



### **2023 PRIOR AUTHORIZATION CRITERIA**

UCare Connect (SNBC) MinnesotaCare Prepaid Medical Assistance Program (PMAP) Minnesota Senior Care Plus (MSC+)

UCare requires your provider to get prior authorization for certain drugs. This means that you'll need to get approval from us before you fill your prescriptions. If you don't get approval, UCare may not cover the drug.

UCare PMAP, MinnesotaCare, and MSC+ members with questions should call UCare Customer Service at 1-800-203-7225 toll free. UCare Connect members with questions should call 1-877-903-0061 toll free. TTY users can call 1-800-688-2534. We're here from 8 am – 5 pm, Monday – Friday.

#### Last updated: 12/1/2023

U6429 (12/2022)

### Toll free 1-800-203-7225, TTY 1-800-688-2534

Attention. If you need free help interpreting this document, call the above number.

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ملاحظة: إذا أردت مساعدة مجانية لترجمة هذه الوثيقة، اتصل على الرقم أعلاه.

သတိ။ ဤစွာရက်စာတမ်းအားအခမဲ့ဘာသာပြန်ပေးခြင်း အကူအညီလိုအပ်ပါက၊ အထက်ပါဖုန်းနံပါတ်ကိုခေါ် ဆိုပါ။

កំណត់សំគាល់ ។ បើអ្នកត្រូវការជំនួយក្នុងការបកប្រែឯកសារនេះដោយឥតគិតថ្លៃ សូមហៅទូរសព្ទតាមលេខខាងលើ ។

請注意,如果您需要免費協助傳譯這份文件,請撥打上面的電話號碼。 Attention. Si vous avez besoin d'une aide gratuite pour interpréter le présent document, veuillez appeler au numéro ci-dessus.

Thov ua twb zoo nyeem. Yog hais tias koj xav tau kev pab txhais lus rau tsab ntaub ntawv no pub dawb, ces hu rau tus najnpawb xov tooj saum toj no.

ဟ်သူဉ်ဟ်သးဘဉ်တက္i. ဖဲနမ့်၊လိဉ်ဘဉ်တ၊်မၤစၢၤကလီလၢတ၊်ကကျိးထံ၀ဲဧဉ်လံဉ် တီလံဉ်မီတခါအံၤန့ဉ်ႇကိးဘဉ် လီတဲစိနို၊်ဂံ၊လၢထးအံၤန့ဉ်တက္i.

알려드립니다. 이 문서에 대한 이해를 돕기 위해 무료로 제공되는 도움을 받으시려면 위의 전화번호로 연락하십시오.

ໂປຣດຊາບ. ຖ້າຫາກ ທ່ານຕ້ອງການການຊ່ວຍເຫຼືອໃນການແປເອກະສານນີ້ຟຣີ, ຈົ່ງ ໂທຣໄປທີ່ໝາຍເລກຂ້າງເທີງນີ້.

Hubachiisa. Dokumentiin kun tola akka siif hiikamu gargaarsa hoo feete, lakkoobsa gubbatti kenname bilbili.

Внимание: если вам нужна бесплатная помощь в устном переводе данного документа, позвоните по указанному выше телефону.

Digniin. Haddii aad u baahantahay caawimaad lacag-la'aan ah ee tarjumaadda (afcelinta) qoraalkan, lambarka kore wac.

Atención. Si desea recibir asistencia gratuita para interpretar este documento, llame al número indicado arriba.

Chú ý. Nếu quý vị cần được giúp đỡ dịch tài liệu này miễn phí, xin gọi số bên trên.

### **Civil Rights Notice**

**Discrimination is against the law. UCare** does not discriminate on the basis of any of the following:

- race
- color
- national origin
- creed
- religion
- sexual orientation
- public assistance status

- age
- disability (including physical or mental impairment)
- sex (including sex stereotypes and gender identity)
- marital status

- political beliefs
- medical condition
- health status
- receipt of health care services
- claims experience
- medical history
- genetic information

You have the right to file a discrimination complaint if you believe you were treated in a discriminatory way by UCare. You can file a complaint and ask for help filing a complaint in person or by mail, phone, fax, or email at:

UCare Attn: Appeals and Grievances PO Box 52 Minneapolis, MN 55440-0052 Toll Free: 1-800-203-7225 TTY: 1-800-688-2534 Fax: 612-884-2021 Email: cag@ucare.org

Auxiliary Aids and Services: UCare provides auxiliary aids and services, like qualified interpreters or information in accessible formats, free of charge and in a timely manner to ensure an equal opportunity to participate in our health care programs. Contact UCare at 612-676-3200 (voice) or 1-800-203-7225 (voice), 612-676-6810 (TTY), or 1-800-688-2534 (TTY).

Language Assistance Services: UCare provides translated documents and spoken language interpreting, free of charge and in a timely manner, when language assistance services are necessary to ensure limited English speakers have meaningful access to our information and services. **Contact** UCare at 612-676-3200 (voice) or 1-800-203-7225 (voice), 612-676-6810 (TTY), or 1-800-688-2534 (TTY).

### **Civil Rights Complaints**

You have the right to file a discrimination complaint if you believe you were treated in a discriminatory way by UCare. You may also contact any of the following agencies directly to file a discrimination complaint.

### U.S. Department of Health and Human Services Office for Civil Rights (OCR)

You have the right to file a complaint with the OCR, a federal agency, if you believe you have been discriminated against because of any of the following:

religion (in some

cases)

• race

• age

- color
- national origin

- disabilitysex
- Contact the OCR directly to file a complaint:

Office for Civil Rights U.S. Department of Health and Human Services Midwest Region 233 N. Michigan Avenue, Suite 240 Chicago, IL 60601 Customer Response Center: Toll-free: 800-368-1019 TDD Toll-free: 800-537-7697 Email: <u>ocrmail@hhs.gov</u>

#### Minnesota Department of Human Rights (MDHR)

In Minnesota, you have the right to file a complaint with the MDHR if you have been discriminated against because of any of the following:

race

• creed

sex

color national origin

- sexual orientation
- public assistance status
- disability

religion

marital status

Contact the **MDHR** directly to file a complaint:

Minnesota Department of Human Rights 540 Fairview Avenue North, Suite 201 St. Paul, MN 55104 651-539-1100 (voice) 800-657-3704 (toll-free) 711 or 800-627-3529 (MN Relay) 651-296-9042 (fax) Info.MDHR@state.mn.us (email)

### Minnesota Department of Human Services (DHS)

You have the right to file a complaint with DHS if you believe you have been discriminated against in our health care programs because of any of the following:

- race
- color
- national origin
- religion (in some cases)
- age
- disability (including physical or mental impairment)
- sex (including sex stereotypes and gender identity)

Complaints must be in writing and filed within 180 days of the date you discovered the alleged discrimination. The complaint must contain your name and address and describe the discrimination you are complaining about. We will review it and notify you in writing about whether we have authority to investigate. If we do, we will investigate the complaint.

DHS will notify you in writing of the investigation's outcome. You have the right to appeal if you disagree with the decision. To appeal, you must send a written request to have DHS review the investigation outcome. Be brief and state why you disagree with the decision. Include additional information you think is important.

If you file a complaint in this way, the people who work for the agency named in the complaint cannot retaliate against you. This means they cannot punish you in any way for filing a complaint. Filing a complaint in this way does not stop you from seeking out other legal or administrative actions.

Contact **DHS** directly to file a discrimination complaint: Civil Rights Coordinator Minnesota Department of Human Services Equal Opportunity and Access Division P.O. Box 64997 St. Paul, MN 55164-0997 651-431-3040 (voice) or use your preferred relay service

## Abiraterone

#### **Products Affected**

abiraterone oral tablet 250 mg, 500 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Prostate Cancer - Regional Risk Group. Prostate Cancer - Very-High Risk Group
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies used in combination
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	PC-VHRG - 2 years. All others - 1 year

PA Criteria	Criteria Details
Other Criteria	Prostate Cancer - Metastatic, Castration-Resistant (mCRPC) - Approve if the medication is used in combination with prednisone or dexamethasone AND pt meets one of the following criteria: The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron, Lupron Depot, Trelstar, Zoladex), the medication is used concurrently with Firmagon, or pt has had a bilateral orchiectomy. Prostate Cancer - Metastatic, Castration-Sensitive (mCSPC) - Approve if the medication is used in combination with prednisone AND pt meets one of the following criteria: The medication is concurrently used with a GnRH analog, the medication is used concurrently with Firmagon, or pt has had a bilateral orchiectomy. Prostate Cancer - Radical Prostatectomy (PCRP) - Approve if the medication is used in combination with prednisone and has PSA persistence or recurrence following radical prostatectomy and pt has pelvic recurrence following radical prostatectomy and pt has pelvic recurrence AND pt meets one of the following criteria: The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron, Lupron Depot, Trelstar, Zoladex), the medication is used concurrently with Firmagon, or pt has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the medication is used in combination with prednisone, pt has regional lymph node metastases and no distant metastases, and pt meets one of the following criteria: The medication is concurrently with Firmagon, or pt has had a bilateral orchiectomy. Prostate Cancer - Very-High Risk Group (PC-VHRG) - Approve if pt is in the very-high-risk group, the medication is used in combination with external beam radiation therapy and prednisone, and pt meets one of the following criteria: The medication is concurrently used with a GnRH analog, the medication is concurrently with Firmagon, or pt has had a bilateral orchiectomy.

### Adakveo

#### **Products Affected**

• ADAKVEO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	16 years of age and older
Prescriber Restrictions	prescribed by, or in consultation with, a physician who specializes in sickle cell disease (e.g., a hematologist)
Coverage Duration	1 year
Other Criteria	Sickle Cell Disease - Approve if pt has had at least 1 sickle-cell related crisis in the previous 12 month period AND the pt is currently receiving a hydroxyurea product OR has tried a hydroxyurea product and experienced inadequate efficacy or significant intorlance OR according to the prescriber the pt is not a candidate for hydroxyurea therapy. Continuation - approve if according to the prescriber the pt is recieving clinical benefit from Adakveo therapy.

# Adalimumab

#### **Products Affected**

- HADLIMA
- HADLIMA PUSHTOUCH
- HADLIMA(CF)
- HADLIMA(CF) PUSHTOUCH
- HUMIRA
- HUMIRA PEDIATRIC CROHNS START
- HUMIRA PEN
- HUMIRA PEN CROHNS-UC-HS START
- HUMIRA PEN PSOR-UVEITS-ADOL HS

- HUMIRA(CF)
- HUMIRA(CF) PEDI CROHNS STARTER
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PEDIATRIC UC
- HUMIRA(CF) PEN PSOR-UV-ADOL HS
- HUMIRA(CF) PEN SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML, 80 MG/0.8 ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded plus Behcet's Disease, Pyoderma Grangrenosum, Sarcoidosis, Scleritis (Sterile Conreal Ulceration), Spondyloarthritis.
Exclusion Criteria	Concurrent use with biologic DMARD or targeted synthetic DMARD (does not include methotrexate, hydroxychloroquine, sulfasalazine, and leflunomide). Polymyalgia rheumatica.
Required Medical Information	Diagnosis and previous medications tried
Age Restrictions	CD - 6 years or older. PP - 18 years or older. UC - 5 years or older
Prescriber Restrictions	RA/JIA/JRA/AS/SpA - rheumatologist. PsA - rheumatologist or dermatologist. PP/PG/HS - dermatologist. UC/CD - gastroenterologist. Uveitis/Scleritis - ophthalmologist. Sarcoidosis - pulmonologist, ophthalmologist, or dermatologist. Bechet's - rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.
Coverage Duration	AS/CD/PsA/UC/UV/Bechet's/Scleritis - 6 months. PG - 4 mos. HS/PP/Sarcoidosis - 3 mo. Continuation

PA Criteria	Criteria Details
Other Criteria	Ankylosing Spondylitis (AS) - Approve. Crohn's Disease (CD) - Approve if the pt has tried corticosteroids (CS), CS are contraindicated, the pt has tried one other conventional systemic therapy for Crohn's disease, the pt has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, or the pt has had ileocolonic resection. Juvenile Idiopathic Arthritis (JIA)- Approve if pt has tried one other systemic therapy for this condition, will be starting on adalimumab concurrently with methotrexate (MTX) sulfasalazine or leflunomide, pt has absolute contraindication to MTX sulfasalazine or leflunomide, or pt has aggressive disease. Hidradenitis Suppurativa (HS) - Approve if pt has tried at least one other therapy. Plaque Psoriasis (PP)- Approve if pt has tried at least one systemic therapy for at least 3 months, unless intolerant, the patient has tried at least one biologic for at least 3 months, or the patient has a contraindication to MTX as determined by the prescriber. Psoriatic Arthritis (PSA) - Approve. Rheumatoid Arthritis (RA) - Approve if pt has tried one conventional DMARD for at least 3 months or the patient has tried one biologic for at least 3 months. Ulcerative Colitis (UC) - Approve if pt has tried one systemic agent or one biologic agent, or the patient has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Uveitis (UV)- Approve if pt has tried one of the following therapies: periocular, intraocular, or systemic corticosteroids, immunosuppressives, or a biologic. Bechet's- Approve if pt has tried at least one conventional therapy or pt has ophthalmic manifestations of Behcet's disease. Pyoderma Gangrenosum (PG)- Approve if pt has tried one systemic corticosteroid or has tried one other immunosuppressant for at least 2 months or was intolerant to one of these agents. Sarcoidosis - Approve if pt has tried at least 1 corticosteroid and at least one immunosuppressive agent. Scleritis- approve if pt has tried one other therapy for this condition. S
	1 conventional DMARD Or pt has axial spondyloarthritis and has objective signs of inflammation (elevated CRP, sacroiliitis on MRI). Continuation - approve if pt has been established on therapy for at least the initial approval duration and pt experienced a beneficial clinical response from baseline when assessed by at least one objective measure or patient experienced an improvement in at least one symptom.

# Ajovy

#### **Products Affected**

- AJOVY AUTOINJECTOR
- AJOVY SYRINGE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Combination use with other prophylactic CGRP agents or Nurtec ODT. Acute treatment of migraines. Cluster headache.
Required Medical Information	Diagnosis, number of migraine headaches per month, prior therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Migraine Headache Prevention - Pt has 4 or more migraine headache days per month (prior to initiating a migraine- preventative medication), and has tried at least two prophylactic pharmacologic therapies from different classes (e.g., tricyclic antidepressant, beta-blocker, ARB, ACEI, CCB, or anticonvulsant) and had an inadequate response or adverse events, according to the prescriber. If a pt is currently taking Ajovy, the pt has had a significant clinical benefit from the medication as determined by the prescriber.

### Alecensa

#### **Products Affected**

• ALECENSA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Anaplastic Large Cell Lymphoma. Erdheim-Chester Disease. Inflammatory Myofibroblastic Tumor.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if the pt has advanced or metastatic disease and anaplastic lymphoma kinase (ALK)-positive disease detected by an approved test. Anaplastic Large Cell Lymphoma - Approve if pt has anaplastic lymphoma kinase (ALK)-positive disease and pt has relapsed or refractory disease. Erdheim-Chester Disease - Approve if pt has anaplastic lymphoma kinase (ALK) rearrangement/fusion- positive disease. Inflammatory Myofibroblastic Tumor (IMT) - Approve if pt has ALK positive disease and advanced, recurrent , or metastatic disease or the tumor is inoperable.

# Alunbrig

### **Products Affected**

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Erdheim- Chester Disease. Inflammatory Myofibroblastic Tumor (IMT).
Exclusion Criteria	
Required Medical Information	mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if pt has advanced or metastatic disease and anaplastic lymphoma kinase (ALK)-positive disease as detected by an approved test. Erdheim-Chester Disease - Approve if pt has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor (IMT) - Approve if pt has ALK positive disease and has advanced, recurrent, or metastatic disease or the tumor is inoperable.

# Amifampridine

### **Products Affected**

- FIRDAPSE
- RUZURGI

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded
Exclusion Criteria	History of seizures (initial therapy)
Required Medical Information	Diagnosis, seizure history, lab and test results
Age Restrictions	Firdapse - 18 years of age or older. Ruzurgi - 6 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a neuromuscular specialist (initial therapy)
Coverage Duration	Initial-3 months, Cont-1 year
Other Criteria	Initial therapy-Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive nerve stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. Continuation- patient continues to derive benefit (e.g., improved muscle strength, improvements in mobility) from Firdapse/Ruzurgi, according to the prescribing physician.

### Aranesp

### **Products Affected**

• ARANESP (IN POLYSORBATE)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Anemia due to myelodysplastic syndrome (MDS). Anemia Associated with Myelofibrosis.
Exclusion Criteria	Anemia associated with cancer in pts not receiving myelosuppressive cancer chemotherapy. Anemia associated with AML, CML or other myeloid cancers. Anemia associated with radiotherapy for cancer. Athletic performance enhancement. Anemia due to acute blood loss.
Required Medical Information	Diagnosis, lab results, other therapies tried
Age Restrictions	Anemia due to MDS - 18 years or older
Prescriber Restrictions	Anemia due to MDS/Anemia due to Myelofibrosis - prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	CKD on dialysis - 3 yrs. CKD/MDS - 1 yr. Chemo - 6 months. Myelofibrosis: 3 mo, cont - 1 year.

PA Criteria	Criteria Details
Other Criteria	Anemia due to CKD on dialysis - approve. Anemia due to CKD not on dialysis - For pts 18 years of age or older, must have a hemoglobin less than 10 g/dL (less than 12 g/dL if already receiving an erythropoiesis-stimulating agent[ESA]). If less than 18 years of age, must have a hemoglobin equal to or less than 11 g/dL (equal to or less than 12 g/dL if already receiving an ESA). Pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to Chemotherapy - Approve if pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) is currently receiving myelosuppressive chemotherapy and according to the prescriber, myelosuppressive chemotherapy is considered non-curative AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to MDS - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to Myelofibrosis - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to Myelofibrosis - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. For pts already receiving an ESA, the pt has responded according to the prescriber as defined by a hemoglobin greater than 10 g/dL or an increase of greater than 2 g/dL.

# ARIKAYCE

#### **Products Affected**

• ARIKAYCE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Cystic Fibrosis.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous medication history, sensitivity results
Age Restrictions	MAC - 18 years or older
Prescriber Restrictions	MAC - Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections. CF - 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	MAC Lung disease - Approve if pt has completed greater than or equal to 6 consecutive months of a background multidrug regimen AND has a positive sputum culture for Mycobacterium avium complex (within the past 3 months, taken after completion of 6 months of therapy) which is susceptible to amikacin with a minimum inhibitor concentration (MIC) of less than 64 µg/mL AND Arikayce will be used in conjunction to a background multidrug regimen. MAC Continuation - Approve if Arikayce will be used in conjunction with a background multidrug regimen AND pt has not achieved negative sputom cultures for at least 12 months (will be approved up to 12 months as needed to result in 12 months of negative sputum cultures). Cystic Fibrosis - Approve if pt has Pseudomonas aeruginosa in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).

### Austedo

### **Products Affected**

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis and previous medications tried
Age Restrictions	18 years or older
Prescriber Restrictions	Chorea - Prescribed by or in consultation with a neurologist. Dyskinesia - Prescribed by or in consultation with a neurologist or psychiatrist.
Coverage Duration	1 year
Other Criteria	Chorea associated with Huntington's Disease - approve if pt has been diagnosed with chorea associated with Huntington's disease AND diagnosis of Huntington's disease is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36.) Tardive Dyskinesia - approve.

### Ayvakit

#### **Products Affected**

• AYVAKIT

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from coverage. Myeloid/Lymphoid Neoplasms with Eosinophilia.
Exclusion Criteria	
Required Medical Information	diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Gastrointestinal Stromal Tumor (GIST) - Approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation (PDGFRA exon 18 mutation includes PDGFRA D842V mutations) or pt has previously tried imatinib, sunitinib or dasatinib, regorafinib, and ripretinib. Systemic Mastocytosis - approve if pt has a platelet count of greater than 50,000/mcL AND indolent systemic mastocytosis OR has aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, or mast cell leukemia. Myeloid/Lymphoid Neoplasms - approve if the pt has eosinophilia and the tumor is positive for platelet- derived growth factor receptor alpha (PDGFRA) D842V mutation.

### Balversa

#### **Products Affected**

• BALVERSA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from coverage.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies, test results
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Urothelial Carcinoma - Approve if the patient has locally advanced or metastatic disease, susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations, and the pt has progressed during or following prior platinum-containing chemotherapy or checkpoint inhibitor therapy.

## Benlysta

### **Products Affected**

• BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concurrent use with other biologics or Lupkynis (voclosporin capsules). Rheumatoid Arthritis.
Required Medical Information	Diagnosis, lab results, other therapies tried
Age Restrictions	Subcutaneous - 18 years or older, IV - 5 years or older
Prescriber Restrictions	LN - Prescribed by or in consultation with a nephrologist or rheumatologist. SLE - Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist, or dermatologist.
Coverage Duration	LN initial - 6 mo. SLE initial - 4 mo. Continuation - 1 year.
Other Criteria	Lupus Nephritis (LN) - Approve if diagnosis confirmed on biopsy and pt has autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA) antibody and the medication is being used concurrently with an immunosuppressive regimen. Continuation - Approve if pt has responded to Benlysta and the medication is being used concurrently with an immunosupressive regimen. Systemic Lupus Erythematosus (SLE) - Approve if pt has autoantibody-positive SLE, defined as positive for antinuclear antibodies (ANA) and/or anti-double-stranded DNA (anti- dsDNA) antibody and the medication is being used concurrently with at least one other standard therapy, unless intolerant as determined by the prescriber. Continuation - Approve if pt has responded to Benlysta and the medication is being used concurrently with at least one other standard therapy, unless intolerant, as determined by the prescriber.

### Berinert

#### **Products Affected**

• BERINERT

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Lab values (C1-INH protein, serum C4)
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an allergist/immunologist or a provider that specializes in the treatment of hereditary angioedema or related disorders
Coverage Duration	Authorization will be for 3 years
Other Criteria	Hereditary angioedema confirmed by low levels of functional C1-INH protein (less than 50% of normal) at baseline and confirmed by lower than normal serum C4 levels at baseline. A diagnosis of HAE with normal C1-INH (also referred to as HAE type III) does NOT satisfy this requirement. Continuation of therapy, must have had favorable clinical response (for example, decrease in number of HAE acute attack frequency, decrease in HAE attack severity, decrease in duration of HAE attacks) since initiating Berinert compared with baseline.

### Bexarotene

#### **Products Affected**

• bexarotene

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies tried
Age Restrictions	
Prescriber Restrictions	prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	1 year
Other Criteria	Cutaneous T-Cell Lymphoma - Approve if pt has cutaneous manifestations and generic bexarotene capsules are requested or pt has tried genreic bexarotene capsules and pt cannot take generic bexarotene capsules due to a formulation difference in the inactive ingredients between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or a derious adverse reaction.

## Bosulif

#### **Products Affected**

 BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Acute Lymphoblastic Leukemia. Myeloid/Lymphoid Neoplasms with Eosinophilia.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	CML - 1 year or older. Others - 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Chronic Myeloid Leukemia - Approve if pt has Philadelphia chromosome positive chronic myeloid leukemia. Acute Lymphoblastic Leukemia - Approve if pt has Philadelphia chromosome-positive acute lymphoblastic leukemia and has tried at least one other tyrosine kinase inhibitor for Philadelphia chromosome-positive acute lymphoblastic leukemia. Myeloid/Lymphoid Neoplasms with Eosinophilia - Approve if tumor has an ABL1 rearrangement.

### Braftovi

#### **Products Affected**

• BRAFTOVI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Colon or Rectal Cancer - approve if pt has BRAF V600E mutation positive disease and has previously received a chemotherapy regimen for colon or rectal cancer and Braftovi will be prescribed as part of a combination regimen for colon or rectal cancer. Melanoma - approve if pt has unresectable, advanced, or metastatic melanoma which is BRAF V600 mutation positive.

## Brukinsa

#### **Products Affected**

• BRUKINSA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Chronic Lymphocytic Leukemia. Marginal Zone Lymphoma. Small Lymphocytic Lymphoma. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, prior treatments
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Mantle Cell Lymphoma - Approve if pt has tried at least one prior systemic therapy unless contraindicated. Marginal Zone Lymphoma - Approve if pt has tried at least one prior systemic therapy. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma - Approve. Chronic Lymphocytic Leukemia - Approve. Small Lymphocytic Leukemia - Approve.

## Cablivi

### **Products Affected**

• CABLIVI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, concurrent medications
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	3 months
Other Criteria	Acquired Thrombotic Thrombocytopenic Purpura (aTTP) - Approve if Cablivi was initiated in the inpatient setting in combination with plasma exchange therapy AND the patient is currently receiving at least one immunosuppressive therapy (e.g. corticosteroids, rituximab, cylosprorine, cyclophosphamide, mycophenolate, hydroxychloroquine, Velcade) AND if the patient has previously received Cablivi, he/she has not had more than two recurrences of aTTP while on Cablivi.

