chronic hepatitis C: Hepatitis C virus (HCV) confirmed by presence of hepatitis C virus HCV RNA in serum prior to starting treatment and the planned treatment regimen.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	HCV 12-48wks. Criteria applied consistent w/current AASLD/IDSA guidance. HBV 48wks. Other Plan Yr
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis), systemic mastocytosis, adult T-cell leukemia/lymphoma, mycosis fungoides/sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders, hairy cell leukemia, Erdheim-Chester disease.
<b>Part B Prerequisite</b>	No

# PEMAZYRE

## Products Affected

- Pemazyre

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No

# PHENYLBUTYRATE

## 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>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
<b>Coverage Duration</b>	Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval
<b>Other Criteria</b>	Urea cycle disorders-approve if genetic or enzymatic testing confirmed a urea cycle disorder or if the patient has hyperammonemia diagnosed with an ammonia level above the upper limit of the normal reference range for the reporting laboratory.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PHEOCHROMOCYTOMA

## Products Affected

- metyrosine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, prior medication trials
<b>Age Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No

# PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

## Products Affected

- Alyq
- sildenafil (pulm.hypertension) oral tablet
- tadalafil (pulm. hypertension)
- Tadiq

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>	
<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>	
<b>Part B Prerequisite</b>	No

# PIQRAY

## Products Affected

- Piqray

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

# PIRFENIDONE

## Products Affected

- pirfenidone oral capsule
- pirfenidone oral tablet 267 mg, 801 mg
- pirfenidone oral tablet 534 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No



# POMALYST

## Products Affected

- Pomalyst

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Kaposi Sarcoma/MM-18 years and older
<b>Prescriber Restrictions</b>	
<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

# POSACONAZOLE (ORAL)

## Products Affected

- posaconazole oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Aspergillus/Candida prophylaxis, mucormycosis-6 mo, all others-3 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	mucomycosis - maintenance, fusariosis, invasive - treatment fungal infections (systemic) in patients with human immunodeficiency virus (HIV) infections (e.g., histoplasmosis, coccidioidomycosis) - treatment.
<b>Part B Prerequisite</b>	No

# PRALUENT

## Products Affected

- Praluent Pen

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of Leqvio or Repatha.
<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>	8 years of age and older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Hyperlipidemia in patients with HeFH -approve if meets all of the following 1. Pt has been diagnosed with 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 3. LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during d/c. Hyperlipidemia Pt with Clinical ASCVD-approve if meets all of the following: 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 tried ONE high intensity statin (as defined above) AND LDL-C remains greater than or equal to 55 mg/dL unless the pt is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during d/c. Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the patient has tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 70mg/dL or higher unless statin intolerant (defined above).
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PREVYMIS

## Products Affected

- Prevymis oral

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For prophylaxis of cytomegalovirus (CMV) infection or disease in allogeneic hematopoietic stem cell transplant (HSCT) recipients: 1) the patient is CMV-seropositive, AND 2) the requested drug will not be used beyond day 100 post-transplantation. For prophylaxis of CMV disease in kidney transplant recipients: 1) the donor is CMV seropositive (D+), 2) the patient/recipient is CMV seronegative (R-), AND 3) the requested drug will not be used beyond day 200 post-transplantation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PROMACTA

## Products Affected

- Promacta

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<b>Prescriber Restrictions</b>	Immune Thrombocytopenia or Aplastic Anemia, prescribed by, or after consultation with, a hematologist (initial therapy). Hep C if prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease (initial therapy). MDS-presc or after consult with heme/onc (initial therapy). Post-transplant, prescribed by or in consult with a hematologist, oncologist or stem cell transplant specialist physician (initial)
<b>Coverage Duration</b>	ImmuneThrombo/MDS init3mo,cont1yr,AAinit4mo,cont1yr,Thrombo/HepC1yr,Transplant- init3mo,cont6mo

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Thrombocytopenia in patients with immune thrombocytopenia, initial-approve if the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy or has undergone a splenectomy. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Treatment of thrombocytopenia in patients with Chronic Hepatitis C initial-approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND to allow for initiation of antiviral therapy if the patient has low platelet counts at baseline (eg, less than 75,000 microliters). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000 microliters) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate mofetil, sirolimus) OR patient will be using Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Thrombocytopenia post-allogeneic transplantation, initial - approve if, according to the prescriber, the patient has poor graft function AND has a platelet count less than 50,000/mcL. Cont- patient demonstrated a beneficial clinical response.</p>
<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

# QINLOCK

## Products Affected

- Qinlock

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, other therapies tried
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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



# QUETIAPINE XR

## Products Affected

- quetiapine oral tablet extended release 24 hr

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex, the acute treatment of depressive episodes associated with bipolar disorder, maintenance treatment of bipolar I disorder, as an adjunct to lithium or divalproex, adjunctive treatment of major depressive disorder, or maintenance monotherapy treatment in bipolar I disorder: The patient experienced an inadequate treatment response, intolerance, or contraindication to one of the following generic products: A) aripiprazole, B) asenapine, C) olanzapine, D) quetiapine immediate-release, E) risperidone, F) ziprasidone. For all indications: If the patient is 65 years of age or older AND is using two or more additional central nervous system (CNS) active medications (e.g., lorazepam, sertraline, clonazepam, escitalopram, alprazolam, zolpidem) with the requested drug, the prescriber determined that taking multiple central nervous system (CNS) active medications is medically necessary. [Note: Use of multiple central nervous system (CNS) active medications in older adults is associated with an increased risk of falls.].
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Maintenance monotherapy treatment in bipolar I disorder, monotherapy treatment of generalized anxiety disorder, monotherapy treatment of major depressive disorder