## Cabometyx

### **Products Affected**

• CABOMETYX

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Bone Cancer. Endometrial Carcinoma. Gastrointestinal Stromal Tumors. Non-Small Cell Lung Cancer.
Exclusion Criteria	Metastatic Castration-Resistant Prostate Cancer
Required Medical Information	Diagnosis, previous therapies tried, mutation status
Age Restrictions	HCC/RCC/Endometrial carcinoma/GIST/NSCLC - 18 years or older. Thyroid carcinoma - 12 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Hepatocellular Carcinoma (HCC) - Approve if pt has been previously treated with at least one systemic therapy. Renal Cell Carcinoma (RCC) - Approve if pt has relapsed or stage IV disease. Thyroid Carcinoma, Differentiated - Approve if pt has differentiated thyroid carcinoma, is refractory to radioactive iodine therapy, and has Lenvima or Nexavar. Bone Cancer - Approve if pt has tried at least one previous systemic regimen and has Ewing sarcoma or osteosarcoma. Endometrial Carcinoma - Approve if pt has tried one systemic regimen. Gastrointestinal Stromal Tumors (GIST) - Approve if pt has tried imatinib or Ayvakit (avapritinib), Sutent (sunitinib) or Sprycel (dasatinib), Stivarga (regorafinib), and Qinlock (ripretinib) . Non-Small Cell Lung Cancer (NSCLC) - Approve if tumor is positive for RET rearrangements.

### Calquence

### **Products Affected**

- CALQUENCECALQUENCE (ACALABRUTINIB MAL)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Marginal Zone Lymphoma. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma.
Exclusion Criteria	
Required Medical Information	diagnosis, prior treatments
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Approve. Mantle Cell Lymphoma - Approve if pt has tried at last one systemic regimen unless contraindicated. Marginal Zone Lymphoma - approve if pt has tried at least one systemic regimen. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma - approve if pt has tried at least one systemic regimen.

## Camzyos

#### **Products Affected**

• CAMZYOS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, LVOT gradient, LVEF, LV wall thickness
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by a cardiologist
Coverage Duration	Initial - 8 months, Continuation -1 year

PA Criteria	Criteria Details
Other Criteria	Obstructive Hypertrophic Cardiomyopathy (OHCM)- Approve if pt has at least 1 symptom associated with OHCM (Note: Examples of symptoms include shortness of breath, chest pain, lightheadedness, fainting, fatigue, and reduced ability to perform physical exercise) and Patient has New York Heart Association Class II or III symptoms of heart failure (Note: Class II signifies mild symptoms with moderate physical activity and some exercise limitations whereas Class III denotes noticeable symptoms with minimal physical activity and patients are only comfortable at rest) and pt has left ventricular hypertrophy defined as maximal left ventricular wall thickness of 15 mm or greater or 13 mm or greater with familial HCM and peak LVOT gradient of 50mmHg or more and LVEF of 55% or greater. Continuation - Approve if pt has been established on therapy for at least 8 months and currently or prior to starting therapy experienced at least one symptom associated with OHCM and is in or was in NYHA Class II or III heart failure and has a current LVEF of 50% or greater and pt has experienced a beneficial clinical response when assessed by at least one objective measure or pt experienced stabilization or improvement in at least one symptom related to OHCM.

# Caprelsa

### **Products Affected**

• CAPRELSA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Differentiated Thyroid Carcinoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Medullary Thyroid Cancer - approve. Differentiated Thyroid Carcinoma (i.e., papillary, follicular, and oncocytic carcinoma (formerly Hürthle cell carcinoma)- approve if refractory to radioactive iodine therapy.

# Carbaglu

### **Products Affected**

• carglumic acid

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Maintenance of Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia
Required Medical Information	diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist, or a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	Genetic test confirmed NAGS mutation - 1 year. Hyperammonia only - 3 months. PA/MA - 7 days.
Other Criteria	N-Acetylglutamate Synthase Deficiency with Hyperammonemia (NAGS) - Approve if pt is on a protein-restricted diet and has hyperammonemia diagnosed with an ammonia level above the upper limit of normal or has had a genetic test confirming a mutation leading to N-acetyleglutamate. Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia, Acute Treatment (PA/MA) - Approve if pts ammonia level is greater than 50 micromol/L and the medication is prescribed in conjunction with other ammonia-lowering therapies.

# Cinryze

#### **Products Affected**

• CINRYZE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Lab values (C1-INH protein, serum C4)
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an allergist/immunologist or a provider who specializes in the treatment of hereditary angioedema or related disorders.
Coverage Duration	Approval duration of 1 year
Other Criteria	Hereditary Angioedema (HAE) (type I or type II) has been confirmed by low levels of functional C1-INH protein (less than 50% of normal) at baseline and lower than normal serum C4 levels at baseline. A diagnosis of HAE with normal C1-INH (also referred to as HAE type III) does NOT satisfy this requirement. Must also meet the requirements of the non-preferred criteria.

# Cometriq

### **Products Affected**

• COMETRIQ

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Non-Small Cell Lung Cancer. Dfferentiated Thyroid Carcinoma.
Exclusion Criteria	Metastatic Castration-Resistant Prostate Cancer
Required Medical Information	Diagnosis, mutation results
Age Restrictions	Differentiated Thyroid Carcinoma - 12 years or older. Medullary Thyroid Carinoma/NSCLC - 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Medullary Thyroid Cancer - Approve. Non-Small Cell Lung Cancer (NSCLC) - approve if pt has RET gene rearrangements. Differentiated Thyroid Carcinoma (i.e., papillary, follicular, and oncocytic carcinoma (formerly Hürthle cell carcinoma))- Approve if refractory to radioactive iodine therapy and pt has tried Lenvima (lenvatinib capsules) or Nexavar (sorafenib tablets).

# Copiktra

### **Products Affected**

• COPIKTRA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Marginal Zone Lymphoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Chronic Lymphocytic Lymphoma - Approve if pt has tried one systemic regimen. Small Lymphocytic Lymphoma - Approve if pt has tried one systemic regimen. T-Cell Lymphoma - Approve if pt has relapsed or refractory disease and breast implant- associated anaplastic large cell lymphoma or hepatosplenic T- cell lymphoma OR the pt has peripheral T-cell lymphoma.

### Cotellic

#### **Products Affected**

• COTELLIC

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Central Nervous System Cancer. Histiocytic Neoplasm.
Exclusion Criteria	
Required Medical Information	Diagnosis. Mutation results. Other therapies tried.
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Melanoma - approve if pt has unresectable, advanced, or metastatic melanoma, has BRAF V600 mutation-positive disease, and Cotellic is being prescribed in combination with Zelboraf (vemurafenib). Central Nervous System Cancer - Approve if pt has BRAF V600 mutation-positive disease and the medication is being used for adjuvant treatment of pilocytic astrocytoma, pleomorphic xanthoastrocytoma, or ganglioglioma, or for recurrent disease of low-grade glioma, anaplastic glioma, or glioblastoma, or brain metastases due to melanoma AND the medication is prescribed in combination with Zelboraf (vemurafenib). Histiocytic Neoplasm - Approve if pt has BRAF V600 mutation-positive disease and has Langerhans cell histiocytosis and one of the following: multisystem disease, pulmonary disease, or central nervous system lesions.

## Crysvita

#### **Products Affected**

 CRYSVITA SUBCUTANEOUS SOLUTION 10 MG/ML, 20 MG/ML, 30 MG/ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded
Exclusion Criteria	Chronic Kidney Disease (CKD), Severe Renal Impairment or End Stage Renal Disease, Epidermal Nevus Syndrome
Required Medical Information	Diagnosis, lab values
Age Restrictions	TIO - 2 years or older
Prescriber Restrictions	Prescribed by or in consultation with a endocrinologist or nephrologist
Coverage Duration	X-linked Hypophosphotemia - 1 year, Tumor-induced Osteomalacia - 6 months. Continuation - 1 year

PA Criteria	Criteria Details
Other Criteria	Tumor-Induced Osteomalacia - Approve if pt has a mesenchymal tumor that cannot be curatively resected or identified/localized AND, per the prescriber, the patient is currently exhibiting one or more signs or symptoms of tumor- induced osteomalacia AND pt has had a baseline (prior to any tumor-induced osteomalacia treatment) serum phosphorus level that was below the normal range for age AND Patient has had a baseline (prior to any tumor induced osteomalacia treatment) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender AND pt has tried, or has a contraindication to, oral phosphate and calcitriol therapy. Cont - approve if pt is continuing to derive benefit from Crysvita as determined by the prescriber.X-linked Hypophosphotemia (XLH) - Approve if pt has had a baseline (i.e., prior to any XLH treatment [e.g., Crysvita, oral phosphate/vitamin D therapy]) serum phosphorus level that was below the normal range for age AND pt either had a baseline (prior to any XLH treatment) tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) that was below the normal range for age and gender OR pt has had a genetic test confirming the diagnosis of XLH via identification of a PHEX mutation AND If pt is greater than 18 years old, pt is currently exhibiting one or more signs or symptoms of X-linked hypophosphatemia per the prescriber and pt has tried, or has contraindications to, oral phosphate and calcitriol therapy.

## Dalfampridine ER

- AMPYRA
- dalfampridine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	ambulation evaluation measures
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
Coverage Duration	Initial - 4 months. Continuation - 1 year.
Other Criteria	Multiple Sclerosis - Approve if pt is ambulatory but has impaired ambulation as evaluated by an objective measure, and the requested medication is being used to improve or maintain mobility. Continuation - Approve if pt is ambulatory, the requested medication is being used to improve or maintain mobility, and the pt has experienced an improvement or maintenance in walking speed or other objective measures related to ambulation.

### Daurismo

#### **Products Affected**

• DAURISMO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acute Myeloid Leukemia - Approve if the pt will be using the medication in combination with cytarabine.

### Diclofenac 3% gel

#### **Products Affected**

• diclofenac sodium topical gel 3 %

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Actinic Cheilitis. Disseminated Superficial Actinic Porokeratosis.
Exclusion Criteria	Osteoarthritis
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Actinic Keratoses - Approve. Actinic Cheilitis (Actinic Keratoses of the Lips) - Approve. Disseminated Superficial Actinic Porokeratosis - Approve if pt has treid at least two other therapies used for the management of disseminated superficial actinic porokeratosis. Note: Examples of therapies for management of disseminated superficial actinic porokeratosis include topical 5-fluorouracil (5-FU), imiquimod, topical corticosteroids, topical vitamin D3 analogs, topical or oral retinoids, cryotherapy, photodynamic therapy, and laser.

## Dupixent

#### **Products Affected**

 DUPIXENT PEN SUBCUTANEOUS PEN INJECTOR 200 MG/1.14 ML, 300 MG/2 ML SYRINGE 100 MG/0.67 ML, 200 MG/1.14 ML, 300 MG/2 ML

• DUPIXENT SYRINGE SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concurrent use with another Monoclonal Antibody Therapy or JAK inhibitor
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials.
Age Restrictions	Asthma - 6 years or older. Atopic Dermatitis - 6 months or older. NP/PN - 18 years or older. Eosinophilic esophagitis - 12 years or older
Prescriber Restrictions	AD/PN - Prescribed by or in consultation with an allergist, immunologist or dermatologist. Asthma - prescribed by or in consultation with an allergist, immunologist or pulmonologist. Nasal Polyps - prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Eosinophilic Esophagitis - Prescribed by or in consultation with an allergist or gastroenterologist.
Coverage Duration	AD: Initial - 4 mo. Cont - 1 year. Asthma/Nasal Polyps/EE/PN: Initial - 6 mo. Cont - 1 year.

PA Criteria	Criteria Details
Other Criteria	Asthma - Approve if pt blood eosinophil level of 150 cells per mcl or greater within the previous 6 weeks or within 6 weeks prior to treatment with Dupixent or another MoAB therapy OR has oral corticosteroid (CS)-dependent asthma AND Pt has received both an inhaled corticosteroid (ICS) and at least 1 additional asthma controller for at least 3 consecutive months AND Pt's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by (a, b, c, d or e): a) 2 or more asthma exacerbations requiring treatment with systemic CS in the previous year OR b) experienced 1 or more asthma exacerbation requiring hosp., ED or urgent care visit in the previous year OR c) FEV1 less than 80% predicted OR d) has an FEV1/FVC less than 0.80 OR e) The pt's asthma worsens upon tapering of oral CS therapy. Cont Approve if pt continues ICS and received at least 6 months of Dupixent and responded to therapy as determined by the prescriber. Atopic Dermatitis, Initial - Pt has has atopic dermatitis involvement estimated to be greater than 10% of the body surface area (BSA), and has tried a medium-potency or stronger topical CS for at least 28 days with inadequate efficacy, according to the prescriber. Cont Approve if the pt has received at least 4 months of Dupixent and has responded to therapy as determined by the prescriber. Eosinophilic Esophagitis (EE)- Approve if pt weighs at least 40kg and dx confirmed by endoscopic biopsy and pt does not have secondary causes of EE and pt received at least 6 months of therapy with Dupixent and experienced a beneficial clinical response. Nasal Polyps - Pt has chronic rhinosinusitis with nasal polyposis evidenced by direct examination, endoscopy, or sinus CT scan, has been using an intranasal CS for 3 months and will continue to use with Dupixent, and is experiencing 2 or more of the following for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell AND either has received treatment with a systemic CS within the

PA Criteria	Criteria Details
	years (unless contraindicated) or had prior surgery for nasal polyps. Cont Approve if pt continues intranasal CS and received at least 6 months of Dupixent and responded to therapy as determined by the prescriber. Prurigo Nodularis (PN) - Approve if pt has 20 or more identifiable nodular lesions and experienced pruritus for 6 weeks or more and has tried 1 high-super high potency topical corticosteroid for at least 14 consecutive days with inadequate efficacy and the PN is not medication-induced or secondary to a non-derm condition such as neuropathy or a psychiatric disease or the secondary cause identified and adequately managed according to the prescriber. Cont approve if pt received at least 6 months of Dupixent and experienced reduced nodular lesion count or size or decreased pruritus.

## Eligard

- ELIGARD
- ELIGARD (3 MONTH)ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Head and Neck Cancer - Prescribed by or in consultation with an oncologist. Prostate cancer - Prescribed by or in consultation with an oncologist or urologist.
Coverage Duration	1 year
Other Criteria	Prostate Cancer - Approve. Head and Neck Cancer, Salivary Gland Tumors - Approve if pt has distant metastases and androgen receptor-positive disease.

## **Emgality**

- EMGALITY PEN
- EMGALITY SYRINGE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	Combination use with other prophylactic CGRP agents or Nurtec ODT. Acute treatment of migraines.
Required Medical Information	Diagnosis, number of migraine headaches per month, prior therapies tried.
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Cluster Headaches - 6 months. Migraine Prevention - 1 year.
Other Criteria	Episodic Cluster Headache Treatment - Approve if pt has between one headache every other day and eight headaches per day and pt has tried at least one standard prophylactic (preventive) pharmacologic therapy for cluster headache and had inadequate efficacy or experienced an adverse event, according to the prescriber. Migraine Headache Prevention - Pt has 4 or more migraine headache days per month (prior to initiating a migraine-preventative medication), and has tried at least two prophylactic pharmacologic therapies from different classes (e.g., tricyclic antidepressant, beta-blocker, ARB, ACEI, CCB, or anticonvulsant) and had an inadequate response or adverse events, according to the prescriber. If a pt is currently taking Emgality, the pt has had a significant clinical benefit from the medication as determined by the prescriber.

# Empaveli

#### **Products Affected**

• EMPAVELI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	Concurrent use with Soliris or Ultomiris
Required Medical Information	Diagnosis
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	Initial - 4 months. Continuation - 1 year.
Other Criteria	Paroxysmal Nocturnal Hemoglobinuria - Approve if paroxysmal nocturnal hemoglobinuria diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins on at least two cell lineages. If pt is transitioning to Empaveli from Soliris or Ultomiris, the prescriber attests that these such medications will be discontinued within 4 weeks after starting Empaveli. Continuation - Approve if pt is continuing to derive benefit from Empaveli according to the prescriber.

### Enbrel

- ENBREL MINI
- ENBREL SUBCUTANEOUS RECON SOLN ENBREL SURECLICK
- ENBREL SUBCUTANEOUS SOLUTION
- ENBREL SUBCUTANEOUS SYRINGE 25

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded plus Behcet's Disease, Graft-Versus-Host Disease, Pyoderma Gangrenosum, Spondylarthritis, and Still's Disease.
Exclusion Criteria	Concurrent Use with a Biologic DMARD or Targeted Synthetic DMARD. Crohn's disease. Inflammatory myopathies (polymyositis, dermatomyositis, inclusion body myositis). Hidradenitis Suppurativa. Polymyalgia Rheumatica. Large Vessel Vasculitis (Giant Cell Arteritis, Takayasu's Arteritis). Wegener's Granulomatosis.
Required Medical Information	Diagnosis and previous therapies tried
Age Restrictions	PP - 4 years or older
Prescriber Restrictions	Prescribed by or in consultation with: RA/AS/JIA/JRA/SpA/SD - rheumatologist. PP/PG - dermatologist. PsA - rheumatologist or dermatologist. Behcet's - rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. GVHD - oncologist, hematologist, or a physician in a transplant center.
Coverage Duration	RA/AS/JIA/PP/PsA/BD/SpA/SD -3mo GVHD-1mo PG-4mo. Cont:RA/AS/JIA/PP/PsA-3y GVHD-4m others-1yr

PA Criteria	Criteria Details
Other Criteria	Rheumatoid Arthritis (RA) - Pt has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) or biologic DMARD for at least 3 months. Ankylosing Spondylitis (AS) - Approve. Juvenile Idiopathic Arthritis (JIA)/Juvenile Rheumatoid Arthritis (JRA) - Pt has tried one other agent for this condition or a biologic DMARD OR pt will be starting on Enbrel concurrently with methotrexate (MTX), sulfasalazine, or leflunomide OR pt has an absolute contraindication to MTX, sulfasalazine, or leflunomide OR pt has an absolute contraindication to MTX, sulfasalazine, or leflunomide OR pt has aggressive disease, as determined by the prescribing physician. Plaque Psoriasis (PP) - Approve if pt has tried at least one traditional systemic agent for psoriasis (e.g., MTX, cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) or a biologic DMARD for at least 3 months, unless intolerant. Psoriatic Arthritis (PSA) - Approve. Behcet's - Approve if pt has tried at least one conventional therapy or adalimumab or infliximab. Graft vs. Host Disease (GVHD) - Approve if pt has tried one conventional treatment or is currently receiving one of these medications. Pyoderma Gangrenosum (PG) - Approve if pt has tried one systemic corticosteroid OR one other immunosuppressant for at least 2 months or was intolerant. Spondyloarthritis (SpA) - Approve if pt has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic DMARD OR The patient has axial spondyloarthritis with objective measures of inflammation (elevated CRD, sacroiliitis on MRI). Still's Disease - Approve if pt has tried one corticosteroid AND one conventional synthetic DMARD for at least 2 months or was intolerant. Continuation therapy - Approve if the pt has had a response as determined by the prescriber.

### Endari

#### **Products Affected**

• ENDARI

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from coverage.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	5 years of age or older
Prescriber Restrictions	prescribed by, or in consultation with, a physician who specializes in sickle cell disease (e.g., a hematologist)
Coverage Duration	1 year
Other Criteria	Sickle Cell Disease - Approve if documentation of diagnosis is provided

### **Epogen and Retacrit**

#### **Products Affected**

 EPOGEN INJECTION SOLUTION 10,000
 RETACRIT UNIT/ML, 2,000 UNIT/ML, 20,000 UNIT/2 ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Anemia associated with myelodysplastic syndrome (MDS). Anemia associated with Myelofibrosis.
Exclusion Criteria	Anemia associated with cancer in pts not receiving myelosuppressive chemo, AML, CMS, other myeloid cancers, radiotherapy in cancer, or due to acute blood loss. Athletic performance enhancement.
Required Medical Information	Diagnosis, lab results, other therapies tried
Age Restrictions	Anemia due to MDS - 18 years and older.
Prescriber Restrictions	Anemia due to MDS/Anemia due to Myelofibrosis - prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	CKD dialysis-3 yrs. CKD/MDS/HIV-1 yr. Chemo-6 months. Myelofibrosis-3 mo, cont1 yr. Surgery-1 mo

PA Criteria	Criteria Details
Other Criteria	Anemia due to CKD on dialysis - approve. Anemia due to CKD not on dialysis - For pts 18 years of age or older, must have a hemoglobin less than 10 g/dL (less than 12 g/dL if already receiving an erythropoiesis-stimulating agent[ESA]). If less than 18 years of age, must have a hemoglobin equal to or less than 11 g/dL (equal to or less than 12 g/dL if already receiving an ESA). Pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to Chemotherapy - Approve if pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA), is currently receiving myelosuppressive chemotherapy and according to the prescriber, myelosuppressive chemotherapy and according to the prescriber, myelosuppressive chemotherapy is considered non-currative AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia and HIV on Zidovudine - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL, pt is currently receiving zidovudine AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Reduction of Allogenic RBC Transfusions in Pts Undergoing Surgery - Hgb is less than 13 g/dL AND surgery is elective, nonvascular and noncardiac AND pt is not able or willing to donate autologus blood prior to surgery AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to MDS - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal to or less than 500 mU/mL AND pt is currently receiving iron therapy OR pt has adequate iron stores according to the prescriber. Anemia due to Myelofibrosis - Pt has a hemoglobin less than 10 g/dL (equal to or less than 12 g/dL if already receiving an ESA) OR has a serum erythropoietin level equal t
	prescriber as defined by a hemoglobin greater than 10 g/dL or an increase of greater than 2 g/dL.

## Erivedge

#### **Products Affected**

• ERIVEDGE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Central Nervous System Cancer.
Exclusion Criteria	Basal Cell Carcinoma (Locally advanced or metastatic) that progressed while on Odomzo. Metastatic Colorectal Cancer. Ovarian Cancer.
Required Medical Information	Diagnosis. Mutation results. Other therapies tried.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Locally advanced basal cell carcinoma - approve if 1. the pt has recurrent basal cell carcinoma following surgery or radiation therapy or pt is not a candidate for surgery or radiation therapy. Continuation therapy - approve. Basal Cell Carcinoma, Metastatic - Approve. Central Nervous System Cancer - approve if pt has tried at least one chemotherapy agent and has medulloblastoma and has a mutation of the sonic hedgehog pathway according to prescriber.

### Erleada

#### **Products Affected**

• ERLEADA ORAL TABLET 240 MG, 60 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Prostate Cancer - Castration-Resistant - Approve if the medication is used in combination with a gonadotropin-releasing hormone (GnRH) agonist, the medication is used concurrently with Firmagon, or pt has had a bilateral orchiectomy. Prostate Cancer - Metastatic, Castration-Sensitive - Approve if the medication is used in combination with a gonadotropin-releasing hormone (GnRH) agonist, the medication is used concurrently with Firmagon, or pt has had a bilateral orchiectomy.

## Erlotinib

#### **Products Affected**

• erlotinib

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Bone Cancer. Renal Cell Carcinoma. Vulvar Cancer.
Exclusion Criteria	Breast Cancer. Colorectal Cancer, Advanced. Glioblasatoma Multiforme. Head and Neck Cancer, Squamous Cell, Recurrent and/or Metastatic. Hepatocellular Carcinoma (HCC), Advanced. Renal Cell Carcinoma (RCC), Advanced - Clear Cell Histology.
Required Medical Information	Diagnosis, mutation results, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if pt has advanced or metastatic, sensitizing epidermal growth factor receptor (EGFR) mutation-positive disease (examples include: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I). Pancreatic Cancer - Approve if pt has locally advanced, metastatic, or recurrent disease and the medication is used in combination with gemcitabine. Bone Cancer - approve if pt has chordoma and has tried at least one previous therapy. Recal Cell Carcinoma (RCC) - Approve if the pt has has recurrent or advanced renal cell carcinoma of non- clear cell histology or the pt has hereditary leiomyomatosis and renal cell carcinoma and the medication is used in combination with bevacizumab. Vulvar Cancer - Approve if pt has advanced, recurrent, or metastatic disease.

## **Everolimus (antineoplastic)**

- everolimus (antineoplastic) oral tablet
- everolimus (antineoplastic) oral tablet
- for suspension

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Endometrial Carcinoma. Gastrointestinal Stromal Tumors (GIST). Histiocytic Neoplasm (HN). Classic Hodkin Lymphoma. Soft Tissue Sarcoma. Thymomas and Thymic Carcinomas. Differentiated Thyroid Carcinoma. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL). Uterine Sarcoma.
Exclusion Criteria	
Required Medical Information	diagnosis, hormone receptor status, prior therapies
Age Restrictions	Breast cancer/NE tumors/RCC/TC/EC/GIST/CHL/HN/US/STS/TTC/WM/LPL - 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Breast Cancer - Approve if pt has recurrent or metastatic, hormone receptor Positive (HR+) disease and human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND pt has tried at least one prior endocrine therapy (anastrazole, letrozole, or tamoxifen), AND pt meets one of the following: pt is a postmenopausal woman or a man OR pt is a pre-or perimenopausal woman receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., leuprolide, triptorelin, goserelin), or has had surgical bilateral oophorectomy or ovarian irradiation AND pt meets one of the following: if pt is a male and if everolimus will be used in combination with exemestane, then the patient is receiving a GnRH analog OR everolimus will be used in combination with exemestane, fulvestrant or tamoxifen AND the pt has not had disease progression while on everolimus. Neuroendocrine Tumors of the Pancreas, Gastrointestinal Tract, Lung, and Thymus (Carcinoid Tumors) - Approve. Renal Cell Carcinoma (RCC) - Pt has relapsed or stage IV disease. If using for clear cell disease, the pt has tried a systemic therapy previously (e.g. axitinib, pazopanib, sunitinib, cabozantinib, sorafenib). Tuberous Sclerosis Complex (TSC)-Associated Renal Angiomyolipoma - approve. TSC-Associated Subependymal Giant Cell Astrocytoma (SEGA) - Approve if SEGA cannot be curatively resected. TSC-Associated Partial Onset Seizure - approve if everolimus will be used in combination with letrozole. GIST - Pt has tried imatinib or avapritinib, sunitinib or dasatinib, regorafenib, ripretinib and everolimus will be used in combination with imatinib, sunitinib, or regorafenib. Histiocytic Neoplasm - Approve if pt has a PIK3CA mutation and one of the following: Erdheim-Chester disease, Rosai-Dorfman disease, or Langerhans cell histiocytosis with bone disease, central nervous system lesions, multisystem disease, or pulmonary disease. Classical Hodgkin Lympoma - approve if pt has refractory or relapsed disease. Soft Tissue Sarcoma - Approve if p

PA Criteria	Criteria Details
	perivascular epitheloid cell tumor (PEComa) or recurrent angiomyolipoma/lymphangioleiomyomatosis. Thymomas and Thymic Carcinomas - Approve if pt has tried chemotherapy or pt cannot tolerate chemotherapy. Thyroid carcinoma, differentiated - Approve if pt has has differentiated thyroid carcinoma (e.g. papillary, follicular, and Hürthle cell thyroid carcinoma) and the disease is refractory to radioactive iodine therapy. WM/LPL - Approve if pt has not responded to primary therapy or pt has progressive or relapsed disease. Uterine Sarcoma (US) - Approve if pt has advanced, recurrent, metastatic, or inoperable disease and a perivascular epithelioid cell tumor (PEComa) and pt has tried at least one systemic regimen.

## Evrysdi

#### **Products Affected**

• EVRYSDI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded
Exclusion Criteria	Patient has Complete Paralysis of All Limbs. Patient has Permanent Ventilator Dependence.
Required Medical Information	Diagnosis, SMA exam results, genetic testing results, pregnancy status, weight
Age Restrictions	
Prescriber Restrictions	prescribed by or in consultation with a physician who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders
Coverage Duration	4 months

PA Criteria	Criteria Details
Other Criteria	Spinal Muscular Atrophy (SMA) - Approve if baseline motor ability assessment that suggests spinal muscular atrophy (based on age, motor ability, and development) is provided from one of the following exams [documentation required]: Bayley Scales of Infant and Toddler Development, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP- INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam Part 2 (HINE- 2), Motor Function Measure-32 Items (MFM-32), Revised Upper Limb Module (RULM) test, or World Health Organization motor milestone scale AND pt has had a genetic test confirming the diagnosis of SMA with bi-allelic pathogenic variants in the survival motor neuron 1 (SMN1) gene [documentation required] AND has two to four survival motor neuron 2 (SMN2) gene copies [documentation required] AND Pt has 2 or 3 survival motor 2 (SMN2) gene copies OR pt has 4 SMN2 gene gopies and the pt has objective signs consistent with spinal muscular atrophy Types 1, 2, or 3 [documentation required] AND for pts currently receiving or who have received prior treatment with Spinraza, the prescriber attests that further therapy with Spinraza, a female of current reproductive potential must meet BOTH of the following: pt is not currently pregnant and effective contraception will be utilized during treatment and for 1 month after the last Evrysdi dose AND dosing of Evrysdi meets ONE of the following based on the current (within the past 1 month) kg weight (a, b, c or d): a) 0.15 mg/kg once daily if pt is less than 2 months of age OR b) 0.2 mg/kg once daily if the patient is 2 months to less than 2 years of age OR c) 0.25 mg/kg once daily for pts greater than 2 years of age Who weigh less than 20 kg OR d) 5 mg once daily for pts greater than 2 years of age who weigh more than 20 kg. Continuation - must meet initial criteria AND according to the prescriber, the patient has responded to Evrysdi and continues to have benefit from ongoing Evrysdi
	therapy by the most recent (within the past 4 months) objective measurement and/or assessment tool.

## Exkivity

#### **Products Affected**

• EXKIVITY

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if pt is currently receiving Exkivity and has locally advanced or metastatic NSCLC, epidermal growth factor receptor (EGFR) exon 20 insertion mutation determined by an approved test, and previously tried at least one platinum-based chemotherapy

### Fasenra

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	COPD. Concurrent use of Fasenra with another monoclonal antibody therapy. Hypereosinophilic Syndrome.
Required Medical Information	Diagnosis, labs, previous and current medications, spirometry results
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
Coverage Duration	Asthma - 6 months initial, 1 year continuation.

PA Criteria	Criteria Details
Other Criteria	Asthma - Approve if pt has a blood eosinophil count greater than 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with Farsenra or another monoclonal antibody therapy that may lower blood eosinophil levels AND pt has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid and one additional asthma controller or asthma maintenance medication AND pt has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following: two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR one or more asthma exacerbations requiring hospitalization, Emergency Department, or urgent care visit in the previous year OR pt has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR pt has an FEV1/forced vital capacity (FVC) less than 0.80 OR pt has asthma that worsens upon tapering of oral corticosteroid therapy. Continuation - Approve if pt has already received 6 months of Fasenra, continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler, and has responded to therapy as determined by the prescriber.

## Filgrastim

#### **Products Affected**

• ZARXIO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Acute lymphocytic leukemia (ALL). Cytokine Release Syndrome Associated with Chimeric Antigen Receptor (CAR) T-Cell Therapy. Drug induced agranulocytosis or neutropenia. Myelodysplastic syndromes (MDS). Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Radiation-Induced Neutropenia.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Cancer/AML/MDS/ALL-oncologist or a hematologist. Cancer patients w/ BMT or PBPC -oncologist, hematologist, or a physician who specializes in transplantation. SCN, AA - hematologist. HIV/AIDS neutropenia - infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. RS - physician who has expertise in treating acute radiation syndrome. RIN - oncologist, radiologist, or radiation oncologist.
Coverage Duration	chemo/SCN/AML-6 mo. HIV/AIDS-4 mo.MDS-3 mo. Drug induced A/N,AA,ALL,BMT-3 mo. PBPC-1mo. Others-12mo.

PA Criteria	Criteria Details
Other Criteria	Cancer patients receiving chemotherapy - Approve if pt 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% 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% 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, filgrastim 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). Cytokine Release Syndrome Associated with Chimeric Antigen Receptor (CAR) T-Cell Therapy - Approve if pt has neutropenia. Radiation-Induced Neutropenia - Approve fi pt is not currently receiving chemotherapy.

## Firazyr (Non-Preferred)

- FIRAZYR
- icatibant

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	HAE Prophylaxis
Required Medical Information	Diagnosis, lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.
Coverage Duration	1 year
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency (Type I or Type II), Treatment of Acute Attacks: Initial - pt has HAE type 1 or 2 as confrimed by low levels of functional C1-INH protein (less than 50% of normal) at baseline and pt has lower than normal serum C4 levels at baseline. Continuation - pt has treated previous acute HAE type 1 or 2 attacks with icatibant and according to the prescriber, the pt has had a favorable response with icatibant treatment. Must also meet the requirements of the Nonpreferred Drug Prior Authorization Criteria.

### Forteo

#### **Products Affected**

• FORTEO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concurrent use with other medications for osteoporosis (Prolia, oral bisphosphonates, calcitonin nasal spray, Tymlos, and Evenity)[VitD and/or Calcium supplements not excluded from concurrent therapy]. Osteoporosis prevention.
Required Medical Information	diagnosis, other therapies tried, lab results
Age Restrictions	
Prescriber Restrictions	Hypoparathyroidism - prescribed by or in consultation with an endocrinologist
Coverage Duration	All Osteoporosis: Initial or less than 1 year: up to 2 years. Continuation: 1 year. HPT - 1 year

PA Criteria	Criteria Details
Other Criteria	Glucocorticoid-Induced Osteoporosis, Treatment - approve if pt is either initiating or continuing systemic glucocorticoids and meets one of the following: pt has tried zoledronic acid injection OR has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy or experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber or has experienced significant intolerance to an oral bisphosphonate OR pt cannot take an oral bisphosphonate due to difficulty swallowing or inability to remain upright, or pt has a pre-existing gastrointestinal medical condition OR pt has severe renal impairment, chronic kidney disease, or has had an osteoporotic fracture or a fragility fracture. Use beyond 2 years is evaluated annually for continued high risk of fracture. Not at high risk of fracture - up to 2 years/lifetime. Osteoporosis, (to Increase Bone Mass) in Men with Primary or Hypogonadal Osteoporosis - Approve if pt has had a T-score at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% radius, has had an osteoporotic fracture or a fragility fracture, or has low bone mass and is at risk for fracture. Pt also meets one of the following: pt has tried ibandronate injection (Postmenopausal pts only) or zoledronic acid injection OR has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and had an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy or experienced inadequate efficacy to oral bisphosphonate therapy after a trial duration of 12 months as determined by the prescriber or has experienced significant intolerance to an oral bisphosphonate OR pt cannot take an oral bisphosphonate therapy after a trial duration of racin take an oral bisphosphonate due to difficulty swallowing or inability to remain upright, or pt has a pre-existing gastrointestinal medical co
	high risk of fracture. Not at high risk of fracture - up to 2 years/lifetime. Hypoparathyroidism (HPT) - Approve if pt has tried Natpara or Natpara is unavailable.

### Fotivda

#### **Products Affected**

• FOTIVDA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Renal Cell Carcinoma (RCC) - Approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens.

### Gavreto

#### **Products Affected**

• GAVRETO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	NSCLC-18 years or older, Thyroid Cancers-12 years or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if pt has recurrent, advanced, or metastatic disease and rearranged during transfection (RET) fusion-positive disease as detected by an approved test. Differentiated Thyroid Cancer - Approve if patient has unresectable, recurrent, or metastatic disease and rearranged during transfection (RET)- fusion positive disease or RET-mutation-positive diease and the disease requires treatment with systemic therapy and the disease is radioactive iodine-refractory. Anaplastic Thyroid Cancer - Approve if patient has unresectable, recurrent, or metastatic disease and rearranged during transfection (RET)- fusion positive disease or RET-mutation-positive diease. Medullary Thyroid Cancer - Approve if patient has unresectable, recurrent, or metastatic disease and rearranged during transfection (RET)- fusion positive disease or positive disease or RET-mutation-positive diease. Medullary Thyroid Cancer - Approve if patient has unresectable, recurrent, or metastatic disease and rearranged during transfection (RET)- fusion positive disease or RET-mutation-positive diease and the pt. is continuing therapy with Gavreto.

## Gilotrif

#### **Products Affected**

• GILOTRIF

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Head and Neck Cancer.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer - Epidermal Growth Factor Receptor (EGFR) Mutation-Positive - Approve if pt has advanced or metastatic disease and has sensitizing EGFR mutation-positive non-small cell lung cancer as detected by an approved test. Non-Small Cell Lung Cancer - Squamous Cell Carcinoma - Approve if pt has metastatic squamous cell carcinoma and has disease progression after treatment with platinum-based chemotherapy. Head and Neck Cancer - Approve if pt has non- nasopharyngeal head and neck cancer and has disease progression on or after platinum-based chemotherapy.

### Gleostine

### **Products Affected**

• GLEOSTINE

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded. Breast Carcinoma. Colorectal Cancer. Lung Cancer. Malignant Tumor of the Thymus. Melanoma.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Hodgkin's disease - Approve if requested medication will be used in combination with other chemotherapy and disease has progressed following initial therapy. Intracranial Tumor - Approve. Breast Carcinoma - Approve. Colorectal Cancer - Approve. Lung Cancer - Approve. Malignant Tumor of the Thymus - Approve. Melanoma - Approve.

### **Glucose Test Strips and Meters**

- FORA G20
- FREESTYLE FREEDOM LITE
- FREESTYLE INSULINX
- FREESTYLE INSULINX TEST STRIPS
- FREESTYLE LITE METER
- FREESTYLE LITE STRIPS
- FREESTYLE TEST
- GLUCOCARD EXPRESSION
- GLUCOCARD EXPRESSION KIT
- GLUCOCARD EXPRESSION STRIP
- GLUCOCARD SHINE METER

- GLUCOCARD SHINE XL METER
- ONETOUCH ULTRA TEST
- ONETOUCH ULTRA2 METER

- ONETOUCH ULTRAMINI
- ONETOUCH VERIO FLEX METER
- ONETOUCH VERIO IQ METER
- ONETOUCH VERIO METER
- ONETOUCH VERIO TEST STRIPS
- PRECISION XTRA KETONE-GLUCOSE
- PRECISION XTRA MONITOR
- PRECISION XTRA TEST
- PRODIGY NO CODING
- PRODIGY POCKET METER
- PRODIGY VOICE GLUCOSE METER
- GLUCOCARD SHINE METER KIT
  GLUCOCARD SHINE TEST STRIPS
  TRUE METRIX AIR GLUCOSE METER
  TRUE METRIX GLUCOSE METER

  - TRUE METRIX GLUCOSE TEST STRIP
  - WAVESENSE PRESTO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Previous supplies tried and failed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Approval duration of 1 year
Other Criteria	Required to try two different preferred Contour or Accu-Chek meters and tests strips or have a clinical reason why these cannot be tried. Approve if the patient requires a specific brand meter and test strip due to insulin pump requirements or due to vision impairment.

### **Growth Hormones**

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- NORDITROPIN FLEXPRO
- NUTROPIN AQ NUSPIN
- OMNITROPE

- SAIZEN
- SAIZEN SAIZENPREP
- SEROSTIM SUBCUTANEOUS RECON SOLN 4 MG, 5 MG, 6 MG
- ZOMACTON
- ZORBTIVE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Short Bowel Syndrome in Adults.
Exclusion Criteria	Acute Critical Illness Due to Complications Following Surgery, Multiple Accidental Trauma, or with Acute Respiratory Failure. Aging, To Improve Functional Status in Elderly Patients, and Somatopause. Athletic Ability Enhancement. Central Precocious Puberty. Chronic Fatigue Syndrome. Congenital Adrenal Hyperplasia (CAH). Constitutional Delay of Growth and Puberty (CDGP). Corticosteroid-Induced Short Stature. Fibromyalgia. Human Immunodeficiency Virus (HIV)-Infected Patients with Alterations in Body Fat Distribution. Infertility. Obesity. Osteoporosis.
Required Medical Information	Diagnosis, lab results [documentation required], vitals
Age Restrictions	NGHDSS - 5 years or younger. Children Born Small for Gestational Age or with Intrauterine Growth Restriction (initial) - 2 years or older. SBS, HIV - 18 years or older.
Prescriber Restrictions	GHD, Noonan, PWS, SHOX, born small - eval by endocrinologist. CKD - eval by endocrinologist or a nephrologist.
Coverage Duration	NGHDSS (initial) - 6 months. SBS (initial and cont) - 1 mo. All others - 1 year

PA Criteria	Criteria Details
Other Criteria	GHD-Child/Adolescent- pt had 2 GH tests with poor reponse OR pt has had 1 GH test with poor response and at least 1 risk factor for GHD, brain radiation or tumor resection and either 1 GH test with an poor response or deficiency in other pituitary hormone, pt has congenital hypopituitarism and either 1 GH test with poor response, deficiency in other pituitary hormone, or imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk, multiple pituitary hormone deficiencies, 3 or more pituitary deficiencies, or 1 GH test with an poor response, or hypophysectomy. Short Stature - Pt is at least 5 yo, pts ht below 1.2% or SDS -2.25, velocity below 4cm/yr or 10th percentile, without GH adult ht is 63 in for M or 59 in for F, the epiphyses open and no constitutional delay of growth and puberty. Cont-x6-10mo: Pt is at least 5 yo and growth rate doubled.GHD in Adult/Transition Adolescent - Not for anti-aging therapy, athletic ability or body building, doc. of childhood onset, adult onset from hypopituitarism, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor tx, traumatic brain injury, or subarachnoid hemorrhage, pt has perinatal insults or conenital or genetic defects, or structural hypothalamic-pituitary defects or 3 pituitary hormone deficiencies with a low serum insulin-like growth factor-1 due to GHD, adult pt has had a neg. response to GH stim test or transition adolescent pt off somatropin for 1 mo. and inadequate GH stim test. CKD Child/Adolescent- pt has GFR under 60 and baseline ht is below 5th percentile and ht velocity is below 25th perentile over 3 mo in infants or 6 mo in children. Noonan-Baseline ht is below 5th percentile, dx confirmed by genetic test or clinical diagnosis if genetic test is not definitive. Prader-Willi Syndrome- dx confirmed by genetic testing. Short Stature Homeobox (SHOX) - Approve if pt has SHOX deficiency dx by chromosome analysis, epiphyses open, and ht below 5th percentile. Born Small/Silver-Russell Syndrome- pt was bor

PA Criteria	Criteria Details
	karyotypoe analysis and baseline ht below 5th percentile. Short Bowel Syndrome - Approve if pt is on nutritional support and dependent on parenteral nutrition. Cont - Approve if prescriber attests to response. HIV w/ wasting or cachexia - approve if unintended wt loss of 10% or more or wt less than 90% of LL of IBW or BMI 20 or less and has wasting or cachexia, on antiretroviral tx for 30 days or more and will cont., not solely for tx of alteration in body fat distribution and pt tried 1 appetite stim. Cont (CKD, Noonan, PWS,SHOX,Born Small,Turner)- ht increased by 2cm/yr and epiphyses are open. Cont (CHD, CKD, SS w/ tx longer than 10mo) - Ht has increased by 2cm/yr, if greater than 11 yo epiphysis are open, and if 18yo, mid parental ht not obtained.

# Haegarda (Non-Preferred)

### **Products Affected**

• HAEGARDA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concomitant Use with Other Hereditary Angioedema (HAE) Prophylactic Therapies
Required Medical Information	Diagnosis, lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders.
Coverage Duration	1 year
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis - Approve if pt has HAE type I or type II as confirmed by low levels of functional C1-INH protein (less than 50% of normal) and lower than normal serum C4 levels at baseline [documentation required]. Continuation - Approve if pt has a diagnosis of HAE type I or type II [documentation required] and according to the prescriber, the patient has had a favorable clinical response with Haegarda treatment. Must also meet the requirements of the Nonpreferred Drug Prior Authorization Criteria.

# Hemlibra

### **Products Affected**

• HEMLIBRA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	lab results, other medications tried
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hemophilia specialist
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Hemophilia A with Factor VIII Inhibitors - Approve if pt is using Hemilibra for routine prophylaxis to prevent or reduce the frequency of bleeding episodes AND either has had a positive Factor VIII inhibitor titer greater than 5 Bethesda Units OR has had a positive Factor VIII inhibitor titer less than or equal to 5 Bethesda Units with an anamnestic response (current or past) to Factor VIII product dosing or experienced an inadequate clinical response (current or past) to increased Factor VIII product dosing. Prescriber also attests that the patient will not be undergoing immune tolerance induction therapy while receiving Hemlibra, that if the patient is currently receiving a bypassing agent for prophylaxis, the bypassing agent therapy will be discontinued the day prior to initiation of Hemlibra and prophylactic use of bypassing agents will not occur while using Hemlibra, AND if the pt is currently receiving a Factor VIII product for prophylactic use, the Factor VIII product will be discontinued within the initial 4-week loading dose period with Hemlibra and that prophylactic use of Factor VIII products will not occur while using Hemlibra. Continuation - prescriber must make Factor VIII and bypassing agent attestations and the pt must have experienced a beneficial response, according to prescriber. Hemophilia A without Factor VIII Inhibitors - Approve if pt is using Hemlibra for routine prophylaxis to prevent or reduce the frequency of bleeding episodes AND has severe to moderate severe disease as defined by pretreatment Factor VIII levels less than 2% of normal OR has moderate to mild disease as defined by pretreatment Factor VIII levels greater than 2% to less than 40% of normal and meets one of the following criteria: pt has experienced a severe, traumatic, or spontaneous bleeding episode as determined by the prescriber, has hemophilia-related joint that is subject to recurrent bleeding (presence of a target joint), or is in a perioperative situation and/or has an additional clinical scenario regarding bleed
	prophylactic use of bypassing agent will not occur while using Hemlibra, that if pt is receiving a Factor VIII product for prophylactic use, therapy will be discontinued within the initial 4-week loading dose period with Hemlibra, and prophylactic use of Factor VIII products will not occur while using Hemlibra. Continuation - prescriber must make Factor VIII and bypassing agent attestations and the pt must have experienced a beneficial response, according to prescriber.

### **Hepatitis C Agents**

- EPCLUSA ORAL TABLET
- HARVONI
- ledipasvir-sofosbuvir
- MAVYRET ORAL TABLET
- sofosbuvir-velpatasvir

- SOVALDI
- VIEKIRA PAK
- VOSEVI
- ZEPATIER

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Consistent with MN DHS criteria.
Required Medical Information	Consistent with MN DHS criteria.
Age Restrictions	Consistent with MN DHS criteria.
Prescriber Restrictions	Consistent with MN DHS criteria.
Coverage Duration	Consistent with AASLD guidelines
Other Criteria	Consistent with MN DHS criteria.

## Hydroxyprogesterone

- hydroxyprogest(pf)(preg presv)
- hydroxyprogesterone cap(ppres)
- hydroxyprogesterone capr(bulk)
- hydroxyprogesterone caproate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Hx of threatened preterm birth. Infertility. Pts pregnant with multiple gestations (twins, or other multiples). Pregnant pt with short cervix without a hx of a prior Singleton Spontaneous Preterm Birth.
Required Medical Information	Pregnancy status and history
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Reduce Risk of Preterm Birth - 5 months.
Other Criteria	Reduce Risk of Preterm Birth - Pt is pregnant with singleton pregnancy with history of single spontaneous preterm birth prior to 37 weeks gestation and the pt is currently receiving hydroxyprogesterone caproate. NOTE: In cases where there was an inaccuracy in dating the pregnancy, a one-month authorization may be granted to patients who have already received 21 injections and are less than 37 weeks pregnant.

### Ibrance

### **Products Affected**

• IBRANCE ORAL CAPSULE

PA Criteria	Criteria Details
Covered Uses	All-FDA approved indications not otherwise excluded. Liposarcoma.
Exclusion Criteria	
Required Medical Information	diagnosis, hormone receptor status, concurrent therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Breast Cancer - approve if pt has advanced 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: Pt is postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) or has had surgical bilateral oophorectomy or ovarian irradiation AND Ibrance will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant. Breast Cancer in Men - approve if pt has advanced or metastatic hormone receptor positive (HR+) (i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+))disease, and HER2- negative breast cancer and pt is receiving a gonadotropin- releasing hormone (GnRH) AND Ibrance will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant. Lipsarcoma - Approve if pt patient has well- differentiated/dedifferentiated liposarcoma (WD-DDLS).

# Iclusig

### **Products Affected**

• ICLUSIG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Myeloid/Lymphoid Neoplasms with Eosinophilia. Gastrointestinal Stromal Tumor.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acute Lymphoblastic Leukemia - Approve if pt has Philadelphia chromosome-positive acute lymphoblastic leukemia and has tried at least two other tyrosine kinase inhibitors for Philadelphia chromosome-positive acute lymphoblastic leukemia. Chronic Myeloid Leukemia - Approve if pt has Philadelphia chromosome positive chronic myeloid leukemia and either has tried at least two other tyrosine kinase inhibitors for Philadelphia chromosome-positive chronic myeloid leukemia or the chronic myeloid leukemia is T315I-positive or the pt has accelerated-phase CML or blast-phase CM and no other tyrosine kinase inhibitor is indicated. Myeloid/Lymphoid Neoplasms with Eosinophilia - Approve if tumor has an ABL1 or FGFR1 rearrangement. Gastrointestinal Stromal Tumor - Approve if pt has tried imatinib or Ayvakit AND sunitinib or Sprycel AND Stivarga AND Qinlock.

# Idhifa

### **Products Affected**

• IDHIFA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acute Myeloid Leukemia (AML) - approve if the disease is isocitrate dehydrogenase-2 (IDH2)-mutation positive as detected by an approved test.