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

# QUININE SULFATE

## Products Affected

- quinine sulfate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 month
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Babesiosis, uncomplicated Plasmodium vivax malaria.
Part B Prerequisite	No

# RADICAVA ORS

## Products Affected

- Radicava ORS
- Radicava ORS Starter Kit Susp

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	ALSFRS-R score, FVC %, time elapsed since diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS (initial and continuation).
<b>Coverage Duration</b>	Initial, 6 months. Continuation, 6 months
<b>Other Criteria</b>	ALS, initial therapy - approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, based on the application of the El Escorial or the revised Airlie house diagnostic criteria AND 2. Patient has a score of two points or more on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. Patient has a percent predicted FVC greater than or equal to 80% (ie, has normal respiratory function), AND 4. Patient has been diagnosed with ALS for less than or equal to 2 years. 5. Patient has received or is currently receiving riluzole tablets. 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>	
<b>Part B Prerequisite</b>	No

# RELISTOR INJ

## Products Affected

- Relistor subcutaneous solution
- Relistor subcutaneous syringe

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the treatment of opioid-induced constipation in a patient with chronic non-cancer pain, including chronic pain related to prior cancer or its treatment who does not require frequent (e.g., weekly) opioid dosage escalation: 1) the patient is unable to tolerate oral medications OR 2) the patient meets one of the following criteria A) experienced an inadequate treatment response or intolerance to an oral drug indicated for opioid-induced constipation in a patient with chronic non-cancer pain (e.g., Movantik) OR B) the patient has a contraindication that would prohibit a trial of an oral drug indicated for opioid-induced constipation in a patient with chronic non-cancer pain (e.g., Movantik).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	4 months
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# REMICADE

## Products Affected

- Remicade

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 Ulcerative Colitis. 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 consult w/RA/AS/Still's/JIA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's- rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarcoidosis-pulmonol, ophthalmol, or dermatol.
<b>Coverage Duration</b>	FDAind ini-3 mo,cont1yr,GVHD ini-1 mo,cont-3 mo,Pyo Gang-ini4 mo,cont1 yr,others-ini 3mo,cont-12 mo

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 for RA are not required to step back and try a conventional synthetic DMARD). CD approve if the pt has tried corticosteroid (CS) or if CSs contraindicated or if currently on CS or if the patient has tried one other conventional systemic therapy for CD OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had ileocolonic resection. Note-a previous trial of a biologic also counts as a trial of one other agent for CD. Ulcerative colitis (UC). Tried one systemic agent or was intolerant to one of these agents OR the patient has pouchitis AND has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Note-a previous trial of a biologic also counts as a trial of one systemic agent for UC. Behcet's. Pt has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa). NOTE: An exception to the requirement for a trial of one conventional therapy can be made if the patient has already had a trial of at least one tumor necrosis factor for Behcet's disease. These patients who have already tried a biologic for Behcet's disease are not required to "step back" and try a conventional therapy) OR has ophthalmic manifestations. SD. Tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant. UV. Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab. Sarcoidosis. Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. Pyoderma gangrenosum (PG). Tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents. Hidradenitis suppurativa (HS). Tried 1 tx (eg, intralesional/oral CS, systemic antibiotic, isotretinoin). GVHD. Tried one conventional systemic treatment (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.). JIA (regardless of type of onset) approve if pt has tried 1 other agent for this condition (eg, MTX, sulfasalazine, or leflunomide, an NSAID, or one biologic DMARD [eg, Humira, Orencia, Enbrel, Kineret, Actemra]) or the pt has aggressive disease. PP- approve if the patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant or the patient has a contraindication to methotrexate (MTX), as determined by the</p>
	<p>prescriber. Note-a previous trial of a biologic also counts as a trial of a systemic agent. cont tx - approve if patient has had a response, as determined by the prescriber. For all covered diagnoses, if the request is for infliximab a trial of Remicade is required prior to approval</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<b>Off Label Uses</b>	Patients already started on infliximab for a covered use plus Behcet's Disease, Still's Disease, Uveitis, Pyoderma gangrenosum (PG), Hidradenitis suppurativa (HS), Graft-versus-host disease (GVHD), Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis
<b>Part B Prerequisite</b>	No



# RETEVMO

## Products Affected

- Retevmo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors-2 years and older, all others 18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has recurrent, advanced or metastatic disease AND the tumor is RET fusion-positive. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion positive or RET mutation positive disease or RET pathogenic variant AND the patient meets i 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

# REZLIDHIA

## Products Affected

- Rezlidhia

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# REZUROCK

## Products Affected

- Rezurock

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	12 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# RINVOQ

## Products Affected

- Rinvoq

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic DMARD, Concurrent use with other potent immunosuppressants, Concurrent use with an anti-interleukin monoclonal antibody, Concurrent use with other janus kinase inhibitors, or concurrent use with a biologic immunomodulator.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	PsA - 2 years and older (initial therapy), RA/UC/AS/CD-18 years and older (initial therapy), AD-12 years and older (initial therapy)
<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 dermatologist. UC/CD-prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	Approve through 12/31/24
<b>Other Criteria</b>	RA/PsA/UC/AS/CD/JIA initial-approve if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AD-approve if the patient has had a 3 month trial of at least one traditional systemic therapy or has tried at least one traditional systemic therapy but was unable to tolerate a 3 month trial. Note: 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 Therapy - Patient must have responded, as determined by the prescriber
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ROZLYTREK

## Products Affected

- Rozlytrek

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

# RUBRACA

## Products Affected

- Rubraca

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<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>Off Label Uses</b>	Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma

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



# RUFINAMIDE

## Products Affected

- rufinamide

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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

## Products Affected

- Rydapt

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For AML, FLT3 status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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

# SAPROPTERIN

## Products Affected

- sapropterin

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Palynziq
<b>Required Medical Information</b>	Diagnosis, Phe concentration
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)
<b>Coverage Duration</b>	Initial-12 weeks, Continuation-1 year
<b>Other Criteria</b>	Initial - approve. Continuation (Note-if the patient has received less than 12 weeks of therapy or is restarting therapy with sapropterin should be reviewed under initial therapy) - approve if the patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescribing physician OR patient had a 20 percent or greater reduction in blood Phe concentration from baseline OR treatment with sapropterin has resulted in an increase in dietary phenylalanine tolerance.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SAVELLA

## Products Affected

- Savella

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to duloxetine or pregabalin.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# SCSEMBLIX

## Products Affected

- Scemblix

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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 Tasigna (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

## Products Affected

- Signifor

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<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>	
<b>Part B Prerequisite</b>	No

# SIRTURO

## Products Affected

- Sirturo

PA Criteria	Criteria Details
<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 or Mycobacterium tuberculosis resistant to at least rifampin and isoniazid, and the requested medication is prescribed as part of a combination regimen with other anti-tuberculosis agents
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<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
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	Diagnosis, Previous medication use
Age Restrictions	PP/UC-18 years of age and older (initial therapy)
Prescriber Restrictions	PP-Prescribed by or in consultation with a dermatologist (initial therapy), PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy), CD/UC-presc/consult-gastro
Coverage Duration	Approve through 12/31/24



PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>PP-Initial-meets 1 of the following conditions (a or b):a)tried at least 1 traditional systemic agent for psoriasis (e.g.,MTX, cyclosporine, acitretin tablets, or PUVA) for at least 3 mos,unless intolerant.NOTE:An exception to the requirement for a trial of 1 traditional systemic agent can be made if pt has already had a 3-mo trial or previous intol to at least 1 biologic(e.g.,adalimumab product, certolizumab pegol product, etanercept product, infliximab product, Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Stelara [ustekinumab SC injection], Taltz [ixekizumab SC injection], or Tremfya [guselkumab SC injection]).Pts who have already tried a biologic for psoriasis are not required to step back and try a traditional systemic agent)b)pt has contraindication to MTX, as determined by the prescribing physician.Cont-Pt responded, as determined by the prescriber.UC, Initial-meets ALL of the following (i and ii): i.pt will receive 3 induction doses with Skyrizi IV within 3 mos of initiating therapy with Skyrizi subcutaneous, AND ii.meets 1 of the following (a or b): a)Pt has had a trial of 1 systemic agent for UC,Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or corticosteroid such as prednisone, methylprednisolone.A trial of a mesalamine product does not count as a systemic therapy for UC.A trial of 1 biologic other than the requested drug also counts as a trial of 1 systemic agent for UC.A biosim of requested biologic does not count.OR b)Pt meets BOTH of the following [1 and 2]: 1.Pt has pouchitis, AND 2.Pt has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema.Note: Examples of antibiotics include metronidazole and ciprofloxacin.Examples of corticosteroid enemas include hydrocortisone enema.Cont-Pt responded, as determined by the prescriber.Psoriatic arthritis (initial)-approve. Cont-pt responded as determined by the prescriber. CD, initial-pt has tried or is currently taking corticosteroids, or corticosteroids are contraindicated or if pt has tried 1 other conventional systemic therapy for CD (Please note: Examples of conventional systemic therapy for CD include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the pt has already tried at least 1 biologic other than the requested medication. A biosim of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for CD.) or if pt has enterocutaneous (perianal or abdominal) or</p>
	<p>rectovaginal fistulas or if pt had ileocolonic resection (to reduce the chance of CD recurrence). Pts must be receiving an induction dosing with Skyrizi IV within 3 month of initiating therapy with Skyrizi subcutaneous. Cont-pt must have responded as determined by the prescriber.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# SOMATULINE DEPOT

## Products Affected

- lanreotide subcutaneous syringe 120 mg/0.5 mL
- Somatuline Depot

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, previous treatments/therapies
<b>Age Restrictions</b>	
<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)

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

# SOMAVERT

## Products Affected

- Somavert

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, previous therapy, concomitant therapy
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. patient has had an inadequate response to surgery and/or radiotherapy OR ii. The patient 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) AND patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender for the reporting laboratory.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SORAFENIB

## Products Affected

- sorafenib

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
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, Hurthle) 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>
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<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>	Yes