# Imatinib

### **Products Affected**

• imatinib oral tablet 100 mg, 400 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. All FDA approved indications not otherwise excluded. Chordoma. Fibromatosis (Desmoid Tumors). Graft Versus Host Disease, Chronic. Kaposi Sarcoma. Melanoma, cutatneous. Myeloid/Lymphoid Neoplasms with Eosinophilia. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor.
Exclusion Criteria	
Required Medical Information	Diagnosis. Mutation results.
Age Restrictions	ASM/DP/HS/MMD/KS/MC - 18 or older.
Prescriber Restrictions	
Coverage Duration	Graft Versus Host Disease, Chronic - 1 year. All others - 3 years

PA Criteria	Criteria Details
Other Criteria	Acute Lymphoblastic Leukemia - Approve if pt has Philadelphia chromosome-positive acute lymphoblastic leukemia. Aggressive Systemic Mastocytosis (AMS) - Approve. Chronic Myeloid Leukemia - Approve if pt has Philadelphia chromosome-positive chronic myeloid leukemia. Dermatofibrosarcoma Protuberans (DP) - Approve. Gastrointestinal Stromal Tumors - Approve. Hypereosinophilic Syndrome and/or Chronic Eosinophilic Leukemia (HS) - Approve. Myelodysplastic/Myeloproliferative Disease (MMD) - Approve if condition is associated with platelet- derived growth factor receptor (PDGFR) gene rearrangements. Chordoma - Approve. Graft Versus Host Disease, Chronic - Approve if pt has tried at least one conventional systemic treatment for graft versus host disease. Kaposi Sarcoma (KS) - Approve if pt has tried at least one medication and has relapsed or refractory disease. Melanoma, cutaneous (MC) - Approve if pt has an activating KIT mutation and metastatic or unresectable disease and has tried at least one systemic regimen. Myeloid/Lymphoid Neoplasms with Eosinophilia - Approve if pt has tumor has an ABL1, FIP1L1-PDGFRA or PDGFRB rearrangement. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor - Approve if pt has tried pexidartinib or cannot take pexidartinib, according to the prescriber.

## Imbruvica

#### **Products Affected**

• IMBRUVICA ORAL CAPSULE 140 MG, 70 MG

280 MG, 420 MG, 560 MG

- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 140 MG,

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. B-Cell Lymphoma. Central Nervous System Lymphoma (Primary). Hairy Cell Leukemia. Mantle Cell Lymphoma. Marginal Zone Lymphoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	GVHD - 1 year or older, All other indications - 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Chronic Lymphocytic Leukemia (CLL) - Approve. Graft-Versus- Host Disease, Chronic (GVHD) - Approve if pt has tried at least one conventional systemic treatment for graft-versus-host disease. Mantle Cell Lymphoma - Approve if pt is continuing Imbruvica and has tried at least one systemic regimen unless contraindicated or imbruvica is used in combination with rituximab prior to induction therapy or Imbruvica is used as induction or maintenance therapy in combination with chemotherapy. Marginal Zone Lymphoma (MZL) - Approve if pt is continuing Imbruvica and tried at least one systemic regimen. Small Lymphocytic Lymphoma - Approve. Waldenström Macroglobulinemia (includes lymphoplasmacytic lymphoma and Bing-Neel syndrome) - Approve. B-Cell Lymphoma (BCL) - Approve if pt has tried at least one systemic regimen. Central Nervous System Lymphoma (Primary) (CNSL) - Approve if pt has tried at least one therapy and according to the prescriber, the patient is not a candidate for or is intolerant to high-dose methotrexate. Hairy Cell Leukemia (HCL) - Approve if pt has tried at least two systemic regimens.

### Immunomodulators Non-preferred Step 1

- ACTEMRA ACTPEN
- ACTEMRA INTRAVENOUS
- ACTEMRA SUBCUTANEOUS
- COSENTYX
- COSENTYX (2 SYRINGES)
- COSENTYX PEN
- COSENTYX PEN (2 PENS)
- COSENTYX UNOREADY PEN
- ENTYVIO

- INFLECTRA
- infliximab
- ORENCIA
- ORENCIA (WITH MALTOSE)
- ORENCIA CLICKJECT
- OTEZLA
- OTEZLA STARTER
- RENFLEXIS
- STELARA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Must meet non-preferred criteria

### **Immunomodulators Non-preferred Step** 2

- CIMZIA
- CIMZIA POWDER FOR RECONST
- CIMZIA STARTER KIT
- ENSPRYNG
- ILARIS (PF)
- ILUMYA
- KEVZARA
- KINERET
- OLUMIANT ORAL TABLET 1 MG, 2 MG, 4 MG
- REMICADE
- RINVOQ ORAL TABLET EXTENDED RELEASE 24 HR 15 MG, 30 MG, 45 MG
- SILIQ
- SIMPONI
- SIMPONI ARIA

- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.83 ML
- SKYRIZI SUBCUTANEOUS SYRINGE
   KIT
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR 180 MG/1.2 ML (150 MG/ML), 360 MG/2.4 ML (150 MG/ML)
- TALTZ AUTOINJECTOR
- TALTZ AUTOINJECTOR (2 PACK)
- TALTZ AUTOINJECTOR (3 PACK)
- TALTZ SYRINGE
- TREMFYA
- UPLIZNA
- XELJANZ XR

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Must meet non-preferred criteria having tried 2 preferred agents and at least one non-preferred step 1 agent prior to approval unless contraindicated pursuant to the pharmaceutical manufacturer's prescribing information or, due to a documented adverse event or medical condition, is likely to result in the following: cause an adverse reaction, decrease the ability of the member to achieve or maintain reasonable functional ability in performing daily activities, or cause physical or mental harm to the member.

# Inlyta

#### **Products Affected**

• INLYTA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	ARCC/DTC/STS - 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Advanced Renal Cell Carcinoma (ARCC) - Approve. Differentiated Thyroid Cancer (DTC) (examples include papillary, follicular, and oncocytic carcinoma (formerly Hürthle cell thyroid carcinoma) - Approve if patient is refractory to radioactive iodine therapy. Soft Tissue Sarcoma (STS) - Approve if pt has alveolar soft part sarcoma and the medication will be used in combination with Keytruda.

# Inqovi

### **Products Affected**

• INQOVI

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from coverage
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Chronic Myelomonocytic Leukemia - Approve. Myelodysplastic Syndrome - Approve. Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Neoplasms - Approve

## Inrebic

#### **Products Affected**

• INREBIC

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from coverage. Myeloid/Lymphoid neoplasms with Eosinophilia.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or 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 pt has intermediate-2 or high-risk disease. Myeloid/Lymphoid neoplasms - Approve if the pt has eosinophilia and tumor has a JAK2 rearrangement.

### Iressa

### **Products Affected**

• gefitinib

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer - Approve if the pt has advanced or metastatic disease and has has sensitizing EGFR mutation- positive disease(e.g. exon 19 deletions, exon 21 [L858R] substitution mutations, L861Q, G719X, and S768I.) and the mutation was detected by an approved test.

## **Iron Chelators**

- deferasirox
- deferiprone

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded. Deferiprone only: Iron Overload, Chronic - Non-Transfusion- Dependent Thalassemia Syndromes.
Exclusion Criteria	
Required Medical Information	diagnosis, serum ferritin level
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	1 year
Other Criteria	Iron Overload, Chronic - Non-Transfusion-Dependent Thalassemia Syndromes - Approve if prior to starting chelating therapy, serum ferritin level was greater than 300 micrograms/liter. Continuation - Approve if the patient is benefiting from therapy, as confirmed by the prescriber. Iron Overload, Chronic - Transfusion-Related Due to Thalassemia Syndromes, Sickle Cell Disease, or Other Anemias (deferiprone only) - Approve if prior to starting chelating therapy, serum ferritin level was greater than 1,000 micrograms/liter. Continuation - Approve if the patient is benefiting from therapy, as confirmed by the prescriber. Iron Overload, Chronic - Transfusion-Related (deferasirox only) - Approve if pt is receiving blood transfusions at regular intervals for a chronic condition and prior to starting chelating therapy, serum ferritin level was greater than 1,000 micrograms/liter (mcg/L). Continuation - Approve if the patient is benefiting from therapy, as confirmed by the prescriber. Iron Overload, Chronic -

### Isturisa

### **Products Affected**

 ISTURISA ORAL TABLET 1 MG, 10 MG, 5 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, prior surgeries
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's disease/syndrome
Coverage Duration	Cushing's Disease/Syndrome- 1 yr. Patients awaiting surgery or response after radiotherapy- 4 months
Other Criteria	Cushing's Disease - Approve if the patient is not a candidate for surgery or surgery has not been curative. Endogenous Cushing's Syndrome - Approve if, according to the prescriber, the patient is not a candidate for surgery or surgery has not been curative AND pt has tried one of the following: ketoconazole tablets, Korlym, Metopirone, Lysodren, Signifor, or Signifor LAR for the treatment of endogenous Cushing's syndrome OR is currently receiving Isturisa. Endogenous Cushing's Syndrome, pts awaiting surgery or pts awaiting therapeutic response after radiotherapy - approve.

## Ivermectin

#### **Products Affected**

• ivermectin oral

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Ascariasis. Demodex folliculorum infection. Gnathostomiasis. Enterobiasis. Hookworm-related cutaneous larva migrans. Mansonella ozzardi infection. Mansonella streptocerca infection. Pediculosis. Scabies. Trichuriasis. Wucheria bancrofti infection.
Exclusion Criteria	Coronovirus disease 2019 (COVID-19)
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Please see approval durations in other criteria.
Other Criteria	Onchocerciasis - Approve for 1 dose. Strongyloidiasis - Approve for 2 doses. Ascariasis- Approve for 1 dose. Demodex folliculorum infection - Approve for 2 doses. Gnathostomiasis - Approve for 1 dose. Enterobiasis - Approve for 2 doses. Hookworm-related cutaneous larva migrans - Approve for 1 dose. Mansonella ozzardi infection - Approve for 1 dose. Mansonella streptocerca infection - Approve for 1 dose. Pediculosis - Approve for 3 doses if pt has infection causes by head, body, or pubic lice. Scabies - Approve for 2 doses if pt has classic scabies, treatment-resistant scabies, or pt is unable to tolerate topical treatment. Approve for 5 doses if pt has crusted scabies. Approve for 1 dose if pt is using ivermectin for prevention and/or control of scabies. Trichuriasis - Approve for 3 doses. Wucheria bancrofti infection - Approve for 1 dose.

# Jakafi

### **Products Affected**

• JAKAFI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Acute Lymphoblastic Leukemia. Atypical Chronic Myeloid Leukemia. Chronic Monomyelocytic Leukemia-2. Essential Thrombocythemia. Myeloid or Lymphoid Neoplasms.
Exclusion Criteria	
Required Medical Information	Previous therapies tried. Mutation results.
Age Restrictions	GVHD - 12 years or older. MF/PV/CML-2/ET/MLN - 18 years or older. ALL - 21 years or older.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Graft versus Host Disease, Acute - Approve if pt has tried one systemic corticosteroid. Graft versus Host Disease, Chronic - Approve if pt has tried one conventional systemic treatment for graft versus host disease. Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF - approve. Polycythemia Vera (PV) - Approve if pt has tried hydroxyurea or Pegasys (peginterferon alfa-2a). Acute Lymphoblastic Leukemia (ALL) - Approve if the mutation/pathway is Janus Associated Kinase-related. Atypical Chronic Myeloid Leukemia - Approve if pt has a CSF3R mutation or a Janus Associated Kinase 2 rearrangement. Chronic Monomyelocytic Leukemia-2 (CML-2) - Approve if pt is also receiving a hypomethylating agent. Essential Thrombocytopenia - Approve if pt has tried hydroxyurea, peginterferon alfa-2a, or anagrelide. Myeloid or Lymphoid Neoplasms - Approve if pt has eosinophilia and the tumor has a Janus Associated Kinase 2 (JAK2) rearrangement.

# Jaypirca

#### **Products Affected**

• JAYPIRCA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Chronic Lymphocytic Leukemia. Small Lymphocytic Leukemia.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Mantle Cell Lymphoma - Approve if pt has tried at least one prior systemic therapy unless contraindicated and pt has tried one Bruton tyrosine kinase inhibitor (BTK) for mantle cell lymphoma. Chronic Lymphocytic Leukemia - Approve if pt has resistance or intolerance to Imbruvica, Calquence or Brukinsa OR pt has relapsed or refractory disease and has tried a Bruton tyrosine kinase inhibitor and Venclexta. Small Lymphocytic Leukemia - Approve if pt has resistance or intolerance to Imbruvica, Calquence or Brukinsa OR pt has relapsed or refractory disease and has tried a Bruton tyrosine kinase inhibitor and Venclexta.

# Jynarque

#### **Products Affected**

• JYNARQUE ORAL TABLET

(AM)/ 30 MG (PM)

 JYNARQUE ORAL TABLETS, SEQUENTIAL 45 MG (AM)/ 15 MG (PM), 60 MG (AM)/ 30 MG (PM), 90 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concurrent use of Samsca. Hyponatremia.
Required Medical Information	Diagnosis, renal function
Age Restrictions	18 years and older
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist
Coverage Duration	1 year
Other Criteria	Autosomal Dominant Polycystic Kidney Disease - Approve if according to the prescriber the pt has rapidly-progressing autosomal dominant polycystic kidney disease and does not have Stage 5 chronic kidney disease (Note: Stage 5 CKD is definded as glomerular filtration rate less than 15 mL/min/1.73 m2 or receiving dialysis).

# Kalbitor (Non-Preferred)

#### **Products Affected**

• KALBITOR

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Hereditary Angioedema (HAE) Prophylaxis
Required Medical Information	Diagnosis, lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders.
Coverage Duration	1 year
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks - Approve if pt has HAE type I or type II as confirmed by low levels of functional C1-INH protein (less than 50% of normal) and lower than normal serum C4 levels at baseline [documentation required]. Continuation - Approve if pt has a diagnosis of HAE type I or type II [documentation required] and according to the prescriber, the patient has had a favorable clinical response with Kalbitor treatment. Must also meet the requirements of the Nonpreferred Drug Prior Authorization Criteria.

# Kalydeco

- KALYDECO ORAL GRANULES IN PACKET
- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	CF pts who are Homozygous for the phe508del (F508del) Mutation in the CFTR gene. CF pts with unknown CFTR gene mutation. Combination therapy with Orkambi, Symdeko, or Trikafta.
Required Medical Information	Diagnosis, specific CFTR gene mutations
Age Restrictions	1 month and older
Prescriber Restrictions	Must be prescribed by or in consultation with a pulmonologist or physician or specializes in the treatment of CF
Coverage Duration	1 year
Other Criteria	Cystic Fibrosis (CF) - Patient has at least ONE of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, D1270N, G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, G1349D, 2789+5G-A, 3272- 26A-G, 3849+10kbC-T, 711+3A-G, E831X, R117H, A120T, A234D, A349V, D192G, D924N, E882K, F311L, F311delF508C, F508C,S1251N, G178E, G194R, G314E, G576A, G970D, G1249R, H939R, H1375P, I148T, I175V, I807M, I1027T, I1139V, L320V, L967S, L997F, L1480P, M152V, M9521, M952T, Q237E, Q237H, Q359R, Q1291R, R75Q, R117G, R117L, R117P, R170H, R347L, R553Q, R668C, R792G, R933G, R1162L, R1283M, S589N, S737F, S1159F, S1159P, T338I, T1053I, V232D, V562I, V754M, V1293G, W1282R, Y1014C, or Y1032C.

# Kisqali

- KISQALIKISQALI FEMARA CO-PACK

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Breast cancer in men.
Exclusion Criteria	
Required Medical Information	diagnosis, hormone receptor status, concurrent therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Breast Cancer - approve if pt has advanced 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: Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) or has had surgical bilateral oophorectomy or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant. Breast Cancer in Men - approve if pt has advanced or metastatic hormone receptor positive (HR+) (i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+))disease, and HER2- negative breast cancer and pt is receiving a gonadotropin- releasing hormone (GnRH) AND Kisqali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant.

## Koselugo

### **Products Affected**

• KOSELUGO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Circumscribed Glioma. Langerhans Cell Histiocytosis.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, prior therapies tried
Age Restrictions	NT1 - 2 years or older. PA - 3 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Neurofibromatosis Type 1 - approve if the patient is 2 to 18 years of age OR the patient is 19 years of age or older and has been previously started on therapy with Koselugo prior to becoming 19 years of age, AND prior to starting Koselugo the patient has symptomatic, inoperable plexiform neurofibromas, according to the prescriber. Circumscribed Glioma - Approve if pt has recurrent, refractory, or progressive disease, the requested medication will be used as a single agent, and the tumor is BRAF fusion positive or BRAF V600E activating mutation positive or pt has neurofibromatosis type 2 mutated glioma and pt is age 3-21 or if older than 21 pt previously started on therapy with Koselugo prior to becoming 21. Langerhans Cell Histiocytosis (LCH) - Approve if medication will be used as a single agent and pt has multisystem LCH and systemic disease or impending organ dysfunction OR pt has single system lung LCH OR pt has single system bone disease and has not responded to bisphosphonate tx and has more than 2 bone lesions OR pt has central nervous system disease.

## Krazati

#### **Products Affected**

• KRAZATI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, prior therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if pt 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.

### Lenvima

#### **Products Affected**

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Medullary thyroid carcinoma. Thymic Carcinoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous tried therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Endometrial Carcinoma - Approve if pt has advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and is used in combination with Keytruda, after pt has tried at least one systemic therapy and is not a candidate for curative surgery or radiation. Hepatocellular Cancer - Approve if pt has unresectable or metastatic disease. Renal Cell Cancer - Approve if pt has advanced disease and pt either using Lenvima in combinatino with Keytruda OR Lenvima is being used with everolimus and pt either has clear cell histology and has tried one antiangiogenic therapy or pt has non-clear cell histology. Thyroid Carcinoma, Differentiated (papillary, follicular, and oncocytic carcinoma (formerly Hürthle cell carcinoma)) - Approve if disease is refractory to radioactive iodine therapy. Thymic Carcinoma - Approve if pt has tried at least one chemotherapy regimen. Medullary Thyroid Carcinoma - Approve if pt has unresectable or metastatic melanoma and the medication will be used in combination with Keytruda and pt has disease progression on PD-1/PD-L1 based therapy

# Livtencity

#### **Products Affected**

• LIVTENCITY

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, weight
Age Restrictions	12 years or older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center
Coverage Duration	2 months
Other Criteria	Cytomegalovirus Infection - Treatment (CMV) - Approve if pt weights at least 35 kg (77 lbs), the pt is post-transplant, Livtencity is not prescribed in conjunction with ganciclovir or valganciclovir, and the patients CMV is is refractory to treatment with one of cidofovir, foscarnet, ganciclovir, or valganciclovir or the pt has significant intolerance to ganciclovir or valganciclovir.

# **Long Acting Opioids**

- BELBUCA
- fentanyl transdermal patch 72 hour 25 morphine oral tablet extended release mcg/hr, 50 mcg/hr
- hydromorphone oral tablet extended release 24 hr
- morphine oral tablet 15 mg
- 100 mg, 15 mg, 200 mg, 30 mg, 60 тg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded worded as pain severe enough to require daily, around-the-clock, long- term opioid treatment. Plus patients with a cancer or sickle cell diagnosis, patients in a hospice program/end-of-life care/palliative care.
Exclusion Criteria	Acute pain (pain which has been occurring for less than 3 months or is within the time of normal tissue healing).
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried,concurrent pain medications/therapies.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 12 months

PA Criteria	Criteria Details
Other Criteria	For pain severe enough to require daily, around-the-clock, long- term opioid treatment greater than 3 months or past the time of normal tissue healing (with no cancer or sickle cell diagnosis and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naïve (except if a buprenorphine product is prescribed), AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patients history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), unless unavailable in the state, 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. If request is for Oxycontin, pt must have had a trial and failure of oxycodone ER unless prescriber indicates that Oxycontin is needed for abuse-resistant properties. 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. Non-preferred drugs are also required to meet the non-preferred drug criteria.

# Long Acting Opioids (Non-Preferred)

- ARYMO ER
- *buprenorphine*
- *buprenorphine hcl buccal*
- DURAGESIC
- EMBEDA
- EXALGO ER
- fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 37.5 mcg/hour, 62.5 mcg/hour, 75 mcg/hr, 87.5 mcg/hour
- hydrocodone bitartrate
- HYSINGLA ER
- KADIAN
- methadone oral concentrate
- methadone oral solution 10 mg/5 ml, 5 oxymorphone oral tablet extended ma/5 ml
- methadone oral tablet 10 mg, 5 mg
- *methadone oral tablet, soluble*

- MORPHABOND ER •
- morphine oral capsule, er multiphase 24 hr
- morphine oral capsule, extend. release pellets
- MS CONTIN
- NUCYNTA ER
- OPANA ER
- OXYCODONE ORAL TABLET, ORAL ONLY, EXT. REL. 12 HR 10 MG, 15 MG, 20 MG, 30 MG, 40 MG, 60 MG, 80 MG
- OXYCONTIN ORAL TABLET, ORAL ONLY, EXT. REL. 12 HR 10 MG, 15 MG, 20 MG, 30 MG, 40 MG, 60 MG, 80 MG
- release 12 hr
- XTAMPZA ER
- ZOHYDRO ER

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded worded as pain severe enough to require daily, around-the-clock, long- term opioid treatment. Plus patients with a cancer or sickle celldiagnosis, patients in a hospice program/end-of-life care/palliative care.
Exclusion Criteria	Acute pain (pain which has been occurring for less than 3 months or is within the time of normal tissue healing).
Required Medical Information	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For pain severe enough to require daily, around-the-clock, long- term opioid treatment greater than 3 months or past the time of normal tissue healing (Pts with Sickle Cell Disease, Cancer or in Long Term Care are exempt) - Approve if all of the following criteria are met: 1) patient is not opioid naïve (except if a buprenorphine product is prescribed), AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patients 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. If request is for Oxycontin, pt must have had a trial and failure of oxycodone ER unless prescriber indicates that Oxycontin is needed for abuse-resistant properties. 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. Non-preferred drugs are also required to meet the non-preferred drug criteria.

### Lonsurf

#### **Products Affected**

• LONSURF

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	diagnosis, mutation results
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Colon, Rectal, or Appendiceal Cancer - Approve if pt has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5- fluorouracil [5-FU]), oxaliplatin, and irinotecan, and if the pt's tumor or metastases are KRAS and NRAS mutation negative, then Erbitux or Vectibix has been tried. Gastric or Gastroesophageal Junction Adenocarcinoma - Approve if pt has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma.

### Lorbrena

#### **Products Affected**

• LORBRENA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Erdheim- Chester Disease. Inflammatory Myofibroblastic Tumor. Non- Small Cell Lung Cancer - ROS1 Rearrangement-Positive.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, previous therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer - Anaplastic Lymphoma Kinase (ALK) Positive - Approve if pt has advanced or metastatic disease and ALK-positive disease as detected by an approved test. Erdheim-Chester Disease - Approve if pt has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor (IMT) - Approve if pt has ALK positive disease and has advanced, recurrent, or metastatic disease or the tumor is inoperable. Non-Small Cell Lung Cancer - ROS1 rearrangement-positive - Approve if pt has advanced or metastatic disease and ROS1 rearrangement-positive disease and has tried crizotinib, certinib or entrectinib.

## Lumakras

### **Products Affected**

LUMAKRAS ORAL TABLET 120 MG, 320
 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded. Pancreatic Adenocarcinoma
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if pt 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. Pancreatic Adenocarcinoma - Approve if pt 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 or has recurrent disease after resection.

### Lunsumio

### **Products Affected**

• LUNSUMIO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	1 year
Other Criteria	Follicular Lymphoma - Approve if pt has received at least two lines of systemic therapy

### Lupron

#### **Products Affected**

• *leuprolide (3 month)* 

• LUPRON DEPOT (6 MONTH)

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Abnormal Uterine Bleeding. Breast Cancer. Gender Dysphoric/Gender- Incongruent Persons, Persons Undergoing Gender Reassignment. Head and Neck Cancer - Salivary Gland Tumors. Ovarian Cancer. Preservation of Ovarian Function/Fertility in Patients Undergoing Chemotherapy. Prophylaxis or Treatment of Uterine Bleeding in Patients with Hematologic Malignancy, or Undergoing Cancer Treatment, or Prior to Bone Marrow/Stem Cell Transplantation (BMT/SCT).
Exclusion Criteria	Hirsutism. Menstrual Migraine. Premenstrual Syndrome (PMS). Polycystic Ovarian Syndrome (PCOS).
Required Medical Information	Diagnosis, concurrent medications
Age Restrictions	
Prescriber Restrictions	Cancer/Ovarian Function/Bleeding due to Cancer - prescribed by or in consultation with an oncologist. Gender - prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
Coverage Duration	Endo/Cancer/Ov Funct/Bleeding d/t Cancer/Gender/ - 1 yr. Leiomyomata - 3 mo. Abnl Bleeding - 6 mo.

PA Criteria	Criteria Details
Other Criteria	Endometriosis - approve if pt has tried a contraceptive, an oral progesterone, or depo-medroxyprogesterone injection, unless contraindicated. Uterine Leiomyomata - approve. Prostate/Breast/Ovarian cancer - approve. Preservation of Ovarian Function/Fertility in Patients Undergoing Chemotherapy/Prophylaxis or Treatment of Uterine Bleeding in Patients with Hematologic Malignancy, or Undergoing Cancer Treatment, or Prior to Bone Marrow/Stem Cell Transplantation - approve. Abnormal Uterine Bleeding - approve. Head and Neck Cancer - Salivary Gland Tumors - approve if pt has advanced salivary gland tumors with distant metastases and androgen receptor (AR)-positive disease.