# SPRYCEL

## Products Affected

- dasatinib
- Sprycel

PA Criteria	Criteria Details
Exclusion Criteria	UNDER CMS REVIEW
Required Medical Information	UNDER CMS REVIEW
Age Restrictions	UNDER CMS REVIEW
Prescriber Restrictions	UNDER CMS REVIEW
Coverage Duration	UNDER CMS REVIEW
Other Criteria	UNDER CMS REVIEW
Indications	UNDER CMS REVIEW
Off Label Uses	UNDER CMS REVIEW
Part B Prerequisite	No



# STELARA

---

## Products Affected

- Stelara subcutaneous

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	PP-6 years and older (initial therapy).
<b>Prescriber Restrictions</b>	Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy).
<b>Coverage Duration</b>	Approve through 12/31/24

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>PP initial - Approve Stelara SC if the patient has tried one traditional systemic agent for psoriasis for at least 3 months unless intolerant or if the patient has a contraindication to methotrexate. Note: Examples of traditional systemic agents used for psoriasis include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. CD, induction therapy - approve single dose of IV formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumab, infliximab) OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). CD, initial therapy subcutaneous (only after receiving single IV loading dose within 2 months of initiating therapy with Stelara SC) - approve the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one conventional systemic therapy for CD OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). UC, induction therapy, approve if the patient has tried one systemic agent for ulcerative colitis or if the patient has pouchitis and has tried an antibiotic, probiotic, corticosteroid enema or mesalamine enema. UC, initial therapy subcutaneous-before the SC formulation can be approved the patient must have received a single IV loading dose within 2 months of initiating therapy with Stelara SC and try one systemic agent for ulcerative colitis or if the patient has pouchitis and has tried an antibiotic, probiotic, corticosteroid enema or mesalamine enema. PP/PsA/CD/UC cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# STIVARGA

## Products Affected

- Stivarga

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<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, solitary fibrous tumor, or pleomorphic rhabdomyosarcoma. Osteosarcoma/Ewing Sarcoma-approve if the patient has relapsed/refractory or metastatic disease and the patient has tried one systemic chemotherapy regimen. Colon and Rectal 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) 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, Osteosarcoma/Ewing Sarcoma, Glioblastoma, Appendiceal cancer
<b>Part B Prerequisite</b>	No

# SUCRAID

## Products Affected

- Sucraid

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results (as specified in the Other Criteria field)
<b>Age Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No

# SUNITINIB

## Products Affected

- sunitinib malate

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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), clear cell or non-clear cell histology-approve if the patient is at high risk of recurrent clear cell RCC following nephrectomy and Sutent is used for adjuvant therapy or 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.
<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 Hurthle) 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.

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

# SYMDEKO

## Products Affected

- Symdeko

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with unknown CFTR gene mutations, Combination therapy with Orkambi, Kalydeco or Trikafta
<b>Required Medical Information</b>	Diagnosis, specific CFTR gene mutations
<b>Age Restrictions</b>	Six years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	CF - must be homozygous for the F508del mutation or have at least one mutation in the CFTR gene that is responsive to the requested medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TABRECTA

## Products Affected

- Tabrecta

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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



# TAFAMIDIS

## Products Affected

- Vyndaqel

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with Onpattro or Tegsedi. 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>	
<b>Part B Prerequisite</b>	No

# TAFINLAR

## Products Affected

- Tafinlar

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Tafinlar is being used. BRAF V600 mutations
Age Restrictions	1 year and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC, must have BRAF V600E mutation. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafenlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease. 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 Mekinist. 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 metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets). 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 AND patient has BRAF V600-mutation positive disease. Metastatic or solid tumors-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets) AND patient has no satisfactory alternative treatment options. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer-approve if the patient meets the following (A, B, and C): A) Patient has recurrent disease, AND B) Patient has BRAF V600 mutation-positive disease, AND C) The medication will be taken in combination with Mekinist (trametinib tablets). 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 Mekinist.</p>
<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

# TAGRISSEO

## Products Affected

- Tagrisso

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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 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.</p> <p>NSCLC-EGFR T790M mutation positive-approve if the patient has advanced or metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors.</p> <p>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> <p>NSCLC- Unresectable Stage III - approve if the patient has locally advanced, unresectable (stage III) disease AND EGFR exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an approved test AND not had disease progression during or following platinum-based chemoradiation therapy. (Note: Patients could have received concurrent or sequential chemoradiation therapy.)</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# TALTZ

## Products Affected

- Taltz Autoinjector
- Taltz Autoinjector (2 Pack)
- Taltz Autoinjector (3 Pack)
- Taltz Syringe

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis, Previous medication use
<b>Age Restrictions</b>	PP-6 years and older (initial therapy), all other dx-18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	All dx initial therapy only-PP-Prescribed by or in consultation with a dermatologist. PsA prescribed by or in consultation with a rheumatologist or a dermatologist. AS/spondylo -prescribed by or in consultation with a rheum.
<b>Coverage Duration</b>	Approve through 12/31/24
<b>Other Criteria</b>	Initial Therapy - Plaque Psoriasis-approve if the patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant OR the patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic. PsA Initial-Approve. AS initial-approve. Non-Radiographic Axial Spondyloarthritis-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or sacroiliitis reported on magnetic resonance imaging. Continuation Therapy - approve if the patient has responded, as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TALVEY

## Products Affected

- Talvey

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

# TALZENNA

## Products Affected

- Talzenna

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



# TASIGNA

## Products Affected

- Tasigna

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older, ALL - 15 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Patients new to therapy with Acute lymphoblastic leukemia, philadelphia chromosome positive or chronic myeloid leukemia- approve if the patient has tried Sprycel and had an inadequate response or significant intolerance or have a contraindication or are not a candidate for Sprycel. 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

## Products Affected

- tazarotene topical cream 0.1 %
- tazarotene topical gel
- Tazorac topical cream 0.05 %

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Cosmetic uses
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TAZVERIK

## Products Affected

- Tazverik

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

# TECENTRIQ

## Products Affected

- Tecentriq

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For urothelial carcinoma, patient meets one of the following criteria: 1) Patient is ineligible for cisplatin therapy and tumors express PD-L1 (defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5 percent of the tumor area) OR 2) Patient is ineligible for any platinum containing chemotherapy. For non-small cell lung cancer (NSCLC): 1) the patient has recurrent, advanced or metastatic disease AND the requested drug will be used as any of the following: a) first-line treatment of tumors with high PD-L1 expression (defined as PD-L1 stained greater than or equal to 50 percent of tumor cells or PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 10 percent of the tumor area) and no EGFR or ALK genomic tumor aberrations, b) used in combination with carboplatin, paclitaxel, and bevacizumab, or in combination with carboplatin and albumin-bound paclitaxel for nonsquamous NSCLC, or c) the requested drug will be used as subsequent therapy or continuation maintenance therapy, OR 2) the patient has stage II to IIIA disease AND the requested drug will be used as adjuvant treatment following resection and platinum-based chemotherapy for tumors with PD-L1 expression on greater than or equal to 1 percent of tumor cells. For hepatocellular carcinoma, the requested drug will be used as initial treatment in combination with bevacizumab.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<b>Off Label Uses</b>	Recurrent non-small cell lung cancer, single agent maintenance for extensive small cell lung cancer following combination treatment with etoposide and carboplatin, urothelial carcinoma.
<b>Part B Prerequisite</b>	No

# TEMAZEPAM

## Products Affected

- temazepam oral capsule 15 mg, 30 mg, 7.5 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For short-term treatment of insomnia: 1) The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) AND 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	This Prior Authorization only applies to patients 65 years of age or older.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# TEPMETKO

## Products Affected

- Tepmetko

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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

# TERIPARATIDE

## Products Affected

- Forteo
- teriparatide subcutaneous pen injector 20 mcg/dose (620mcg/2.48mL)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<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 hypogondal 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 have already taken teriparatide for 2 years - approve if the patient is at high risk for fracture.



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

# TETRABENAZINE

## Products Affected

- tetrabenazine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<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

# TETRACYCLINE

## Products Affected

- tetracycline oral capsule

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient will use the requested drug orally.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# THALOMID

## Products Affected

- Thalomid

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	MM, myelofibrosis, histiocytic neoplasms-18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). 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 and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). Histiocytic neoplasms-approve if pt has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman cutaneous disease.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<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, histiocytic neoplasms.
<b>Part B Prerequisite</b>	No

# TIBSOVO

## Products Affected

- Tibsovo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, IDH1 Status
<b>Age Restrictions</b>	All diagnoses (except chondrosarcoma)-18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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).</p> <p>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.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Chondrosarcoma, Central nervous system cancer
<b>Part B Prerequisite</b>	No

# TOBRAMYCIN (NEBULIZATION)

## Products Affected

- tobramycin in 0.225 % NaCl

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

# 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>	
<b>Coverage Duration</b>	Authorization will be for 30 days
<b>Other Criteria</b>	Hyponatremia - 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# TOPICAL LIDOCAINE

## Products Affected

- Glydo (40 mg/mL)
- lidocaine HCl laryngotracheal
- lidocaine HCl mucous membrane jelly
- lidocaine HCl mucous membrane solution 4 %
- lidocaine topical ointment
- lidocaine-prilocaine topical cream

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	1) The requested drug is being used for topical anesthesia, AND 2) If the requested drug will be used as part of a compounded product, then all the active ingredients in the compounded product are Food and Drug Administration (FDA) approved for topical use.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TOPICAL RETINOID PRODUCTS

## Products Affected

- tretinoin topical cream
- tretinoin topical gel 0.01 %, 0.025 %

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

# TOPIRAMATE/ZONISAMIDE

## Products Affected

- Eprontia
- Zonisade

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

# TRANSDERMAL FENTANYL

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute (i.e., non-chronic) pain.
<b>Required Medical Information</b>	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, sickle cell disease, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TRANSMUCOSAL FENTANYL DRUGS

## Products Affected

- fentanyl citrate buccal lozenge on a handle

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months.
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# TRAZIMERA

## Products Affected

- Trazimera

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Neoadjuvant therapy for breast cancer: 6 months. Other: Plan Year.
<b>Other Criteria</b>	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Neoadjuvant treatment for human epidermal growth factor receptor 2 (HER2)-positive breast cancer, recurrent or advanced unresectable HER2-positive breast cancer, leptomeningeal metastases from HER2-positive breast cancer, brain metastases from HER2-positive breast cancer, HER2-positive esophageal and esophagogastric junction adenocarcinoma, HER2-positive advanced, recurrent, or metastatic uterine serous carcinoma, HER2-amplified and RAS and BRAF wild-type colorectal cancer in combination with pertuzumab, tucatinib, or lapatinib, HER2-positive recurrent salivary gland tumor.
<b>Part B Prerequisite</b>	No