# Lynparza

### **Products Affected**

• LYNPARZA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, other therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Breast Cancer, Recurrent or Metastatic - approve if pt has germline BRCA mutation-positive recurrent or metastatic breast cancer. Ovarian Cancer - Treatment - approve if pt has a germline BRCA-mutation and has progressed on two or more prior lines of chemotherapy. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance, Monotherapy - Approve if pt has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test and is in complete or partial response to first-line platinum-based chemotherapy regimen OR pt is in complete or partial response after at least two platinum-based chemotherapy regimens. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance, Combination Therapy - approve if being used in combination with bevacizumab AND pt has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test (which includes pts with BRCA mutation-positive disease) AND pt is in complete or partial response to first-line platinum- based chemotherapy regimen. Pancreatic Cancer - Maintenance Therapy - 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 - Approve if pt has metastatic castration resistant prostate cancer, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or pt has had a bilateral orchiectomy, the pt has germline or somatic homologous recombination repair (HRR) gene-mutated disease (HRR gene mutations include BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, or RAD54L), and pt has been previously treated with at least one androgen receptor- directed therapy (e.g. abiraterone, Xtandi, Nubeqa, or Erleada) OR the pt has a BRCA mutation and will be used in combination with abiraterone and prednisone or prednisolone. Breast Cancer, Adjuvant therapy - Approve if pt has germline BRCA mutation-positive, human epide
	adjuvant therapy. Uterine Leiomyosarcoma - Approve if pt has BRCA2-altered disease and has tried one systemic regimen.

### Lysosomal Storage Disease Enzyme Replacement Therapies

- ALDURAZYME
- CEREZYME INTRAVENOUS RECON SOLN 400 UNIT
- ELAPRASE

- FABRAZYME
- LUMIZYME
- VIMIZIM
- VPRIV

•	ELELYSO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, confirmatory testing results
Age Restrictions	Acid alpha-glucosidase deficiency (Pompe disease) - 8 years or older
Prescriber Restrictions	prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Acid alpha-glucosidase deficiency (Pompe disease) - Approve if pt has a laboratory test demonstrating acid alpha-glucosidase (GAA) activity at less than 40% of the lab-specific normal mean value and had a second confirmatory GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblast, or muscle) or by GAA gene sequencing, pt's forced vital capacity (FVC) is 30 percent to 79 percent of predicted value while in the sitting position with a postural drop in FVC of 10 percent or more from upright to supine position, pt has the ability to walk 40 meters on a six minute walk test (assistive devices permitted), and pt has muscle weakness in the lower extremities. Continuation - Approve if pt is ambulatory (assistive devices permitted) and not ventilator dependent. Fabry disease - Approve. Gaucher disease - Approve. Mucopolysaccharidosis Type I (Hurler Syndrome, Hurler-Scheie Syndrome, and Scheie Syndrome) - Approve if the diagnosis was established by a laboratory test demonstrating deficient a- L-iduronidase activity in leukocytes, fibroblasts, plasma, or serum OR a molecular genetic test demonstrating a-L- iduronidase gene mutation. Mucopolysaccharidosis Type II (Hunter Syndrome) - Approve if the diagnosis was established by a laboratory test demonstrating iduronate-2- sulfatase activity in leukocytes, fibroblasts, serum, or plasma OR a molecular genetic test demonstrating iduronate-2- sulfatase gene mutation. Mucopolysaccharidosis Type IVA (Morquio A Syndrome) - Approve if the diagnosis was established by a laboratory test demonstrating deficient N- acetylgalactosamine-6-sulfatase activity in leukocytes or fibroblasts OR a molecular genetic test demonstrating deficient N- acetylgalactosamine-6-sulfatase gene mutation.

# Lytgobi

### **Products Affected**

• LYTGOBI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Cholangiocarcinoma - Approve if pt has unresectable locally advanced or metastatic disease and the tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements as detected by an approved test and the patient has been previouusly treated with at least one systemic regimen.

## Megestrol

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded
Exclusion Criteria	Coverage is not provided for weight gain for cosmetic reasons
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorization will be for 1 year
Other Criteria	

## Mekinist

#### **Products Affected**

• MEKINIST

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Histiocytic Neoplasm. Ovarian/Fallopian Tube/Primary Peritoneal Cancer.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, other therapies tried
Age Restrictions	LGG, ST- 1 year and older. All others - 6 years and older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Melanoma - Approve if pt has unresectable, advanced (including stage III or stage IV disease), or metastatic melanoma and BRAF V600 mutation-positive disease. Solid Tumors (ST) (Unresectable or Metastatic) - Approve if pt has BRAF V600 mutation-positive disease and the medication will be taken in combination with Tafinlar (dabrafenib) and according to the prescriber the pt has no satisfactory alternative treatment options. Non-Small Cell Lung Cancer - Approve if pt has BRAF V600 mutation-positive disease and the medication is prescribed in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Carcinoma - Approve if pt has locally advanced or metastatic anaplastic disease, BRAF V600 mutation-positive disease, and the medication will be taken in combination with Mekinist Tafinlar (dabrafenib), unless intolerant. Low Grade Glioma - Approve if pt has BRAF V600 mutation positive disease, will be taken with Tafinlar (dabrafenib) and the pt requires systemic thearpy Histiocytic Neoplasm - Approve if pt has BRAF V600 mutation-positive disease and has Langerhans cell histiocytosis and one of the following: multisystem disease, pulmonary disease, or central nervous system lesions OR pt has Erdheim- Chester disease OR pt has Rosai-Dorfman disease. Ovarian/Fallopian Tube/Primary Peritoneal Cancer - Approve if pt has recurrent disease and the medication is used for low- grade serous carcinoma.

### Mektovi

### **Products Affected**

• MEKTOVI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Melanoma - Approve if pt has unresectable, advanced, or metastatic melanoma which is BRAF V600 mutation-positive, and the medication will be used in combination with Braftovi (encorafenib).

### **Multiple Sclerosis Agents**

- AUBAGIO
- AVONEX (WITH ALBUMIN)
- AVONEX INTRAMUSCULAR PEN INJECTOR
- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE
- AVONEX INTRAMUSCULAR SYRINGE
   KIT
- BETASERON

- COPAXONE SUBCUTANEOUS SYRINGE
   20 MG/ML
- GILENYA
- REBIF (WITH ALBUMIN)
- REBIF REBIDOSE SUBCUTANEOUS PEN INJECTOR 22 MCG/0.5 ML, 44 MCG/0.5 ML, 8.8MCG/0.2ML-22 MCG/0.5ML (6)
- REBIF TITRATION PACK
- teriflunomide

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Approval duration of 1 year
Other Criteria	

# Myalept

#### **Products Affected**

• MYALEPT

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	General Obesity not associated with Congenital Leptin Deficiency, HIV-related Lipodystrophy, Partial Lipodystrophy
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or geneticist
Coverage Duration	1 year
Other Criteria	Generalized Lipodystrophy (Congenital or Acquired) - Approve if pt has congenital generalized lipodystrophy confirmed by one gene mutation or clininical diagnosis made by specialist with experience in treating patients with lipdystrophy if genetic test did not demonstrate gene mutation OR acuired generalized lipodystrophy. AND pt has experienced one or more manifestations of liptin deficiency and Myalept will be used in conjunction with dietary modification.

## Natpara

### **Products Affected**

• NATPARA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Acute post-surgical hypoparathyroidism. Hypoparathyroidism Caused by Calcium-Sensing Receptor Mutations
Required Medical Information	Diagnosis, lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	1 year
Other Criteria	Chronic hypoparathyroidism - Before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL, 25- hydroxyvitamin D stores are sufficient per the prescribing physician, and pt cannot be well-controlled on calcium supplements and active forms of vitamin D alone. Continuation - The patient cannot be well-controlled on calcium supplements and active forms of vitamin D alone, pt's 25-hydroxyvitamin D stores are sufficient during Natpara therapy according to the prescriber, and pt is responding to Natpara therapy according to the prescriber.

# Nerlynx

#### **Products Affected**

• NERLYNX

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, HER2 status, other therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Breast Cancer, Adjuvant Therapy - Approve if pt has HER2 positive breast cancer, will not be using this medication in combination with HER2 antagonists, and the medication is requested for extended adjuvant therapy after the patient has completed 1 year of adjuvant therapy with trastuzumab intravenous products unless pt has tried adjuvant therapy with trastuzumab intravenous products and could not tolerate 1 year of therapy, according to the prescriber. Breast Cancer, Recurrent or Metastatic - Approve if pt has HER2 positive breast cancer, the medication will be used in combination with capecitabine, and pt has tried at least two prior anti-HER2 based regimens.

### Nexavar

- NEXAVAR
- sorafenib

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Acute Myeloid Leukemia. Bone Cancer. Gastrointestinal Stromal Tumor. Myeloid/Lymphoid Neoplasms with Eosinophilia. Ovarian, Fallopian Tube, Primary Peritoneal Cancer. Soft Tissue Sarcoma. Thyroid Cancer, Medullary.
Exclusion Criteria	
Required Medical Information	diagnosis, previous therapies tried, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Hepatocellular Cancer - Approve if pt has unresectable or metastatic disease. Renal Cell Cancer - Approve if pt has relapesed or advanced disease AND has clear cell histology AND has tried at least one systemic therapy. Thyroid Carcinoma, Differentiated - Approve if pt has differentiated thyroid carcinoma (papillary, follicular, and oncocytic carcinoma (formerly Hürthle cell carcinoma)) and the disease is refractory to radioactive iodine therapy. Acute Myeloid Leukemia - Approve if pt has FLT3-ITD mutation-positive disease as detected by an approved test and will use Nexavar in combination with azacitidine or decitabine or pt has had an allogenic stem cell transplant and is in remission. Bone Cancer - Approve if pt has recurrent chordoma OR pt has osteosarcoma and has tried one systemic chemotherapy regimen. Gastrointestinal Stromal Tumor - Approve if pt has previously tried Sutent or Sprycel and Stivarga and Qinlock, and either imatinib or Avyakit. Myeloid/Lymphoid Neoplasms with Eosinophilia - Approve if pt has an FLT3 rearrangement. Ovarian, Fallopian Tube, Primary Peritoneal Cancer - Approve if pt has platinum-resistant disease and Nexavar will be used in combination with topotecan. Soft Tissue Sarcoma - Approve if pt has one of the following diagnoses: angiosarcoma, desmoid tumors, or solitary fibrous Tumor/Hemangiopericytoma. Thyroid Cancer, Medullary - Approve if pt has tried at least one systemic therapy.

# Nexviazyme

#### **Products Affected**

• NEXVIAZYME

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, lab or mutation results confirming diagnosis
Age Restrictions	1 year or older
Prescriber Restrictions	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.
Coverage Duration	1 year
Other Criteria	Acid Alpha-Glucosidase Deficiency (Pompe Disease) - Approve if pt has late-onset acid alpha-glucosidase deficiency (late-onset Pompe disease) and diagnosis is established by one of the following: a laboratory test demonstrating deficient acid alpha- glucosidase activity in blood, fibroblasts, or muscle tissue or a molecular genetic test demonstrating acid alpha-glucosidase gene mutation.

# Ninlaro

#### **Products Affected**

• NINLARO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Systemic Light Chain Amyloidosis. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma.
Exclusion Criteria	
Required Medical Information	diagnosis, other medication use
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Multiple Myeloma - Approve if Ninlaro will be taken in combination with lenalidomide or cyclophosphamide AND dexamethasone, if pt has received at least one prior regimen for multiple myeloma, or if Ninlaro will be used following autologous stem cell transplantation (ASCT). Systemic Light Chain Amyloidosis - Approve if pt has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma - Approve if Ninlaro will be used in combination with a rituximab product and dexamethasone.

### Nubeqa

### **Products Affected**

• NUBEQA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, concurrent therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Prostate Cancer (Metastatic, Castration-Sensitive) - Approve if the medication is used concurrently with docetaxel or has completed docetaxel therapy AND a gonadotropin-releasing hormone (GnRH) agonist (Examples: Lupron Depot, Telstar, Zoladex, Vantas) or Firmagon or pt has had a bilateral orchiectomy. Prostate Cancer (Non-Metastatic, Castration- Resistant) - Approve if the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist (Examples: Lupron Depot, Telstar, Zoladex, Vantas) or Firmagon or pt has had a bilateral orchiectomy.

# Nucala

#### **Products Affected**

 NUCALA SUBCUTANEOUS AUTO-INJECTOR

• NUCALA SUBCUTANEOUS AUTO- • NUCALA SUBCUTANEOUS SYRINGE

 NUCALA SUBCUTANEOUS RECON SOLN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Atopic dermatitis. COPD. Concurrent use with another monoclonal antibody therapy. Eosinophilic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis.
Required Medical Information	Diagnosis, lab results, previous medication use
Age Restrictions	Asthma - 6 years of age and older. EGPA/NP - 18 years of age and older. Hypereosinophilic syndrome - 12 years of age and older.
Prescriber Restrictions	Asthma - Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA/Hypereosinophilic Syndrome - Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist. NP - prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist.
Coverage Duration	Asthma/EGPA/NP initial-6mo. Hypereosinophilic syndrome - 8mo. Continuation therapy - 1 year.

PA Criteria	Criteria Details
Other Criteria	Asthma - pt has a blood eosinophil level of greater than 150 cells per mL within the previous 6 weeks or within 6 weeks prior to treatment with Nucala or another monoclonal antibody therapy that may lower blood eosinophil levels AND pt has received at least 3 consecutive months of ICS and at least one additional asthma controller/maintenance medication AND pts asthma is uncontrolled or was uncontrolled prior to starting any anti-interleukin therapy as defined by ONE of the following: two or more exacerbations requiring systemic corticosteroids (CS), one exacerbations requiring systemic corticosteroids (CS), one exacerbation which required hospitalization, ED visits or urgent care visit in the previous year, FEV1 of less than 80 percent predicted, or pt has CS dependent asthma. Eosinophilic Granulomatosis with Polyangiitis (EGPA) [formerly known as Churg-Strauss Syndrome] - pt has has active, non-severe disease and a blood eosinophil level of greater than 150 cells per mL within the previous 6 weeks or within 6 weeks prior to treatment with Nucala or another monoclonal antibody therapy that may lower blood eosinophil levels AND pt has received at least 4 weeks of CS. Hypereosinophilic Syndrome (HS) - pt has had HS for greater than 6 months AND has FIP1L1-PDGFRa- negative disease AND according to the prescriber, the patient does NOT have an identifiable non-hematologic secondary cause of HS AND prior to initiating therapy with any anti-interleukin-5 therapy, the patient has/had a blood eosinophil levels AND pt has tried at least one other treatment with any monoclonal antibody therapy that may lower blood eosinophil levels AND pt has tried at least one other treatment with ansal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell. Pt has received at least 3 months of therapy with an intranasal corticosteroid and will continue to receive therapy with an intranasal corticosteroid concomitantly with Nucala AND
	pt has either received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years, has a contraindication to systemic corticosteroid therapy, or has had prior surgery for nasal polyps. Continuation (all) - pt has received at least 6 months of Nucala (8mo for HS) and is responding to therapy as determined by prescriber. Continuation (NP) - Pt must also continue to receive therapy with an intranasal corticosteroid.

### Nuedexta

#### **Products Affected**

• NUEDEXTA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Heroin detoxification. Levodopa-Induced Dyskinesia in Parkinson's Disease. Neuropathic Pain. Psychosis-Related Aggression. Treatment-Resistant Depression
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	1 year
Other Criteria	Treatment of Pseudobulbar Affect - Approve if pt has pseudobulbar affect associated with a chronic neurological condition.

## Ocaliva

## **Products Affected**

OCALIVA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Alcoholic liver disease. Nonalcoholic Fatty Liver Disease, including Nonalcoholic Fatty liver or Nonalcoholic Steatohepatitis.
Required Medical Information	Diganosis, lab results, prior therapies
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician
Coverage Duration	Initial - 6 months. Continuation - 1 year
Other Criteria	Primary Biliary Cholangitis - Approve if pt has a diagnosis of primary biliary cholangitis as defined by TWO of the following: alkaline phosphatase is elevated above the upper limit of normal as defined by normal laboratory reference values, positive anti-mitochondrial antibodies or other primary biliary cholangitis-specific auto-antibodies including, sp100 or gp210, if anti-mitochondrial antibodies are negative, or histologic evidence of primary biliary cholangitis from a liver biopsy AND pt either has been receiving ursodiol therapy for greater than 1 year and has had an inadequate response or is unable to tolerate ursidiol therapy, according to the prescriber AND pt either does not have cirrhosis or has compensated cirrhosis without evidence of portal hypertension. Continuation - Approve if pt either does not have cirrhosis or has compensated cirrhosis without evidence of portal hypertension AND pt has responded to Ocaliva as determined by the prescriber.

## Ofev

## **Products Affected**

OFEV

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded.
Exclusion Criteria	Combination use with pirfenidone (Esbriet).
Required Medical Information	diagnosis
Age Restrictions	Idiopathic Pulmonary Fibrosis - 40 years of age and older. All other indications - 18 years of age and older
Prescriber Restrictions	Idiopathic Pulmonary Fibrosis - prescribed by or in consultation with a pulmonologist. Intersitial Lung Disease Associated with Systemic Sclerosis - prescribed by or in consultation with a pulmonologist or a rheumatologist
Coverage Duration	3 years
Other Criteria	Chronic fibrosing interstitial lung disease-approve if the forced vital capacity is greater than or equal to 45% of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10% of lung volume on high- resolution computed tomography AND according to the prescriber the patient has clinical signs of progression. Idiopathic Pulmonary Fibrosis - 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 FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by HRCT.

# Omnipod

- OMNIPOD 5 G6 INTRO KIT (GEN 5)
- OMNIPOD 5 G6 PODS (GEN 5)
- OMNIPOD CLASSIC PDM KIT(GEN 3)
- OMNIPOD CLASSIC PODS (GEN 3)
- **PA** Criteria **Criteria Details Covered Uses** All FDA approved indications not otherwise excluded. Exclusion Omnipod 5 - Type 2 DM Criteria Required diagnosis, insulin use Medical Information Omnipod 5 - age 6 and older Age Restrictions Prescriber Restrictions Coverage 3 years Duration **Other Criteria** Diabetes mellitus, type 1 - Approve (Omnipod 5 only - pt must be using at least 6 units of insulin daily). Diabetes mellitus, type 2, insulin dependent - Approve if pt is using at least three injections of insulin per day. Continuation - Approve.
- OMNIPOD DASH INTRO KIT (GEN 4)
- OMNIPOD DASH PODS (GEN 4)

## Onureg

### **Products Affected**

• ONUREG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acute Myeloid Leukemia (AML) - Approve if the medication is used for post-remission maintenance therapy, allogeneic hematopoietic stem cell transplant is not planned, and the pt has poor- or intermediate-risk cytogenics.

## Orgovyx

### **Products Affected**

• ORGOVYX

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from coverage
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	3 years
Other Criteria	Prostate Cancer - approve if the pt has advanced disease. Note: Advanced disease is defined as disease that has spread to other parts of the body, beyond the prostate. It can also include patients with persistent prostate specific antigen (PSA) levels or rising PSA levels after radiotherapy or surgery. Metastatic disease is also considered as advanced disease.

# Oriahnn

### **Products Affected**

• ORIAHNN

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Heavy Menstrual Bleeding not associated with Uterine Fibroids
Required Medical Information	Diagnosis, previous therapies, test results
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with an obstetrician- gynecologist or a health care practitioner who specializes in the treatment of women's health
Coverage Duration	2 years
Other Criteria	Uterine Fibroids (Leiomyomas) - Approve for up to 24 months if pt is premenopausal and experiencing heavy menstrual bleeding associated with the uterine fibroids which have been confirmed by a pelvic ultrasound, including transvaginal ultrasonography or sonohysterography, hysteroscopy, or magnetic resonance imaging. Pt must also have tried at least one other therapy for the medical management of heavy menstrual bleeding, and pt has not previously received a continuous regimen of 24 months or longer of therapy with Oriahnn or Myfembree.

## Orilissa

## **Products Affected**

• ORILISSA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Endometriosis - Approve if pt has tried a contraceptive, an oral progesterone, a depo-medroxyprogesterone injection, or a gonadotropin-releasing hormone agonist for endometriosis. Continuation - Approve.

# Orkambi

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Cystic Fibrosis heterozygous for the F508del Mutation. Combination use with Kalydeco, Symdeko, or Trikafta.
Required Medical Information	Diagnosis, mutation results
Age Restrictions	1 year or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of CF.
Coverage Duration	1 year
Other Criteria	Cystic Fibrosis - Approve if pt is homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation).

# Orladeyo (Non-Preferred)

### **Products Affected**

• ORLADEYO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concomitant Use with Other Hereditary Angioedema (HAE) Prophylactic Therapies
Required Medical Information	Diagnosis, lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders.
Coverage Duration	1 year
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis - Approve if pt has HAE type I or type II as confirmed by low levels of functional C1-INH protein (less than 50% of normal) and lower than normal serum C4 levels at baseline [documentation required]. Continuation - Approve if pt has a diagnosis of HAE type I or type II [documentation required] and according to the prescriber, the patient has had a favorable clinical response with Orladeyo treatment. Must also meet the requirements of the Nonpreferred Drug Prior Authorization Criteria.

## Orserdu

### **Products Affected**

ORSERDU ORAL TABLET 345 MG, 86
 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Breast Cancer in Postmenopausal Women or Men - Approve if pt has recurrent or metastatic disease and estrogen receptor positive (ER+) disease and human epidermal growth factor receptor 2 (HER2)-negative disease and estrogen receptor 1 gene(ESR1)-mutated disease and pt has tried at least one endocrine therapy.

## Oxbryta

- OXBRYTA ORAL TABLET 500 MG
- OXBRYTA ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, lab results, previous medication use
Age Restrictions	4 years or older
Prescriber Restrictions	prescribed by or in consultation with a physician who specializes in sickle cell disease
Coverage Duration	1 year
Other Criteria	Sickle Cell Disease - Approve if pt's baseline hemoglobin level was less than 10.5 g/dL and pt meets one of the following: pt is currently receiving a hydroxyurea product, pt has tried a hydroxyurea product and has experienced inadequate efficacy or significant intolerance, or pt is not a candidate for hydroxyurea therapy. If pt is 12 years of age or older, pt must have had at least one sickle cell-related crisis in the previous 12-month period prior to approval. Continuation - Approve if pt is receiving clinical benefit from Oxbryta therapy.

## Oxervate

## **Products Affected**

• OXERVATE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Treatment duration of greater than 16 weeks
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or an optometrist.
Coverage Duration	8 weeks
Other Criteria	Neurotrophic keratitis - Initial - Approve. Continuation - Approve if pt has previously received at least 8 weeks but less than 16 weeks of treatment per affected eye(s) and pt has a recurrence of neurotrophic keratitis. If pt has received less than 8 weeks of treatment review as initial treatment.

# Palforzia

- PALFORZIA (LEVEL 1)
- PALFORZIA (LEVEL 2)
- PALFORZIA (LEVEL 3)
- PALFORZIA (LEVEL 4)
- PALFORZIA (LEVEL 5)
- PALFORZIA (LEVEL 6)
- PALFORZIA (LEVEL 7)

- PALFORZIA (LEVEL 8)
- PALFORZIA (LEVEL 9)
- PALFORZIA (LEVEL 10)
- PALFORZIA (LEVEL 11 UP-DOSE)
- PALFORZIA INITIAL DOSE
- PALFORZIA LEVEL 11 MAINTENANCE

PA Criteria	Criteria Details
PACILIEIIa	
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded
Exclusion Criteria	
Required Medical Information	Lab results
Age Restrictions	4-17 years old OR 18 years or older and has previously been started on therapy with Palforzia prior to becoming 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with an allergist or immunologist
Coverage Duration	1 year
Other Criteria	Per prescriber, the patient has a history of an allergic reaction to peanut that met each of the following: the patient demonstrated signs and symptoms of a significant allergic reaction (e.g. hives, swelling, wheezing, hypotension, and gastrointestinal symptoms) AND this reaction occurred within a short period of time following a known ingestion of peanut or peanut-containing food AND the prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector AND patient has a positive skin prick test (SPT) response to peanut with a wheal diameter 3 mm or larger than the negative control AND patient has a positive in vitro test (i.e., a blood test) for peanut-specific IgE (psIgE) with a level 0.35 kUA/L or greater AND per the prescriber, Palforzia will be used in conjunction with a peanut-avoidant diet.