# TREPROSTINIL INJ

## Products Affected

- treprostinil sodium

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For pulmonary arterial hypertension (World Health Organization [WHO] Group 1), the diagnosis was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than 20 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, AND 3) pretreatment pulmonary vascular resistance is greater than or equal to 3 Wood units.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# TRIENTINE

## Products Affected

- trientine oral capsule 250 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, medication history, pregnancy status, disease manifestations (all as described in Other Criteria)
<b>Age Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No



# TRIKAFTA

## 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 - must have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TRUQAP

## Products Affected

- Truqap

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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.) 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>	
<b>Part B Prerequisite</b>	No

# TRUXIMA

## Products Affected

- Truxima

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For moderately to severely active rheumatoid arthritis (new starts only): 1) patient meets ANY of the following: a) requested drug will be used in combination with methotrexate (MTX) OR b) patient has intolerance or contraindication to MTX, AND 2) patient meets ANY of the following: a) inadequate response, intolerance, or contraindication to MTX OR b) inadequate response or intolerance to a prior biologic disease-modifying antirheumatic drug (DMARD) or a targeted synthetic DMARD. Hematologic malignancies must be CD20-positive. For multiple sclerosis: 1) patient has a diagnosis of relapsing remitting multiple sclerosis and 2) patient has had an inadequate response to two or more disease-modifying drugs indicated for multiple sclerosis despite adequate duration of treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Immune checkpoint inhibitor-related toxicities: 3 months, All other: Plan Year
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<b>Off Label Uses</b>	<p>Non-Hodgkin's lymphoma subtypes [small lymphocytic lymphoma (SLL), mantle cell lymphoma, marginal zone lymphomas (nodal, splenic, gastric mucosa-associated lymphoid tissue [MALT], nongastric MALT), Burkitt lymphoma, primary cutaneous B-cell lymphoma, high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma), high-grade B-cell lymphoma not otherwise specified, histological transformation from follicular lymphoma to diffuse large B-cell lymphoma, histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma, Castleman's disease, acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma, hairy cell leukemia, post-transplant lymphoproliferative disorder (PTLD), B-cell lymphoblastic lymphoma], refractory immune or idiopathic thrombocytopenic purpura (ITP), autoimmune hemolytic anemia, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, chronic graft-versus-host disease (GVHD), Sjogren syndrome, thrombotic thrombocytopenic purpura, refractory myasthenia gravis, Hodgkin's lymphoma (nodular lymphocyte-predominant), primary central nervous system (CNS) lymphoma, leptomeningeal metastases from lymphomas, acute lymphoblastic leukemia, prevention of Epstein-Barr virus (EBV)-related PTLD, multiple sclerosis, immune checkpoint inhibitor-related toxicities, pemphigus vulgaris, pediatric aggressive mature B-cell lymphomas, and Rosai-Dorfman disease, and pediatric mature B-cell acute leukemia.</p>
<b>Part B Prerequisite</b>	No

# TUKYSA

## Products Affected

- Tukysa

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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)-positive disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type). Biliary tract cancer- approve if the patient meets all of (a, b, c, and d): a) unresectable or metastatic disease, b) HER2 positive disease, c) tried at least one systemic regimen, d) will use in combination with trastuzumab.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Biliary tract cancer
<b>Part B Prerequisite</b>	No

# TURALIO

## Products Affected

- Turalio oral capsule 125 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Histiocytic Neoplasms
Part B Prerequisite	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>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Authorization will be for 2 years of total therapy over a patient's lifetime
<b>Other Criteria</b>	Treatment of PMO and treatment of osteoporosis in men, approve if the patient meets ONE of the following criteria: patient has tried one oral bisphosphonate or cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or patient cannot remain in an upright position post oral bisphosphonate administration or patient 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 patient has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR patient has severe renal impairment or CKD, OR patient has had an osteoporotic fracture or fragility fracture. Patients must have a trial of teriparatide prior to approval of Tymlos.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# UCERIS

## Products Affected

- budesonide oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient has experienced an inadequate treatment response, intolerance to a systemic corticosteroid.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No



# VALCHLOR

## Products Affected

- Valchlor

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Cutaneous lymphoma-18 years and older
<b>Prescriber Restrictions</b>	
<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

# VANFLYTA

## Products Affected

- Vanflyta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# VELCADE

## Products Affected

- bortezomib injection recon soln 1 mg, 2.5 mg
- bortezomib injection recon soln 3.5 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Systemic light chain amyloidosis, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, multicentric Castleman's disease, adult T-cell leukemia/lymphoma, acute lymphoblastic leukemia, Kaposi's sarcoma, Hodgkin lymphoma, POEMS syndrome
Part B Prerequisite	No