# Palynziq

### **Products Affected**

 PALYNZIQ SUBCUTANEOUS SYRINGE 10 MG/0.5 ML, 2.5 MG/0.5 ML, 20 MG/ML

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, lab results
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease specialist
Coverage Duration	1 year
Other Criteria	Phenylketonuria - Initial therapy - Approve if the pt has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., restriction of dietary phenylalanine and protein intake, prior treatment with Kuvan). Continuation - Approve if the pt meets one of the following conditions: Pt is continuing to titrate Palynziq to an effective maintenance dose, per the prescriber AND if the pt is receiving a dose of Palynziq 60 mg once daily, the treatment duration at this dose has not exceeded 16 weeks OR pt's blood phenylalanine concentration is less than or equal to 600 micromol/L or the pt has achieved at least a 20% reduction in blood phenylalanine concentration from pre- treatment baseline AND pt is not receiving concomitant therapy with sapropterin (Kuvan, generic).

# Pegfilgrastim

## **Products Affected**

- NEULASTA
- NEULASTA ONPRO
- UDENYCA
- UDENYCA AUTOINJECTOR

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Peripheral Blood Progenitor Cell Transplantation in Patients with Cancer.
Exclusion Criteria	Myelodysplastic Syndrome.
Required Medical Information	Diagnosis, other therapies
Age Restrictions	
Prescriber Restrictions	Cancer pts receiving chemotherapy - prescribed by or in consultation with an oncologist or hematologist. RS - prescribed by or in consultation with a physician with expertise in treating acute radiation syndrome. PBPC - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in tranplantation.
Coverage Duration	Cancer pts receiving chemo - 6 months, RS - 1 month, PBPC - 1 dose

• ZIEXTENZO

PA Criteria	Criteria Details
Other Criteria	Cancer in a Patient Receiving Myelosuppressive Chemotherapy - Approve if pt is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 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% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, age greater than or equal to 65 years), history of previous chemotherapy or radiation therapy, pre-existing neutropenia, open wounds or active infection, poor performance status, 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. Radiation Syndrome (RS) (Hematopoietic Syndrome of Acute Radiation Syndrome) - Approve. Peripheral Blood Progenitor Cell Transplantation in Patients with Cancer (PBPC) - Approve.

## Pemazyre

### **Products Affected**

• PEMAZYRE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Cholangiocarcinoma - Approve if pt has unresectable locally advanced or metastatic disease with 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 pt has eosinophilia, the cancer has fibroblast growth factor receptor 1 (FGFR1) rearrangement as detected by an approved test, and the cancer is in chronic or blast phase.

# Penicillamine

### **Products Affected**

• penicillamine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	diagnosis, other therapies tried
Age Restrictions	
Prescriber Restrictions	Wilson's disease - Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
Coverage Duration	1 year
Other Criteria	Wilson's Disease - Approve if pt has Wilson's Disease confirmed by genetic testing results confirming biallelic pathogenic ATP7B mutations or prescence of at least two of the following: Presence of Kayser-Fleischer rings, serum ceruloplasmin level less than 20 mg/dL, liver biopsy findings consistent with Wilson's disease, or 24-hour urinary copper greater than 40 mcg/24 hours. Pt must also have tried Galzin, another zinc product, already been started on a penacillamine product, or the pt has symptoms of Wilson's disease and zinc would not be an appropriate therapy. Cystinuria - Approve if, according to the prescriber, patient has tried increased fluid intake, restriction of sodium and protein, and urinary alkalinization.

# Phenylbutyrate

- RAVICTI
- sodium phenylbutyrate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded.
Exclusion Criteria	Concomitant use with more than one phenylbutyrate product
Required Medical Information	diagnosis
Age Restrictions	
Prescriber Restrictions	prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
Coverage Duration	genetic test confirmed mutation - 1 year. hyperammonemia - 3 months.
Other Criteria	Urea Cycle Disorders - Approve if the medication is prescribed in conjunction with a protein-restricted diet and according to the prescriber, the diagnosis was confirmed by genetic testing which confirmed a mutation resulting in a urea cycle disorder OR the patient has hyperammonemia diagnosed with an ammonia level above the upper limit of the normal reference range for the reporting laboratory.

# Piqray

## **Products Affected**

• PIQRAY

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from coverage.
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Breast Cancer - Approve if pt is a postmenopausal female, a male, or a pre/perimenopausal female who is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation AND has advanced or metastatic hormone receptor (HR)-positive disease, human epidermal growth factor receptor 2 (HER2)-negative disease, and PIK3CA-mutated breast cancer as detected by an approved test AND has progressed on or after at least one prior endocrine-based regimen AND Piqray will be used in combination with fulvestrant injection.

# Pirfenidone

### **Products Affected**

pirfenidone oral tablet 267 mg, 801 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concomitant use with Ofev.
Required Medical Information	Diagnosis, test results
Age Restrictions	18 years or older
Prescriber Restrictions	prescribed by or in consultation with a pulmonologist.
Coverage Duration	1 year
Other Criteria	Idiopathic Pulmonary Fibrosis - Approve if pt has forced vital capacity (FVC) greater than 40% of predicted value and the diagnosis is confirmed by either findings on high-resolution computed tomography which indicate usual interstitial pneumonia or a surgical lung biopsy which demonstrates usual interstitial pneumonia. Continuation - Approve if pt has experienced a beneficial response to therapy over the last year while receiving Esbriet (pirfenidone).

# Pomalyst

### **Products Affected**

• POMALYST

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Central Nervous System Lymphoma. POEMS Syndrome. Systemic Light Chain Amyloidosis.
Exclusion Criteria	
Required Medical Information	diagnosis, other therapies tried
Age Restrictions	KS/MM/POEMS/SLCA - 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Kaposi Sarcoma (KS) - approve if pt is HIV negative OR if pt is HIV positive and continues to receive highly active antiretroviral therapy. Multiple Myeloma (MM) - Approve if pt has received at least one other Revlimid (lenalidomide tablets)-containing regimen. Central Nervous System Lymphoma - approve if pt has relapsed or refractory disease. POEMS Syndrome - approve if Pomalyst is in combination with dexamethasone. Systemic Light Chain Amyloidosis (SLCA) - approve if Pomalyst is in combination with dexamethasone and pt has tried at least one other regimen.

## Promacta

- PROMACTA ORAL POWDER IN PACKET
   12.5 MG
- PROMACTA ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	The patient must be 18 years or older for use in Patients with Chronic Immune (Idiopathic) Thrombocytopenia Purpura (ITP) and Thrombocytopenia in Patients with Chronic Hepatitis C.
Prescriber Restrictions	For treatment of Patients with Chronic Immune (Idiopathic) Thrombocytopenia Purpura (ITP)or Aplastic Anemia Promacta must be prescribed by in consultation with a hematologist. For treatment of Thrombocytopenia in Patients with Chronic Hep C Promacta must be prescribed by or in consultation with either a gastroenterologist, a hepatologist, or a physician that specializes in infectious disease.
Coverage Duration	Authorization will be for 12 months.

PA Criteria	Criteria Details
Other Criteria	Treatment of Patients with Chronic Immune (Idiopathic) Thrombocytopenia Purpura (ITP). Approve Promacta if the patient meets the one of the following: The patient has tried corticosteroids OR The patient has tried IVIG OR The patient has undergone splenectomy. Treatment of Thrombocytopenia in Patients with Chronic Hepatitis C to Allow for Initiation and Maintenance of Interferon-Based Therapy. Approve Promacta if the patient meets the following: The patient has low platelet counts at baseline (pretreatment) [e.g., less than 75,000 mm3] AND The patient has chronic HCV infection and is a candidate for hepatitis C therapy (e.g., Pegasys or PegIntron plus ribavirin, with or without direct-acting antiviral agents [e.g., Victrelis {boceprevir capsules}, Incivek {telaprevir tablets}). For Aplastic Anemia approve if the patient meets the following: The patient has low platelet counts at baseline (pretreatment) [e.g., less than 30,000 mm3] AND the patient has tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate moefetil, sirolimus, Atgam [lymphocyte immune globulin, anti- thymocyte globulin [equine] sterile solution for intravenous use only]).

# PTH analogues

### **Products Affected**

 TYMLOS SUBCUTANEOUS PEN INJECTOR 80 MCG (3,120 MCG/1.56 ML)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded
Exclusion Criteria	Concomitant use with other medications for osteoporosis (e.g.,Prolia [denosumab for SC injection], bisphosphonates[alendronate, risedronate, ibandronate, zoledronic acid injection {Reclast}], calcitonin nasal spray, PTH analogues (e.g. Tymlos, Forteo), except calcium and Vitamin D. Previous use of Forteo and/or Tymlos for a Combined total no greater than 2 years duration during a patients Lifetime.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year, up to a max of 2 years in a patient's lifetime

PA Criteria	Criteria Details
Other Criteria	Treatment of PMO, osteoporosis in men, and glucocorticoid induced osteoporosis, approve if pt has tried one oral bisphosphonate for at least 12 months with an inadequate response OR the patient has experienced intolerability to an 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 35mL/min) or CKD or pt has had multiple osteoporotic fractures.

## **Pulmonary Arterial Hypertension Agents**

#### **Products Affected**

- ambrisentan
- sildenafil (pulm.hypertension) oral suspension for reconstitution

tablet

- TRACLEER ORAL TABLET
- sildenafil (pulm.hypertension) oral

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Tracleer only: Chronic Thromboembolic Pulmonary Hypertension and Digital Ulcers/Systemic Sclerosis. Sildenafil tablets only: Raynaud phenomenon.
Exclusion Criteria	Erectile Dysfunction.
Required Medical Information	diagnosis, other therapies tried, right heart catheterization results
Age Restrictions	
Prescriber Restrictions	Pulmonary Arterial Hypertension/Chronic Thromboembolic Pulmonary Hypertension - prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	3 years
Other Criteria	Pulmonary Arterial Hypertension (PAH) - pt must have had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Documentation of right heart catheterization is required for initial starts. Chronic Thromboembolic Pulmonary Hypertension - Approve. Digital Ulcers/Systemic Sclerosis - Approve if pt has tried two other therapies for this condition such as calcium channel blockers (CCBs), phosphodiesterase type 5 (PDE5) inhibitors, alpha-adrenergic blockers, nitroglycerin, or angiotensin converting enzyme (ACE) inhibitors OR pt has tried one vasodilator/prostanoid therapy. Raynaud phenomenon - pt must have previously tried at least one calcium channel blocker for this indication.

## Pulmonary Arterial Hypertension Agents (Non-Preferred)

- ADCIRCA
- ADEMPAS
- bosentan
- LETAIRIS
- OPSUMIT
- ORENITRAM
- REVATIO ORAL SUSPENSION FOR RECONSTITUTION
- REVATIO ORAL TABLET
- tadalafil (pulm. hypertension)

- TRACLEER ORAL TABLET FOR SUSPENSION
- TYVASO
- TYVASO INSTITUTIONAL START KIT
- TYVASO REFILL KIT
- TYVASO STARTER KIT
- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLETS, DOSE PACK
- VENTAVIS

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	1 year
Other Criteria	Pulmonary Arterial Hypertension - Approve if pt has had a right heart catheterization to confirm the diagnosis of pulmonary arterial hypertension (WHO group 1). Must also meet the requirements of the Nonpreferred Drug Prior Authorization Criteria.

# Pyrimethamine

#### **Products Affected**

• pyrimethamine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Cystoisosporiasis (treatment and secondary prophylaxis). Pneumocystis Pneumonia (primary and secondary prophylaxis). Toxoplasma gondii Encephalitis (primary and secondary prophylaxis).
Exclusion Criteria	Malaria (treatment or prophylaxis)
Required Medical Information	Diagnosis, other therapies
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an infectious diseases specialist or a physician specializing in the treatment of human immunodeficiency virus (HIV) infection
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Toxoplasmosis - Approve if the medication is prescribed in combination with leucovorin and either 1) sulfadiazine OR 2) atovaquone or systemic clindamycin if pt is unable to take sulfadiazine. Cystoisoporiasis/isosporiasis (treatment or secondary prophylaxis) - Approve if pt has tried one other therapy for this condition and the medication is prescribed in combination with leucovorin. Pneumocystis Pneumonia (primary or secondary prophylaxis) - Approve if pt has tried one other therapy for this condition and the medication is prescribed in combination with leucovorin and either systemic dapsone or atovaquone. Toxoplasma gondii Encephalitis (primary prophylaxis) - Approve if pt has tried one other therapy for this condition and the medication is prescribed in combination with leucovorin and either systemic dapsone or atovaquone. Toxoplasma gondii Encephalitis (secondary prophylaxis) - Approve if the medication is prescribed in combination leucovorin and either 1) sulfadiazine OR 2) atovaquone or systemic clindamycin if pt is unable to take sulfadiazine.

# Qinlock

## **Products Affected**

• QINLOCK

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Menalnoma, Cutatneous.
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Gastrointestinal stromal tumor (GIST) - Approve if pt has been previously treated with imatinib or Ayvakit (avapritinib) AND pt has tried sunitinib and Stivarga (regorafenib) or Sprycel (dasatinib) or pt is intolerant of sunitinib. Melanoma, Cutaneous - APprove if pt has metastatic or unresectable disease and an activating KIT mutations and has tried one systemic regimen.

## Repatha, Praluent (Non-Preferred)

- PRALUENT PEN
- REPATHA PUSHTRONEX
- REPATHA SURECLICK
- REPATHA SYRINGE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concurrent use of Leqvio, Juxtapid or Praluent/Repatha.
Required Medical Information	Diagnosis, lab values, other therapies tried
Age Restrictions	Repatha: ASCVD/Primary Hyperlipidemia - 18 years or older, HoFH/HeFH - 10 years or older, Praluent: ASCVD/Primary Hyperlipidemia/HoFH/HeFH - 18 years or older
Prescriber Restrictions	ASCVD/HoFH/HeFH - Prescribed by or in consultation with a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
Coverage Duration	1 year
Other Criteria	Primary hyperlipidemia/Secondary Prevention for ASCVD/Heterozygous Familial Hyperlimipidemia (HeFH)/Homozygous Familial Hyperlimipidemia (HoFH) - Approve if provider attests that the patient has tried statins and/or ezetimibe and was unable to meet LDL goals after 8 weeks with maximally tolerated therapy or is intolerant of both. Must also meet the requirements of the Nonpreferred Drug Prior Authorization Criteria.

## Restasis

- cyclosporine ophthalmic (eye) RESTASIS
- RESTASIS MULTIDOSE

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded. Dry Eye Conditions due to Systemic Inflammatory Diseases (e.g., Sjögren syndrome, rheumatoid arthritis, systemic lupus erythematosus). Dry Eye Conditions due to Ocular Surface Diseases (e.g., ocular rosacea, atopic keratoconjunctivitis, acute corneal graft rejection, blepharitis, herpetic stromal keratitis, conjunctival graft versus host disease).
Exclusion Criteria	Concomitant use with Xiidra (lifitegrast) or Cequa.
Required Medical Information	Diagnosis
Age Restrictions	16 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Dry Eye Conditions due to Ocular Inflammation Associated with Keratoconjunctivitis Sicca (e.g., dry eye syndrome or dry eye disease) - Approve. Dry Eye Conditions due to Systemic Inflammatory Diseases (e.g., Sjögren syndrome, rheumatoid arthritis, systemic lupus erythematosus) - Approve. Dry Eye Conditions due to Ocular Surface Diseases (e.g., ocular rosacea, atopic keratoconjunctivitis, acute corneal graft rejection, blepharitis, herpetic stromal keratitis, conjunctival graft versus host disease) - Approve.

## Retevmo

### **Products Affected**

RETEVMO ORAL CAPSULE 40 MG, 80
 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Histiocytic Neoplasm
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	Thyroid Cancer-12 years or older. All others - 18 years or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if the pt has advanced, recurrent, or metastatic disease and the tumor is RET fusion-positive. Thyroid Cancer - Approve if the pt has RET fusion-positive or RET mutation-positive disease and the pt has anaplastic thyroid cancer or the disease requires treatment with systemic therapy and the pt has medullary thyroid cancer or the disease is radioactive iodine-refractory. Solid Tumors - Approve it pt has advanced, recurrent, or metastatic disease and the tumor is RET fusion-positive. Histiocytic Neoplasm - Approve if pt has Langerhans cell histiocytosis orr has Erdheim-Chester disease or Rosai-Dorfman disease AND pt has RET fusion.

## Revcovi

## **Products Affected**

REVCOVI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from coverage.
Exclusion Criteria	
Required Medical Information	Diagnosis, baseline labs or genetic testing results
Age Restrictions	
Prescriber Restrictions	prescribed by or in consultation with an immunologist, hematologist/oncologist, or physician that specializes in ADA- SCID or related disorders
Coverage Duration	1 year
Other Criteria	Adenosine Deaminase Severe Combined Immunodeficiency (ADA-SCID) - Approve if pt has a diagnosis of ADA-SCID confirmed by molecular genetic testing confirming bi-allelic mutations in the ADA gene or at baseline (i.e., prior to initiating enzyme replacement therapy), the patient has had absent or very low (less than 1% of normal) adenosine deaminase (ADA) catalytic activity.

# Revlimid

- *lenalidomide*
- REVLIMID ORAL CAPSULE 10 MG, 15 MG, 2.5 MG, 20 MG, 25 MG, 5 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. B Cell Lymphomas. Kaposi Sarcoma. Castleman's Disease. Central Nervous System Lymphoma. Classical Hodgkin Lymphoma. Langerhans Cell Histiocytosis. Myelofibroisis. Peripheral T-Cell Lymphomas. POEMS Syndrome. Systemic Light Chain Amyloidosis. T-Cell Leukemia/Lymphoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies tried, other medications, lab results
Age Restrictions	FL/MCL/MZL/MM/MDS/BCL/CHL/MF/PTCL/POEMS/SLCA/TCL - 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Follicular Lymphoma (FL) - approve if pt is using Revlimid in combination with rituximab or pt has tried at least one other regimen. Mantle Cell Lymphoma (MCL) - Approve if pt is using Revlimid in combination with rituximab or pt has tried at least two other regimens. Marginal Zone Lymphoma (MZL) - is using Revlimid in combination with rituximab or pt has tried at least one other regimen. Multiple Myeloma (MM) - approve. Myelodysplastic Syndrome (MDS) - approve if pt has symptomatic anemia, has transfusion-dependent anemia, or has anemia that is not controlled with an erythroid stimulating agent. B-Cell Lymphomas, Other (BCL) - Approve if pt has tried at least one other regimen. Kaposi Sarcoma - approve if pt has relapsed or refractory disease and has tried at least one other medication. Castleman's Disease - apporve if pt has relapsed or refractory disease. Classical Hodgkin Lymphoma (CHL) - approve if pt has tried at least one other medication. Castleman's Disease - lassical Hodgkin Lymphoma (CHL) - approve if pt has tried at least one other regimen. Langerhans Cell Histiocytosis - approve if pt has multifocal skin disease. Myelofibrosis (MF) - approve if pt has anemia, according to prescriber AND either pt has serum erythropoietin levels less than 500 mU/mL and has experienced no response or loss of response to an erythropoiesis-stimulating stimulating agent. Peripheral T-Cell Lymphomas - approve if pt has tried at least one other regimen. POEMS syndrome - approve if Revlimid is used in combination with dexamethasone. Systemic Light Chain Amyloidosis (SLCA) - Approve if Revlimid is used in combination with dexamethasone. T-Cell Leukemia/Lymphoma - approve if pt has tried one other regimen.

# Rezlidhia

#### **Products Affected**

REZLIDHIA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acute Myeloid Leukemia - Approve if pt has relapsed or refractory disease and disease and isocitrate dehydrogenase-1 (IDH1) mutation possitive disease as detected by an approved test.

### Rezurock

#### **Products Affected**

• REZUROCK

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	12 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Graft-vs-Host Disease - Approve if pt has chronic graft-versus- host disease and has tried at least two conventional systemic treatments for chronic graft-versus-host disease.

# Rituxan Hycela

#### **Products Affected**

• RITUXAN HYCELA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Hairy Cell Leukemia. Hodgkin Lymphoma. Waldenstroms Macroglobulinemia/Lymphoplasmacytic Lymphoma.
Exclusion Criteria	Granulomatosis with Polyangiitis (Wegener's granulomatosis) or Microscopic Polyangiitis. Pemphigus Vulgaris. Rheumatoid Arthritis.
Required Medical Information	Diagnosis, previous rituximab use
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	1 year
Other Criteria	Approve if pt has already received at least one full dose of rituximab intravenous AND Rituxan Hycela is administered under the care of a healthcare professional.

# Rozlytrek

#### **Products Affected**

ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Pediatric Diffuse High-Grade Gliomas
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	NSCLC/PDHGG - 18 year or older. Solid Tumors - 12 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC)- Approve if the patient has ROS1-positive metastatic disease detected by an approved test. Solid Tumors - Approve if pt'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. Pediatric Diffuse High-Grade Gliomas (PDHGG) - Approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used as adjuvant therapy or for recurrent or progressive disease.

### Rubraca

#### **Products Affected**

• RUBRACA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	diagnosis, mutation results, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Treatment: Approve if pt has a BRCA-mutation (germline or somatic) as confirmed by an approved test and has progressed on two or more prior lines of chemotherapy. Maintenance: Approve if pt is in complete or partial response after at least two platinum-based chemotherapy regimens and patient is in complete or partial response to first-line primary treatment or pt has recurrent disease and a BRCA mutation. Prostate Cancer - Approve if pt has castration resistant metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or pt has had a bilateral orchiectomy AND pt has been previously treated with at least one androgen receptor-directed therapy AND pt has been previously treated with at least one taxane-based chemotherapy or is not a candidate or is intolerant to taxane-based chemotherapy, according to the prescriber. Uterine Leiomyosarcoma - Approve if pt has BRCA2-altered disease and has tried one systemic regimen.

# **Ruconest (Non-Preferred)**

#### **Products Affected**

• RUCONEST

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Hereditary Angioedema (HAE) Prophylaxis
Required Medical Information	Diagnosis, lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders.
Coverage Duration	1 year
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks - Approve if pt has HAE type I or type II as confirmed by low levels of functional C1-INH protein (less than 50% of normal) and lower than normal serum C4 levels at baseline [documentation required]. Continuation - Approve if pt has a diagnosis of HAE type I or type II [documentation required] and according to the prescriber, the patient has had a favorable clinical response with Ruconest treatment. Must also meet the requirements of the Nonpreferred Drug Prior Authorization Criteria.

## RYDAPT

#### **Products Affected**

• RYDAPT

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Myeloid or Lymphoid Neoplasms.
Exclusion Criteria	
Required Medical Information	diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acute Myeloid Leukemia - Approve if pt is FLT3-mutation positive AML as detected by an approved test. Aggressive Systemic Mastocytosis (ASM) - Approve. Systemic Mastocytosis Associated with Acute Hematologic Neoplasm - Approve. Mast Cell Leukemia - approve. Myeloid or Lymphoid Neoplasms - Approve if pt has eosinophilia and an FGFR1 rearrangement or an FLT3 rearrangement.

### Scemblix

#### **Products Affected**

• SCEMBLIX

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Chronic Myeloid Leukemia - Approve if pt has Philadelphia chromosome positive chronic myeloid leukemia and the chronic myeloid leukemia is T315I-positive or pt has tried at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia. Myeloid/Lymphoid Neoplasms with Eosinophilia - Approve if tumor has an ABL1 rearrangement.

# Signifor

#### **Products Affected**

• SIGNIFOR

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Endogenous Cushing's Syndrome - Patient Awaiting Surgery. Endogenous Cushing's Syndrome - Patient Awaiting Therapeutic Response After Radiotherapy.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years and older (initial therapy)
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy)
Coverage Duration	Initial - 4 months, Continuation - 1 year. Awaiting surgery or response after radiotherapy-4 months
Other Criteria	Cushings disease, initial - Approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushings disease, continuation - Approve if the patient has already been started on Signifor and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response. Endogenous Cushing's Syndrome - Patient Awaiting Surgery or Awaiting Therapeutic Response After Radiotherapy - Approve.

### Somatuline Depot

#### **Products Affected**

• SOMATULINE DEPOT

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Pheochromocytoma and Paraganglioma.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous treatments/therapies
Age Restrictions	
Prescriber Restrictions	Acromegaly - prescribed by or in consultation with an endocrinologist. Carcinoid syndrome, Neuroendocrine Tumors - prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. Pheochromocytoma and Paraganglioma - prescribed by or in consultation with an endocrinologist, oncologist, or neurologist.
Coverage Duration	1 year
Other Criteria	Acromegaly - Approve if the pt 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 one of the following: has had an inadequate response to surgery and/or radiotherapy, is not an appropriate candidate for surgery and/or radiotherapy, or the pt 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. Pheochromocytoma and Paraganglioma - Approve.

### Spravato

#### **Products Affected**

• SPRAVATO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by a psychiatrist
Coverage Duration	MDDSI - 2 months. TRD - 6 months.
Other Criteria	Major Depressive Disorder with Acute Suicidal Ideation or Behavior (SI) - Pt has major depressive disorder that is considered to be severe, according to the prescriber AND pt is concomitantly receiving at least one oral antidepressant AND pt has no history of psychosis or the prescriber believes that the benefits of Spravato outweigh the risks. Treatment-Resistant Depression - Pt has demonstrated nonresponse (greater than 25% improvement in depression symptoms or scores) to at least two different antidepressants, each from a different pharmacologic class, according to the prescriber AND each antidepressant was used at therapeutic dosages for at least 6 weeks in the current episode of depression, according to the prescriber AND pt is concomitantly receiving at least one oral antidepressant AND pt has no history of psychosis OR the prescriber believes that the benefits of Spravato outweigh the risks AND pts history of controlled substance prescriptions has been checked using the state prescription drug monitoring program, according to the prescriber.

# Sprycel

#### **Products Affected**

• SPRYCEL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Bone Cancer. Gastrointestinal Stromal Tumor. Myeloid/Lymphoid Neoplasms with Eosinophilia. Melanoma, Cutaneous
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	Bone Cancer, Gastrointestinal Stromal Tumor, Melanoma Cuatneous, Meyloid/Lymphoid Neoplasms with Eosinophilia - 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acute Lymphoblastic Leukemia - Approve if pt has Philadelphia chromosome-positive acute lymphoblastic leukemia. Chronic Myeloid Leukemia - Approve if pt has Philadelphia chromosome positive chronic myeloid leukemia. Bone Cancer - Approve if pt has chondrosarcoma or chordoma. Gastrointestinal Stromal Tumor - Approve if pt has previously tried imatinib or avapritinib. Myeloid/Lymphoid Neoplasms with Eosinophilia - Approve if tumor has an ABL1 rearrangement. Melanoma, Cutaneous - Approve if pt has metastatic or unresectalbe disease and an activating KIT mutation and has tried at least one systemic regimen.

### Stivarga

#### **Products Affected**

• STIVARGA

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded. Glioblastoma. Osteosarcoma. Soft Tissue Sarcoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies tried, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Colon and Rectal Cancer - Approve if pt has advanced or metastatic disease, has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-fluorouracil (5-FU)), oxaliplatin, and irinotecan. If the pt's tumor or metastases are wild-type RAS (KRAS and/or NRAS negative), then Erbitux (cetuximab injection for intravenous infusion) or Vectibix (panitumumab injection for intravenous infusion) has also been tried. Gastrointestinal Stromal Tumor (GIST) - Approve if pt has previously tried sunitinib or dasatinib and either imatinib or avapritinib. Hepatocellular Carcinoma - Approve if pt has been previously treated with at least one systemic regimen. Glioblastoma - Approve if pt has recurrent disease. Osteosarcoma - Approve if pt has relapsed/refractory or metastatic disease and pt has tried one systemic chemotherapy regimen. Soft Tissue Sarcoma - Approve if pt has advanced or metastatic disease AND one of the following: Non-adipocytic extremity/body wall, head/neck, or retroperitoneal/intra- abdominal sarcoma OR Pleomorphic rhabdomyosarcoma OR Angiosarcoma OR Solitary fibrous tumor.

## Strensiq

#### **Products Affected**

• STRENSIQ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, genetic testing results
Age Restrictions	
Prescriber Restrictions	prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of hypophosphatasia or related disorders
Coverage Duration	1 year
Other Criteria	Hypophosphatasia - Infantile- and Juvenile-Onset - Approve if pt has a diagnosis supported by one of the following: molecular genetic testing documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation, low baseline serum alkaline phosphatase activity, or an elevated level of a tissue non- specific alkaline phosphatase substrate (i.e., serum pyridoxal 5'- phosphate, serum or urinary inorganic pyrophosphate, urinary phosphoethanolamine) AND one of the following: pt currently has a history of clinical manifestations consistent with hypophosphatasia (e.g. skeletal abnormalities, premature tooth loss, muscle weakness, poor feeding, failure to thrive, respiratory problems, vitamin B6-dependent seizures) or pt has a family history (parent or sibling) of hypophosphatasia without current clinical manifestations of hypophosphatasia AND disease onset was before 19 years of age.

### Sunosi

#### **Products Affected**

• SUNOSI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concomitant use of Sunosi with Xyrem (sodium oxybate oral solution), Xywav (calcium, magnesium, potassium, and sodium oxybates oral solution), and/or Wakix (pitolisant tablets).
Required Medical Information	Diagnosis, test results, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	Narcolepsy - prescribed by or in consultation with a sleep specialist physician or a neurologist
Coverage Duration	1 year
Other Criteria	Excessive Daytime Sleepiness Associated with Narcolepsy - Approve if pt has been evaluated using polysomnography and a multiple sleep latency test, the diagnosis of narcolepsy has been confirmed, and the pt has tried modafinil or armodafinil. Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea - Approve if Sunosi will be used in conjunction with continuous positive airway pressure (CPAP), unless pt is unable to tolerate CPAP, and the pt has tried modafinil or armodafinil.

### Sutent

#### **Products Affected**

• sunitinib malate oral capsule 12.5 mg, 25 mg, 37.5 mg, 50 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Bone Cancer. Meningioma. Myeloid/Lymphoid Neoplasms. Pheochromocytoma/Paraganglioma. Soft Tissue Sarcoma. Thymic Carcinoma. Differentiated Thyroid Carcinoma. Medullary Thyroid Carcinoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Gastrointestinal stromal tumors (GIST) - Approve if pt has tried imatinib or avapritinib or has succinate dehydrogenase (SDH)- deficient gastrointestinal stromal tumor. Neuroendocrine Tumors of the Pancreas - Approve if pt has advanced or metastatic disease. Renal Cell Cancer - Approve if pt has relapsed or advanced disease. Bone Cancer - Approve if pt has recurrent chordoma. Meningioma - Approve if pt has recurrent or progressive disease. Myeloid/Lymphoid Neoplasms- Approve if pt has esosinophilia and the tumor has an FLT3 rearrangement. Pheochromocytoma/Paraganglioma - Approve if pt has unresectable or metastatic disease. Soft Tissue Sarcoma - Approve if the pt has Alveolar Soft Part Sarcoma, Angiosarcoma, or Solitary Fibrous Tumor/Hemangiopericytoma. Thymic Carcinoma - Approve if pt has tried at least one systemic chemotherapy regimen. Thyroid Carcinoma, Differentiated - Approve if pt has differentiated thyroid carcinoma which is refractory to radioactive iodine therapy. Thyroid Carcinoma, Medullary - Approve if pt has tried at least one systemic therapy.

### Symdeko

#### **Products Affected**

• SYMDEKO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	CF pts with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco, or Trikafta.
Required Medical Information	Diagnosis, specific CFTR gene mutations
Age Restrictions	6 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	CF - approve if pt is homozygous for F508del mutation or has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A-G, S945L, S977F, F1052V, E831X, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G-A, 3272-26A-G, 3849 + 10kbC-T, A120T, A234D, A349V, A554E, A1006E, D192G, D443Y, D443Y,G57A,R668C, D614G, D836Y, D924N, D979V, I618T, I807M, I980K, I1027T, I1139V, I1269N, I1366N, L15P, L320V, R170H, R258G, R334L, R334Q, R347L, R347P, R352W, R553Q, R668C, R751L, V1293G, E60K, E92K, E116K, E403D, E558V, E822K, F191V, F311del, F311L, F508C, F508C,S1251N, F575Y, L346P, L967S, L997F, L1324P, L1335P, L1480P, M152V, M265R, M9521, R1066H, R1070Q, R1162L, R1283M, R1283S, S549N, S549R, S589N, S737F, S912L, F1016S, F1099L, G126D, G178E, G178R, G194R, G194V, G314E, G551D, G551S, G576A, G576A,R668C, M952T, P5L, P205S, Q98R, Q237E, Q237H, Q359R, Q1291R, R31L, S1251N, S1255P, T3381, T1036N, T10531, V201M, V232D, V5621, V754M, V1153E, G622D, G970D, G1069R, G1244E, G1249R, G1349D, H939R, H1054D, H1375P, I148T, I175V, I336K, I601F, R74Q, R74W,D1270N, R74W,V201M, R74W,V201M,D1270N, R75Q, R117G, R117H, R117L, R117P, W1282R, Y109N, Y161S, Y1014C, Y1032C, R792G, R933G, S1159F, S1159P, or V1240G.

### Tabrecta

#### **Products Affected**

• TABRECTA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if the patient has advanced or metastatic disease and the patient has either high-level MET amplification or mesenchymal epithelial transition (MET) exon 14 skipping mutations as detected by an approved test.

# Tafinlar

#### **Products Affected**

- TAFINLAR ORAL CAPSULE
- TAFINLAR ORAL TABLET FOR
- SUSPENSION

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Histiocytic Neoplasm
Exclusion Criteria	Colon or Rectal Cancer
Required Medical Information	Diagnosis, mutation results, other therapies tried
Age Restrictions	LGG, ST- 1 year and older. All others - 6 years and older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Melanoma - Approve if pt has unresectable, advanced (including stage III or stage IV disease), or metastatic melanoma and BRAF V600 mutation-positive disease. Solid Tumors (ST) (Unresectable or Metastatic) - Approve if pt has BRAF V600 mutation-positive disease and the medication will be taken in combination with Mekinist (trametinib) and according to the prescriber the pt has no satisfactory alternative treatment options. Non-Small Cell Lung Cancer (NSCLC) - Approve if pt has BRAF V600 mutation-positive disease. Anaplastic Thyroid Carcinoma (ATC) - Approve if pt has locally advanced or metastatic anaplastic disease, BRAF V600 mutation-positive disease, and the medication will be taken in combination with Mekinist (trametinib), unless intolerant. Low Grade Glioma (LGG) - Approve if pt has BRAF V600 mutation-positive disease, will be taken with Mekinist (trametinib) and the pt requires systemic thearpy. Histiocytic Neoplasm (HN) - Approve if pt has BRAF V600 mutation-positive disease and has Langerhans cell histiocytosis and one of the following: multisystem disease, pulmonary disease, or central nervous system lesions OR pt has Erdheim-Chester disease.

## Tagrisso

#### **Products Affected**

• TAGRISSO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Other therapies tried and mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if pt has advanced or metastatic disease and has sensitizing EGFR mutation-positive non-small cell lung cancer as detected by an approved test OR the pt has epidermal growth factor receptor (EGFR) T790M mutation-positive disease as detected by an approved test and pt has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. Non-Small Cell Lung Cancer - Post Resection - Approve if pt has completely resected disease, EGFR exon 19 deletion or exon 21 (L858R) substitution mutation as detected by an approved test, and pt has either received previous adjuvant chemotherapy or is ineligible to receive platinum-based chemotherapy.

# Takhzyro (Non-Preferred)

#### **Products Affected**

• TAKHZYRO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concomitant Use with Other Hereditary Angioedema (HAE) Prophylactic Therapies
Required Medical Information	Diagnosis, lab results
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders.
Coverage Duration	1 year
Other Criteria	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis - Approve if pt has HAE type I or type II as confirmed by low levels of functional C1-INH protein (less than 50% of normal) and lower than normal serum C4 levels at baseline [documentation required]. Continuation - Approve if pt has a diagnosis of HAE type I or type II [documentation required] and according to the prescriber, the patient has had a favorable clinical response with Takhzyro treatment. Must also meet the requirements of the Nonpreferred Drug Prior Authorization Criteria.

## Talzenna

#### **Products Affected**

• TALZENNA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, BRCA mutation status, HER2 status
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Breast Cancer - Approve if pt has recurrent or metastatic breast cancer which is germline BRCA mutation-positive. Prostate Cancer - Approve if pt has metastatic castration resistant prostate cancer and homologous recombination repair (HRR) gene-mutated disease and the medication is used in combination with Xtandi and the medication is used concurrently with a GnRH analog or pt. has had a bilateral orchiectomy.

# Targretin (Topical)

#### **Products Affected**

• bexarotene

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	1 year
Other Criteria	Cutaneous T-Cell Lymphoma - Approve if pt has cutaneous lesions and generic bexarotene gel is requested or pt has tried generic bexarotene gel and pt cannot use generic bexarotene gel due to a formularion difference in the inactive ingredients between the brand and the bioequivalent generic product which, per the prescriber would result in a significan tallergy or a serious adverse reaction.

# Tarpeyo

#### **Products Affected**

• TARPEYO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, pathology results, lab results, other therapies tried
Age Restrictions	18 or older
Prescriber Restrictions	Prescribed by or on consultation with a nephrologist.
Coverage Duration	10 months (10 month consecutive max)

PA Criteria	Criteria Details
Other Criteria	Primary Immunoglobulin A Nephropathy - Approve if diagnosis has been confirmed by biopsy, pt has an estimated glomerular filtration rate greater than 30 mL/min/1.73 m2, pt has not previously been treated with Tarpeyo, and pt is at high risk of disease progression, defined by meeting the following criteria: pt either has proteinuria greater than 0.75 g/day or a urine protein-to-creatinine ratio greater than 1.5 g/g and pt has been receiving the maximum or maximally tolerated dose of an ACEI or ARB for at least 90 days. According to the prescriber, the patient has received at least 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification. Continuation - Approve for up to 10 consecutive months if diagnosis has been confirmed by biopsy, pt has an estimated glomerular filtration rate greater than 30 mL/min/1.73 m2, and pt has been receiving the maximum or maximally tolerated dose of an ACEI or ARB for at least 90 days. According to the prescriber, the patient has received at least 90 days of optimized supportive care, including blood pressure months if diagnosis has been confirmed by biopsy, pt has an estimated glomerular filtration rate greater than 30 mL/min/1.73 m2, and pt has been receiving the maximum or maximally tolerated dose of an ACEI or ARB for at least 90 days. According to the prescriber, the patient has received at least 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification.

# Tasigna

#### **Products Affected**

• TASIGNA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Acute Lymphoblastic Leukemia. Gastrointestinal Stromal Tumor. Myeloid/Lymphoid Neoplasms with Eosinophilia. Melanoma, Cutaneous
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies
Age Restrictions	Acute Lymphoblastic Leukemia, Gastrointestinal Stromal Tumor, Melanoma Cutaneous, Meyloid/Lymphoid Neoplasms with Eosinophilia - 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Chronic Myeloid Leukemia - Approve if pt has Philadelphia chromosome positive chronic myeloid leukemia. Acute Lymphoblastic Leukemia - Approve if pt has Philadelphia chromosome-positive acute lymphoblastic leukemia. Gastrointestinal Stromal Tumor - Approve if pt has tried imatinib or avapritinib, sunitinib or dasatinib, regorafinib, and ripretinib. Myeloid/Lymphoid Neoplasms with Eosinophilia - Approve if tumor has an ABL1 rearrangement. Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor - Approve if pt has tried pexidartinib or pt cannot take pexidartinib, according to the prescriber. Melanoma, Cutaneous - Approve if pt has metastatic or unresectalbe disease and an activating KIT mutation and has tried at least one systemic regimen.

# Tazverik

#### **Products Affected**

• TAZVERIK

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies tried, mutation results
Age Restrictions	Epithelioid Sarcoma - 16 and older, Follicular Lymphoma - 18 and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Epithelioid Sarcoma - Approve if pt has metastatic or locally advanced disease and is not eligible for complete resection. Follicular Lymphoma - Approve if pt has relapsed or refractory disease and meets one of the following: pt has tried at least two prior systemic therapies or according to the prescriber, there are no appropriate alternative therapies.

# Tepmetko

#### **Products Affected**

• TEPMETKO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) - Approve if the patient has advanced or metastatic disease and the patient has either high-level MET amplification or mesenchymal epithelial transition (MET) exon 14 skipping mutations as detected by an approved test.

### Tetrabenazine

#### **Products Affected**

• tetrabenazine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Hyperkinetic dystonia. Tardive dyskinesia (TD). Tourette syndrome and related tic disorders.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years or older
Prescriber Restrictions	CHD/HD/TS and RTD - prescribed by or in consultation with a neurologist. TD - prescribed by or in consultation with a neurologist or psychiatrist.
Coverage Duration	1 year
Other Criteria	Chorea associated with Huntington's Disease (CHD) - approve if pt has been diagnosed with chorea associated with Huntington's disease AND diagnosis of Huntington's disease is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36). Hyperkinetic Dystonia (HD) - approve. Tardive Dyskinesia (TD) - approve. Tourette Syndrome and Related Tic Disorders (TS) - approve.

# Thalomid

#### **Products Affected**

• THALOMID ORAL CAPSULE 100 MG, 150 MG, 200 MG, 50 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Castleman's Disease. Discoid Lupus Erythematosus or Cutaneous Lupus Erythematosus. Kaposi Sarcoma. Langerhans Cell Histiocytosis. Myelofibrosis. Prurigo Nodularis. Recurrent Aphthous Ulcers or Aphthous Stomatitis. Rosai-Dorfman Disease.
Exclusion Criteria	Cancer Cachexia. Crohn's Disease.
Required Medical Information	Diagnosis, previous therapies tried, other medications, lab results
Age Restrictions	Multiple Myeloma, Myelofibrosis - 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Erythema nodosum Leprosum - approve. Multiple Myeloma - approve if Thalomid is being taken in combination with at least two other medications. Castleman's Disease - approve if pt relapsed/refractory or progressive disease OR pt has multi- centric Castleman's Disease and is negative for the human immunodeficiency virus and human herpesvirus-8. Discoid Lupus Erythematosus or Cutaneous Lupus Erythematosus - approve if pt has tried at least two other medications. Kaposi Sarcoma - approve if pt has tried at least one other medication. Langerhans Cell Histiocytosis - approve if pt has multifocal skin disease. Myelofibrosis - approve if pt has anemia, according to prescriber AND either pt has serum erythropoietin levels greater than 500 mU/mL OR pt has serum erythropoietin levels less than 500 mU/mL and has experienced no response or loss of response to an erythropoiesis-stimulating stimulating agent. Prurigo Nodularis - approve if pt has tried at least two other medications. Recurrent Aphthous Ulcers or Aphthous Stomatitis - approve if pt has tried at least two other medications. Rosai- Dorfman Disease - approve if pt has cutaneous disease.

## Tibsovo

### **Products Affected**

• TIBSOVO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Bone Cancer. Central Nervous System Cancer.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acute Myeloid Leukemia (AML) - approve if disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Cholangiocarcinoma - approve if disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and pt has been previously treated with at least one chemotherapy regimen. Bone Cancer - Approve if pt has chondrosarcoma and disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Central Nervous System Cancer - Approve if pt has recurrent or progressive disease and has WHO grade 2 or 3 oligodendroglioma or grade 2 astrocytoma

# Tiopronin

## **Products Affected**

• tiopronin

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, weight
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a nephrologist, urologist, or physician who specializes in the treatment of cystinuria.
Coverage Duration	1 year
Other Criteria	Cystinuria - Approve if pt weighs 20kg or more and diagnosis of cystinuria has been confirmed based on laboratory testing and the patient has had an inadequate response to high fluid intake, dietary modification, and urinary alkalization, according to the prescriber.

## **Topical Testosterone**

#### **Products Affected**

- TESTOSTERONE TRANSDERMAL GEL
- testosterone transdermal gel in metered-dose pump 10 mg/0.5 gram /actuation, 12.5 mg/ 1.25 gram (1 %),

20.25 mg/1.25 gram (1.62 %)

- testosterone transdermal gel in packet
- testosterone transdermal solution in metered pump w/app

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Gender- Dysphoric/Gender-Incongruent Persons/Persons Undergoing Female-To-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).
Exclusion Criteria	Not covered if used to enhance athletic performance.
Required Medical Information	Diagnosis, lab values
Age Restrictions	
Prescriber Restrictions	Female-to-male gender reassignment - prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
Coverage Duration	1 year
Other Criteria	Hypogonadism (Primary or Secondary) in Males [Testicular Hypofunction/Low Testosterone with Symptoms] - Approve if pt has had persistent signs and symptoms of androgen deficiency (pre-treatment), has had two pre-treatment serum testosterone (total or bioavailable) measurements, each taken in the morning, on two separate days and the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Gender-Dysphoric/Gender-Incongruent Persons/Persons Undergoing Female-To-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization) - Approve.

# **Transmucosal Fentanyl**

#### **Products Affected**

• fentanyl citrate buccal lozenge on a handle 1,200 mcg, 1,600 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Acute pain. Postoperative pain.
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Breakthrough Pain in Patients with Cancer - Approve if pt is unable to swallow, has dysphagia, esophagitis, mucositis, uncontrollable nausea/vomiting or patient is unable to take two other short-acting narcotics due to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic, or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics.

## Trikafta

### **Products Affected**

• TRIKAFTA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded
Exclusion Criteria	Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko.
Required Medical Information	Diagnosis, specific CFTR gene mutations, concurrent medications
Age Restrictions	2 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Cystic Fibrosis (CF) - Patient has at least one copy of one of the following mutations in the cystic fibrosis conductance regulator gene: F508del, 3141del9, E822K, G1069R, L967S, R117L, S912L, 546insCTA, F191V, G1244E, L997F, R117P, S945L, A46D, F311del, G1249R, L1077P, R170H, S977F, A120T, F311L, G1349D, L1324P, R258G, S1159F, A234D, F508C, H139R, L1335P, R334L, S1159P, A349V, F508C, S1251N, H199Y, L1480P, R334Q, S1251N, A455E, H939R, M152V, R347H, S1255P, A554E, F575Y, H1054D, M265R, R347L, T338I, A1006E, F1016S, H1085P, M952I, R347P, T1036N, A1067T, F1052V, H1085R, M952T, R352Q, T1053I, D110E, F1074L, H1375P, M1101K, R352W, V201M, D110H, F1099L, I148T, P5L, R553Q, V232D, D192G, G27R, I175V, P67L, R668C, V456A, D443Y, G85E, I336K, P205S, R751L, V456F, D443Y,G576A,R668C, G126D, I502T, P574H, R792G, V562I, D579G, G178E, I601F, Q98R, R933G, V754M, D614G, G178R, I618T, Q237E, R1066H, V1153E, D836Y, G194R, I807M, Q237H, R1070Q, V1240G, D924N, G194V, I980K, Q359R, R1070W, V1293G, D979V, G314E, I1027T, Q1291R, R1162L, W361R, D1152H, G463V, I1139V, R31L, R1283M, W1098C, D1270N, G480C, I1269N, R74Q, R1283S, W1282R, E56K, G551D, I1366N, R74W, S13F, Y109N, E60K, G551S, K1060T, R74W, D1270N, S341P, Y161D, E92K, G576A, L15P, R74W, V201M, S364P, Y161S, E116K, G576A, R668C, L165S, R74W, V201M, D1270N, S492F, Y563N, E193K, G622D, L206W, R75Q, S549N, Y1014C, E403D, G628R, L320V, R117C, S549R, Y1032C, E474K, G970D, L346P, R117G, S589N, E588V, G1061R, L453S, R117H, or S737F.

# Triptodur

### **Products Affected**

• TRIPTODUR

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Gender- Dysphoric/Gender-Incongruent Persons/Persons Undergoing Gender Reassignment (Female-To-Male or Male-To-Female).
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Gender dysphoria - Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
Coverage Duration	1 year
Other Criteria	Central Precocious Puberty - Approve. Gender- Dysphoric/Gender-Incongruent Persons/Persons Undergoing Gender Reassignment (Female-To-Male or Male-To-Female) - Approve.

# **Triptodur/Lupron Depot-Ped**

### **Products Affected**

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Gender- Dysphoric/Gender-Incongruent Persons/Persons Undergoing Gender Reassignment (Female-To-Male or Male-To-Female).
Exclusion Criteria	
Required Medical Information	Diagnosis
Age Restrictions	
Prescriber Restrictions	Gender dysphoria - Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.
Coverage Duration	1 year
Other Criteria	Central Precocious Puberty - Approve. Gender- Dysphoric/Gender-Incongruent Persons/Persons Undergoing Gender Reassignment (Female-To-Male or Male-To-Female) - Approve.

# Truseltiq

### **Products Affected**

 TRUSELTIQ ORAL CAPSULE 100 MG/DAY (100 MG X 1), 125 MG/DAY(100 MG X1-25MG X1), 50 MG/DAY (25 MG X 2), 75 MG/DAY (25 MG X 3)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Cholangiocarcinoma - Approve if pt is currently recieving Truseltiq, has unresectable locally advanced or metastatic disease, has fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test, and Truseltiq is used as subsequent therapy.

# Tukysa

### **Products Affected**

• TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from coverage
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies used
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Breast Cancer- Approve if the pt has recurrent or metastatic breast cancer, human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti- HER2-based regimen in the metastatic setting, and the medication is used in combination with trastuzumab and capecitabine. Colon and Rectal Cancer - Approve if pt has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-amplified disease, wild-type RAS tumor or metastases, AND the medication is used in combination with trastuzumab.

# Turalio

## **Products Affected**

• TURALIO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Histiocytic Neoplasms.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis) - Approve if the tumor is not amenable to improvement with surgery, according to the prescriber. Histiocytic Neoplasms - Approve if pt has a colony stimulating factor 1 receptor (CSF1R) mutation and has one of the following conditions: Langerhans cell histiocytosis, Erdheim-Chester disease, or Rosai-Dorfman disease.