# VENCLEXTA

## Products Affected

- Venclexta
- Venclexta Starting Pack

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

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

# VERSACLOZ

## Products Affected

- Versacloz

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For the treatment of a severely ill patient with schizophrenia who failed to respond adequately to standard antipsychotic treatment (i.e., treatment-resistant schizophrenia): 1) the patient has tried two oral antipsychotic agents (e.g., risperidone tablets/orally disintegrating tablets [ODT]/solution [Risperdal, generics], olanzapine tablets/ODT [Zyprexa/Zydis, generics], quetiapine tablets [Seroquel, generics], quetiapine extended-release tablets [Seroquel XR, generics], aripiprazole tablets [Abilify, generics], ziprasidone capsules [Geodon, generics], Fanapt tablets, Latuda tablets, Rexulti tablets, Vraylar capsules, asenapine sublingual tablets [Saprhis, generics], paliperidone ER tablets [Invega, generics]), Caplyta capsules OR 2) the patient is currently taking clozapine OR 3) the patient has taken clozapine at any time in the past
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VERZENIO

## Products Affected

- Verzenio

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast cancer: HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1year

PA Criteria	Criteria Details
<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.</p> <p>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 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.</p> <p>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.</p>
	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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Endometrial cancer



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

# V-GO

## Products Affected

- V-GO 20
- V-GO 30
- V-GO 40

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: 1) The patient has diabetes requiring insulin management with multiple daily injections AND 2) The patient is self-testing glucose levels 2 or more times per day OR the patient is using a continuous glucose monitor AND 3) For patients with Type 2 diabetes: The patient has a history of problematic hypoglycemia defined as 1) Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan OR 2) A history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia. Continuation: the patient has stable or improved glycemic control.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# VIGABATRIN

## Products Affected

- vigabatrin
- Vigadrone
- Vigpoder

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

# VITRAKVI

## Products Affected

- Vitrakvi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, NTRK gene fusion status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# VIZIMPRO

## Products Affected

- Vizimpro

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, EGFR status, exon deletions or substitutions
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# VONJO

## Products Affected

- Vonjo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# VORANIGO

## Products Affected

- Voranigo

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

# VORICONAZOLE (ORAL)

## Products Affected

- voriconazole

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Aspergillus-Prophy, systemic w/risk neutropenia-Prophy, systemic w/HIV-Prophy/Tx-6 mo, others-3 mo
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Aspergillus Infections - prophylaxis, oropharyngeal candidiasis (fluconazole-refractory) - treatment, candida endophthalmitis - treatment, blastomycosis - treatment, fungal infections (systemic) in patients at risk of neutropenia - prophylaxis, fungal infections (systemic) in patients with human immunodeficiency virus (HIV) - prophylaxis or treatment.
<b>Part B Prerequisite</b>	No



# VOSEVI

## Products Affected

- Vosevi

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Genotype, prescriber specialty, other medications tried or used in combination with requested medication
<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
- Votrient

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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. 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.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma, bone cancer.

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

# VUMERITY

## Products Affected

- Vumerity

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

# VYVANSE

## Products Affected

- lisdexamfetamine
- Vyvanse

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) OR 2) The requested drug is being prescribed for the treatment of moderate to severe binge eating disorder (BED) in an adult.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# WELIREG

## Products Affected

- Welireg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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>	
<b>Part B Prerequisite</b>	No

# XALKORI

## Products Affected

- Xalkori

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<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 received at least one prior systemic treatment. 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>Off Label Uses</b>	NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous.

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



# XDEMIVY

## Products Affected

- Xdemivy

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

# XELJANZ

## Products Affected

- Xeljanz
- Xeljanz XR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a Targeted Synthetic DMARD for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	AS/PsA/RA/UC-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	RA, JIA/JRA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	Approve through 12/31/24
<b>Other Criteria</b>	RA initial-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. PsA initial, approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial and the requested medication will be used in combination with methotrexate or another conventional synthetic disease modifying antirheumatic drug (DMARD), unless contraindicated. UC-Approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least ONE tumor necrosis factor inhibitor for ulcerative colitis or was unable to tolerate a 3-month trial. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthritis/active sacroiliac arthritis]-initial-approve Xeljanz immediate release tablets or solution if the patient meets the following: patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AS-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber.

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

# XERMELO

## Products Affected

- Xermelo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapy, concomitant therapy
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# XGEVA

## Products Affected

- Xgeva

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# XHANCE

## Products Affected

- Xhance

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient has experienced an inadequate treatment response to generic fluticasone nasal spray.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# XIFAXAN

## Products Affected

- Xifaxan oral tablet 550 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For irritable bowel syndrome with diarrhea (IBS-D): 1) The patient has not previously received treatment with the requested drug OR 2) The patient has previously received treatment with the requested drug AND a) the patient is experiencing a recurrence of symptoms AND b) the patient has not already received an initial 14-day course of treatment and two additional 14-day courses of treatment with the requested drug.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Reduction in risk of overt HE recurrence: 6 Months, IBS-D: 14 Days
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<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>	Moderate to severe persistent asthma baseline (defined as prior to receiving any treatment with Xolair or another monoclonal antibody that may lower IgE levels) IgE level of at least 30 IU/mL. For asthma, patient has a baseline (baseline is defined as prior to receiving any Xolair or another monoclonal antibody that may interfere with allergen testing) positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay (eg, immunoCAP, ELISA) or the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). CIU - must have urticaria for more than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine).
<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



PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Moderate to severe persistent asthma approve if pt meets criteria 1 and 2: 1) pt has received at least 3 months of combination therapy with an inhaled corticosteroid and at least one additional asthma controller or asthma maintenance medication (Examples: LABA, LAMA, leukotriene receptor antagonist, monoclonal antibody therapies for asthma) and 2) patient's asthma is uncontrolled or was uncontrolled prior to receiving Xolair or another monoclonal antibody therapy for asthma as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring hospitalization, urgent care visit or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy</p> <p>NOTE: An exception to the requirement for 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. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For CIU cont tx - have responded to therapy as determined by the prescribing physician.</p> <p>Nasal Polyps Initial-Approve if the patient has a baseline (defined as prior to receiving any treatment with Xolair or another monoclonal antibody therapy that may lower IgE) IgE level greater than or equal to 30 IU/ml, patient is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell and patient is currently receiving therapy with an intranasal corticosteroid. Nasal polyps continuation-approve if the patient continues to receive therapy with an intranasal corticosteroid and has responded to therapy.</p> <p>IgE-Mediated Food Allergy-approve if pt meets (A, B, C and D): (A) baseline IgE greater than or equal to 30 IU/mL, and (B) positive skin prick test to one or more foods and positive in vitro test for IgE to one or more foods, and (C) history of allergic reaction that met all of the following: pt demonstrated signs and symptoms of a significant systemic allergic reaction, and reaction occurred within a short period of time following a known ingestion of the food, and</p>
	<p>prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector, and (D) pt has been prescribed an epinephrine auto-injector.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

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

# XOSPATA

## Products Affected

- Xospata

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis, FLT3-mutation status
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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>	
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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 Pomalyst (pomalidomide capsules). Note: Examples include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Revlimid/dexamethasone, bortezomib 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>Off Label Uses</b>	Treatment of multiple myeloma in combination with daratumumb or pomalidomide

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

# XTANDI

## Products Affected

- Xtandi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis for which Xtandi is being used.
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	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), 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.]
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# XYREM

## Products Affected

- sodium oxybate

PA Criteria	Criteria Details
<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, dextroamphetamine) 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>	
<b>Part B Prerequisite</b>	No

# ZARXIO

## Products Affected

- Zarxio

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<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- 3 mo.Other=12mo. Radi-1 mo.
<b>Other Criteria</b>	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than 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), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgramstim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).



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

# ZEJULA

## Products Affected

- Zejula oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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 mutation and has tried one systemic regimen.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Uterine Leiomyosarcoma
Part B Prerequisite	No

# ZELBORAF

## Products Affected

- Zelboraf

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<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>	
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	<p>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, c or d): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) Ganglioglioma/neuroglioma/glioneuronal tumor OR d) pediatric diffuse high-grade glioma OR ii. Recurrent or progressive disease for one of the following conditions (a or b): a) glioma/circumscribed glioma OR b) Glioblastoma OR iii. Melanoma with brain metastases AND the medication will be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis and 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.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

PA Criteria	Criteria Details
<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 Hurthle cell) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm
<b>Part B Prerequisite</b>	No

# ZIEXTENZO

## Products Affected

- Ziextenzo

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Cancer patients receiving chemotherapy, if 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 is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia 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 the 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

# ZIRABEV

## Products Affected

- Zirabev

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	Breast cancer, central nervous system (CNS) tumor types: adult low-grade (WHO Grade I or II) glioma, adult intracranial and spinal ependymoma, anaplastic gliomas, adult medulloblastoma, primary central nervous system lymphoma, meningiomas, limited and extensive brain metastases, and metastatic spine tumors, malignant pleural mesothelioma, ovarian cancer/fallopian tube cancer/primary peritoneal cancer types: carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, mucinous carcinoma, grade 1 endometrioid carcinoma, low-grade serous carcinoma, ovarian borderline epithelial tumors (low malignant potential) with invasive implants, and malignant sex cord-stromal tumors, soft tissue sarcoma types: angiosarcoma and solitary fibrous tumor/hemangiopericytoma, uterine neoplasms, endometrial carcinoma, vulvar squamous cell carcinoma, and ophthalmic-related disorders: diabetic macular edema, neovascular (wet) age-related macular degeneration including polypoidal choroidopathy and retinal angiomatous proliferation subtypes, macular edema following retinal vein occlusion, proliferative diabetic retinopathy, choroidal neovascularization, neovascular glaucoma and retinopathy of prematurity, hepatocellular carcinoma, small bowel adenocarcinoma.

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

# ZOLINZA

## Products Affected

- Zolinza

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No



# ZTALMY

## Products Affected

- Ztalmy

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	2 years and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# ZURZUVAE

## Products Affected

- Zurzuvae

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

# ZYDELIG

## Products Affected

- Zydelig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 3 years.
Other Criteria	
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off Label Uses	small lymphocytic lymphoma
Part B Prerequisite	No

# ZYKADIA

## Products Affected

- Zykadia

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<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. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off Label Uses</b>	Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement. Erdheim-Chester disease. Peripheral T-Cell Lymphoma.
<b>Part B Prerequisite</b>	No

# ZYPREXA RELPREVV

## Products Affected

- Zyprexa Relprevv

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Tolerability with oral olanzapine has been established.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# ZYTIGA

---

## Products Affected

- abiraterone

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year

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