## Tykerb

### **Products Affected**

• lapatinib

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Bone Cancer - Chordoma. Colon or Rectal Cancer.
Exclusion Criteria	Cervical Cancer. Gastric, Esophageal, or Gastroesophageal Adenocarcinoma Cancer. Head and Neck, Squamous Cell Carcinoma. Renal Cell Carcinoma (RCC). Urothelial Carcinoma.
Required Medical Information	Diagnosis, lab results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Breast Cancer - Approve if pt has recurrent or metastatic human epidermal growth factor receptor 2 positive (HER2+) breast cancer and either the pt has tried at least two prior anti- HER2 based regimens and will use the medication in combination with capecitabine or trastuzumab OR the pt has hormone receptor-positive (HR+) (i.e., estrogen receptor positive {ER+}- and/or progesterone receptor positive {PR+})disease, will use the medication in combination with an aromatase inhibitor and one of the following applies: pt is a postmenopausal woman, is a pre- or peri- menopausal woman and is is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, surgical bilateral oophorectomy, or ovarian irradiation, or pt is a man and is receiving a gonadotropin-releasing hormone (GnRH) analog. Bone Cancer - Approve if pt has a recurrent chordoma and has epidermal growth-factor receptor (EGFR)-positive recurrent disease. Colon or Rectal Cancer - Approve if pt has unresectable advanced or metastatic disease that is human epidermal receptor2 (HER2)-amplified with wild-type RAS and BRAF disease, the pt has not been previously treated with a HER2-inhibitor (e.g. traztuzumab, Nerlyx, Kadcyla, Perjeta), and the pt has tried at least one chemotherapy regeimen or is not a candidate for intensive therapy, and the medication will be used in combinatino with trastuzumab.

# Ubrelvy

## **Products Affected**

UBRELVY ORAL TABLET 100 MG, 50
 MG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Migraine, Acute Treatment - Approve if pt has tried at least one triptan therapy or has a contraindication to triptans, according to the prescriber.

## Venclexta

### **Products Affected**

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Mantle Cell Lymphoma. Multiple Myeloma. Systemic Light Chain Amyloidosis. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, previously tried therapies, mutation status
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acute myeloid Leukemia (AML) - Approve if Venclexta is used in combination with either azacitidine, decitabine, or cytarabine. Chronic Lymphocytic Leukemia (CLL) - Approve. Small Lymphocytic Leukemia (SLL) - Approve. Mantle Cell Lymphoma - Approve if pt has tried at least one systemic regimen. Multiple Myeloma - Approve if pt has t (11,14) translocation, has tried at least one systemic therapy for multiple myeloma, and Venclexta is used in combination with dexamethasone. Systemic Light Chain Amyloidosis - Approve if pt has t (11,14) translocation and has tried at least one systemic regimen. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma - Approve if pt has tried at least one systemic regimen.

## Verkazia

## **Products Affected**

• VERKAZIA

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, previously tried therapies, mutation status
Age Restrictions	4 years or older
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist or an optometrist.
Coverage Duration	1 year
Other Criteria	Vernal Keratoconjunctivitis - Approve if according to the prescriber the pt has moderate to severe vernal keratoconjunctivitis and the pt has tried 2 single action ophthalmic medications (i.e., ophthalmic mast-cell stabilizers or ophthalmic antihistamines) for the maintenance treatment of vernal keratoconjunctivitis or tried 1 dual action ophthalmic mast-cell stabilizer/antihistamine product. or at least one ophthalmic cyclosporine product.

## Verzenio

### **Products Affected**

• VERZENIO

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	diagnosis, hormone receptor status, concurrent therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	Breast Cancer, Early - 2 years. Breast Cancer, Advanced or Metastatic - 3 years

PA Criteria	Criteria Details
Other Criteria	Breast Cancer, Early - Approve if pt has hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, HER2-negative breast cancer, node-positive disease at high risk of recurrence (High risk includes patients with greater than 4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: Grade 3 disease, tumor size greater than 5 cm, or a Ki-67 score of greater than 20%), and meets one of the following: 1) Verzenio will be used in combination with anastrozole, exemestane, or letrozole and pt is a postmenopausal woman, a pre/perimenopausual woman who is receiving ovarian suppression/ablation with a gonadotropin- releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation, or is a man and is receiving a gonadotropin-releasing hormone (GnRH) analog OR 2) Verzenio will be used in combination with tamoxifen and pt is postmenopausal or is a pre/perimenopausual woman who is receiving ovarian suppression/ablation with a gonadotropin- releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer, Recurrent or Metastatic in women - Approve if pt has hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, HER2-negative breast cancer, pt is postmenopausal or is a pre/perimenopausual woman who is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation, and meets one of the following: 1) Verzenio will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant OR 2) Verzenio will be used as monotherapy, the pt's breast cancer has progressed on at least one prior endocrine therapy, and the pt has tried chemotherapy for metastatic breast cancer. Breast Cancer in Men, Recurrent or Metatastic - Approve if pt has hormone receptor positive (HR+) [i.e., estrogen recept
	breast cancer, and pt meets one of the following: 1) Verzenio will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant and pt is receiving a gonadotropin- releasing hormone (GnRH) analog OR 2) Verzenio will be used in combination with fulvestrant OR 3) Verzenio will be used as monotherapy, the pt's breast cancer has progressed on at least one prior endocrine therapy, and the pt has tried chemotherapy for metastatic breast cancer.

# Vijoice

## **Products Affected**

• VIJOICE

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	2 years and older
Prescriber Restrictions	Prescribed by or in consultation with a physician that specializes in treatment of genetic disorders
Coverage Duration	Initial - 6 months. Continuation - 1 year

PA Criteria	Criteria Details
Other Criteria	PIK3CA-Related Overgrowth Spectrum (PROS) (Note: Examples of PROS include congenital lipomatous overgrowth, vascular malformations, epidermal nevi, scoliosis/skeletal and spinal (CLOVES) syndrome, megalencephaly-capillary malformation (MCAP) syndrome, Klippel-Trenaunay syndrome (KTS), facial infiltrating lipomatosis (FIL), dysplastic megalencephaly (DMEG), hemimegalencephaly (HMEG), focal cortical dysplasia (FCD), or capillary vascular malformation of the lower lip, lymphatic malformations of the head and neck, asymmetry and partial or generalized overgrowth (CLAPO) syndrome)- Approve if pt has at least one severe clinical manifestations include excessive tissue growth, blood vessel malformations, scoliosis, vascular tumors, cardiac or renal manifestations, and those that require systemic treatment) as determined by the prescriber and has a PIK3CA mutation as confirmed by genetic testing. Continuation - Approve if pt has been established on Vijoice for at least 6 months and the pt has experienced a reduction in volume from baseline in at least one lesion as confirmed by measurement and has experienced an improvement in at least one sign or symptom of PROS from baseline. (Note: Examples of signs or symptoms of PROS include pain, fatigue, vascular malformation, limb asymmetry, or disseminated intravascular coagulation)

## Vitrakvi

### **Products Affected**

• VITRAKVI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
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 has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion and the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity.

# Vizimpro

### **Products Affected**

• VIZIMPRO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, tumor mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer - Approve if the pt has advanced or metastatic disease and has has sensitizing EGFR mutation- positive (e.g. exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X, and S768I.) non-small cell lung cancer as detected by an approved test.

# Vonjo

## **Products Affected**

• VONJO

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from coverage
Exclusion Criteria	
Required Medical Information	Diagnosis, lab results
Age Restrictions	18 years or 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 pt has a platelet count of less than 50,000/mcL AND intermediate or high risk disease and is not a candidate for transplant or lower-risk disease and has tried at least one prior therapy (examples: Jakafi, Pegasys, or hydroxyurea) OR pt has a platelet count of 50,000/mcL or more and high risk disease, is not a candidate for transplant and has tired Jakafi or Inrebic.

## Votrient

### **Products Affected**

• VOTRIENT

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Bone Cancer. Gastrointestinal Stromal Tumor Ovarian Cancer, Fallopian Tube, or Primary Peritoneal Cancer. Differentiated Thyroid Carcinoma. Medullary Thyroid Carcinoma. Uterine Sarcoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, previously tried therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Renal Cell Cancer - Approve if pt has relapsed or advanced disease or has von Hippel-Lindau disease. Soft Tissue Sarcoma - Approve if pt does not have gastrointestinal stromal tumor, 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- adipcytic sarcoma, pleomorphic rhabdomyosarcoma, or solitary fibrous tumor/hemangiopericytoma. Bone Cancer - Approve if pt has chondrosarcoma and either has metastatic disease or the prescriber indicates pt has widespread disease. Gastrointestinal Stromal Tumor (GIST) - Approve if pt has succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor or has tried imatinib or avapritinib, sunitinib or dasatinib, regorafinib, and ripretinib. Ovarian Cancer, Fallopian Tube, or Primary Peritoneal Cancer - Approve if pt has persistent or recurrent disease. Thyroid Carcinoma, Differentiated - Approve if pt has differentiated thyroid carcinoma which is refractory to radioactive iodine therapy. Thyroid Carcinoma, Medullary - Approve if pt has tried at least one systemic therapy. Uterine Sarcoma (e.g., endometrial stromal sarcoma, undifferentiated uterine sarcoma, uterine leiomyosarcomas) - Approve if pt has recurrent or metastatic disease and has tried at least one systemic regimen (doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine, epirubicin, or vinorelbine).

## Voxogo

### **Products Affected**

• VOXZOGO

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Hypochondroplasia, Thanatophoric Dysplasia, or other Short Stature Conditions other than Achondroplasia (e.g., trisomy 21, pseudoachondroplasia). Concurrent Treatment with Growth Hormone (e.g., somatropin), Long-Acting Growth Hormone (e.g., lonapegsomatropin), or Insulin-like Growth Factor- 1 (IGF-1) [i.e., Increlex® {mecasermin}] Agents.
Required Medical Information	Diagnosis
Age Restrictions	5-17 years old
Prescriber Restrictions	Prescribed by or in consultation with a pediatric endocrinologist
Coverage Duration	1 year
Other Criteria	Acondroplasia - Approve if the diagnosis of achondroplasia has been confirmed by genetic testing with an identifiable mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene, the pts epiphyses are open and there is evidence of annualized growth velocity of at least 1.5 cm/year, pt will not not have limb-lengthening surgery during treatment with Voxzogo, and the prescriber has confirmed the patient is able to drink approximately 240 to 300 mL of fluid in the hour prior to Voxzogo administration. Continuation - Approve if pt continues to meet initial criteria and pts most recent annualized growth velocity continues to be above their baseline annualized growth velocity value prior to starting on Voxzogo.

# Vyndaqel/Vyndamax

## **Products Affected**

- VYNDAMAX
- VYNDAQEL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from coverage.
Exclusion Criteria	Concomitant Use With Onpattro or Tegsedi. Concurrent Use of Vyndaqel and Vyndamax. Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR)
Required Medical Information	Diagnosis
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis
Coverage Duration	1 year
Other Criteria	Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis - approve if the diagnosis was confirmed by a technetium pyrophosphate scan (i.e., nuclear scintigraphy) OR Amyloid deposits are identified on cardiac biopsy OR pt had genetic testing which, according to the prescriber, identified a transthyretin (TTR) mutation, in addition to diagnostic cardiac imaging which has demonstrated cardiac involvement AND pt has heart failure, but does not have New York Heart Association class IV disease.

## Weight Loss Drugs - Preferred

## **Products Affected**

- CONTRAVE
- SAXENDA
- WEGOVY

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concurrent use of other weight loss medications other than phentermine
Required Medical Information	Diagnosis, weight, baseline BMI and baseline weight, previous medications tried
Age Restrictions	Contrave -18 years or older. Others - 12 years or older
Prescriber Restrictions	
Coverage Duration	Initial - 6 months. Continuation - 1 year
Other Criteria	Weight loss - Approve if pt has a baseline BMI of 30 kg/m2 or greater or has a BMI of 27 kg/m2 or greater with at least one weight-related comorbidity AND pt has tried phentermine (unless contraindictaed) in combination with lifestyle modifications for at least 3 months and has been unsuccessful in meeting their weight loss goals or unable to tolerate phentermine and will continue these lifestyle modifications while taking the requested weight loss medication. Documentation of phentermine trial or contraindication is required. Continuation - Approve if pt continues to utilize lifestyle modifications for weight loss and has maintained at least a 5% reduction in body weight from baseline.

## Welireg

## **Products Affected**

• WELIREG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indication not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, genetic testing results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Von Hippel-Lindau Disease - Approve if pt has a von Hippel- Lindau (VHL) germline alteration as detected by genetic testing, does not require immediate surgery, and requires therapy for one of the following conditions: central nervous system hemangioblastomas, pancreatic neuroendocrine tumors, renal cell carcinoma, or retinal hemangioblastoma.

# Xalkori

## **Products Affected**

• XALKORI

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Histiocytic Neoplasms, Cutaneous Melanoma, NSCLC with MET Mutation.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	ALCL/IMT - 1 year or older. All others - 18 years or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer (NSCLC) Anaplastic Lymphoma Kinase (ALK)-positive - Approve if pt has advanced or metastatic disease and ALK positive disease as detected by an approved test. Non-Small Cell Lung Cancer (NSCLC) with ROS1 Rearrangement - approve if pt has advanced or metastatic disease and ROS1 rearrangement has been detected by an approved test. Anaplastic Large Cell Lymphoma (ALCL) - Approve if pt has ALK-positive disease and pt has relapsed or refractory disease. Histiocytic Neoplasms - Approve if pt has ALK-positive disease and pt has one of the following: Langerhans cell histiocytosis, Erdheim-Chester disease, or Rosai-Dorfman disease. Non-Small Cell Lung Cancer (NSCLC) with MET Mutation - Approve if pt has high level MET amplification or MET exon 14 skipping mutation. Inflammatory Myofibroblastic Tumor (IMT) - Approve if pt has ALK positive disease or ROS1 fusion disease.

# Xeljanz

#### **Products Affected**

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Concurrent use with Biologic or Targeted Synthetic DMARDs. Concurrent use with other potent immunosuppressants (azathioprine, tacrolimus, cyclosporine, mycophenolate). COVID-19. Renal Transplantation.
Required Medical Information	Diagnosis, other therapies tried
Age Restrictions	AS/PsA/RA/UC - 18 years or older
Prescriber Restrictions	AS/RA/JIA-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a dermatologist or rheumatologist. UC-prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Initial - 6 months. Continuation - 1 yr.

PA Criteria	Criteria Details
Other Criteria	Ankylosing Spondylitis (AS) -Approve if pt has had a 3 month trial of at least one tumor necrosis factor inhibitor, unless intolerant. Juvenile Idiopathic Arthritis (JIA) - Approve if pt has had a 3 month trial of at least one tumor necrosis factor inhibitor, unless intolerant. Psoriatic Arthritis (PSA) -Approve if pt has had a 3 month trial of at least one tumor necrosis factor inhibitor, unless intolerant and the medication will be used in combination with methotrexate or another conventional synthetic disease-modifying antirheumatic drug (DMARD), unless contraindicated. Rheumatoid Arthritis (RA) -Approve if pt has had a 3 month trial of at least one tumor necrosis factor inhibitor, unless intolerant. Ulcerative Colitis (UC) -Approve if pt has had a 3 month trial of at least one tumor necrosis factor inhibitor, unless intolerant. Continuation - Approve if pt has been established on therapy for at least the initial approval duration and pt experienced a beneficial clinical response from baseline when assessed by at least one objective measure or patient experienced an improvement in at least one symptom.

## Xenleta

### **Products Affected**

• XENLETA ORAL

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D plus patients already started on Xenleta for a covered use.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	Community Acquired Pneumonia: Diagnosis must be confirmed via chest radiograph AND the member has a documented intolerance, adverse reaction, or resistance to at least two formulary alternatives from different antibiotic classes approved for CAP (macrolides, fluoroquinolones, beta-lactam, tetracycline (doxycycline))

## Xifaxan

## **Products Affected**

• XIFAXAN

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Helicobacter pylori Infection
Required Medical Information	other medications used
Age Restrictions	Hepatic Encephalopathy/IBSD - 18 years or older. Traveler's Diarrhea - 12 years or older.
Prescriber Restrictions	
Coverage Duration	Hepathic Encephalopathy - 6 mo. IBSD/SIBO - 14 days. Traveler's Diarrhea - 3 days.
Other Criteria	Hepatic Encephalopathy - Approve if pt has previously had overt hepatic encephalopathy, according to the prescriber, and Xifaxin will be used concomitantly with lactulose, unless pt has a contraindication or significant intolerance to treatment with lactulose (550mg tablets only). Irritable Bowel Syndrome with Diarrhea (IBSD) - approve (550mg tablets only). Traveler's Diarrhea - Approve if pt is afebrile and does not have blood in the stool (200mg tablets only). Small Intestine Bacterial Overgrowth (SIBO) - approve if SIBO is diagnosed by glucose hydrogen breath test, lactulose hydrogen breath test, or small bowel aspiration and culture.

# Xolair

## **Products Affected**

• XOLAIR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Atopic Dermatitis. Concurrent use with anotehr monoclonal antibody (eg., Cinqair, Fasenra, Dupixent, Nucala, Adbry, or Tezspire). Eosinophilic Gastroenteritis, Eosinophilic Esophagitis, or Eosinophilic Colitis. Latex Allergy in Health Care Workers with Occupational Latex Allergy. Peanut and Other Food Allergies.
Required Medical Information	Diagnosis, other medications tried.
Age Restrictions	Asthma - 6 years and older. Urticaria - 12 years and older. Nasal Polyps - 18 years and older.
Prescriber Restrictions	Asthma - prescribed by or in consultation with an allergist, immunologist, or pulmonologist. Chronic Idiopathic Urticaria - prescribed by or in consultation with an allergist, immunologist, or dermatologist. Nasal Polyps - prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist.
Coverage Duration	Initial Asthma/Urticaria - 4 mo. Initial Polyps - 6 mo. Cont therapy for all - 1 year.

PA Criteria	Criteria Details
Other Criteria	Asthma - approve if pt has baseline immunoglobulin E (IgE) level greater than 30 IU/mL AND a baseline positive skin test or a blood test for allergen-specific IgE for one or more perennial aeroallergens (e.g. house dust mite, animal dander, cockroach, feathers, and mold spores) and/or for one or more seasonal aeroallergens (e.g. grass, pollen, and weeds) AND has received at least 3 consecutive months of combination therapy with BOTH an inhaled corticosteroid (ICS) and at least one additional asthma controller/maintenance medication (e.g. inhaled long- acting beta2-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, theophylline, anti-IL-4/13 [e.g. Dupixent or Tezspire]) AND has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following: a)Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, b)Patient experienced one or more asthma exacerbation requiring hospitalization, Emergency Department visit, or urgent care visit in the previous year, c)Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted, d)Patient has an FEV1/forced vital capacity (FVC) less than 0.80, e)Patient has anthat worsens upon tapering of oral corticosteroid therapy. Continuation - approve if pt is concomitantly using an ICS and has responded to therapy as determined by the prescriber. Chronic Idiopathic Urticaria (Chronic Spontaneous Urticaria) - Approve if pt has/had urticaria for greater than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days per week despite daily non-sedating H1 antihistamine therapy with doses that have been titrated up to a maximum of four times the standard FDA-approved dose. Continuation - approve if pt has responded to therapy as determined by the prescriber. Nasal Polyps - Approve if pt has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan

PA Criteria	Criteria Details
	obstruction, nasal discharge, and/or reduction/loss of smell AND has a baseline immunoglobulin E (IgE) level greater than 30 IU/mL AND pt has received at least 3 months of therapy with an intranasal corticosteroid and will continue to receive therapy with an intranasal corticosteroid concomitantly with Xolair AND pt meets one of the following: Pt has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years, pt has a contraindication to systemic corticosteroid therapy, or pt has had prior surgery for nasal polyps. Continuation - approve if pt has already received at least 6 months of therapy with Xolair and is concomitantly using a nasal corticosteroid and has responded to therapy as determined by the prescriber.

## Xospata

## **Products Affected**

• XOSPATA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Myeloid/Lymphoid Neoplasms.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Acute Myeloid Leukemia - Approve if pt has relapsed or refractory disease and disease is FLT3-mutation positive. Myeloid/Lymphoid Neoplasms - Approve if pt has eosinophilia and disease is FLT3-mutation positive.

# Xpovio

## **Products Affected**

• XPOVIO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, prior therapies tried
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Diffuse Large B-Cell Lymphoma (including pts with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma) - Approve if pt has been treated with at least two prior systemic therapies. Multiple Myeloma - Approve if the medication will be taken in combination with dexamethasone and pt meets one of the following: pt has tried at least four prior regimens for multiple myeloma, pt has tried at least one prior regimen for multiple myeloma and the medication will be taken in combination with bortezomib, or pt has tried at least one prior regimen for multiple myeloma and the medication will be taken in combination with Darzalex (daratumumb), Darzlaex Faspro (daratumumab and hyaluronidase-fihj), Kyprolis (carfilzomib) or Pomalyst (pomalidomide).

## Xtandi

### **Products Affected**

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

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	Diagnosis, other therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Prostate Cancer - Castration-Resistant - Approve if the medication is used in combination with a gonadotropin-releasing hormone (GnRH) agonist, the medication is used concurrently with Firmagon, or pt has had a bilateral orchiectomy. Prostate Cancer - Metastatic, Castration-Sensitive - Approve if the medication is used in combination with a gonadotropin-releasing hormone (GnRH) agonist, the medication is used concurrently with Firmagon, or pt has had a bilateral orchiectomy.

## ZEJULA

#### **Products Affected**

- ZEJULA ORAL CAPSULE
- ZEJULA ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Uterine Leiomyosarcoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, previous therapies tried, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Maintenance) - Approve if pt has had a complete or partial response after a platinum-based chemotherapy regimen and pt is in complete or partial response to first-line primary treatment and pt has recurrent disease and BRCA mutation. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Treatment) - Approve if pt has tried at least 3 prior chemotherapy regimens and has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test. [Note: HRD-positive disease includes patients with BRCA mutation-positive disease.] Uterine Leiomyosarcoma - Approve if pt has tried one systemic regimen and has a BRCA2 mutation.

## Zelboraf

## **Products Affected**

• ZELBORAF

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Central Nervous System Cancer. Hairy Cell Leukemia. Histiocytic Neoplasm. Non-Small Cell Lung Cancer. Differentiated Thyroid Carcinoma.
Exclusion Criteria	
Required Medical Information	Diagnosis. Mutation results. Other therapies tried.
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Erdheim-Chester Disease - Approve if pt has BRAF V600 mutation-positive disease. Melanoma - Approve if pt has unresectable, advanced, or metastatic melanoma and BRAF V600 mutation-positive disease. Central Nervous System Cancer - Approve if pt has BRAF V600 mutation-positive disease and the medication is being used for adjuvant treatment of pilocytic astrocytoma, pleomorphic xanthoastrocytoma, or ganglioglioma, or for recurrent disease of low-grade glioma, anaplastic glioma, or glioblastoma, or brain metastases due to melanoma AND the medication is prescribed in combination with Cotellic (cobimetinib). Hairy Cell Leukemia - Approve if pt has tried at least one other systemic therapy for hairy cell leukemia or is unable to tolerate purine analogs and Zelboraf is used in cobmination with Gazyva as initial therapy. Histiocytic Neoplasm - Approve if pt has BRAF V600 mutation-positive disease and has Langerhans cell histiocytosis and one of the following: multisystem disease, pulmonary disease, or central nervous system lesions. Non-Small Cell Lung Cancer - Approve if pt has BRAF V600E mutation-positive disease. Differentiated Thyroid Carcinoma - Approve if pt has differentiated thyroid carcinoma that is refractory to radioactive iodine therapy and is BRAF mutation-positive.

# Zokinvy

## **Products Affected**

• ZOKINVY

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	Progeroid Laminopathies. Other Progeroid Syndromes.
Required Medical Information	Diagnosis, test results
Age Restrictions	1 year or older
Prescriber Restrictions	Prescribed by or in consultation with a geneticist or pediatric cardiologist
Coverage Duration	1 year
Other Criteria	Hutchinson-Gilford Progeria Syndrome - Approve if the pt has a body surface area greater than or equal to 0.39 m2 and genetic testing demonstrates a confirmed pathogenic mutation in the LMNA gene consistent with Hutchinson-Gilford Progeria Syndrome.

# Zydelig

## **Products Affected**

• ZYDELIG

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Marginal Zone Lymphoma.
Exclusion Criteria	
Required Medical Information	Diagnosis, previously tried therapies
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Chronic Lymphocytic Leukemia (CLL) - Approve if pt has tried at least one systemic regimen. Small Lymphocytic Leukemia (SLL) - Approve if pt has tried at least one systemic regimen.

# Zykadia

### **Products Affected**

• ZYKADIA

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded. Erdheim- Chester Disease. Inflammatory Myofibroblastic Tumor (IMT). Non-Small Cell Lung Cancer with ROS1 Rearrangement.
Exclusion Criteria	
Required Medical Information	Diagnosis, mutation results
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Non-Small Cell Lung Cancer - Apporve if pt has advanced or metastatic disease and anaplastic lymphoma kinase (ALK)- positive disease as detected by an approved test. Erdhem- Chester Disease - Approve if pt has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor (IMT) - Approve if pt has ALK positive disease and has advanced, recurrent, or metastatic disease or the tumor is inoperable. Non-Small Cell Lung Cancer with ROS1 rearrangement - Approve if pt has advanced or metastatic disease and ROS1 rearrangement-positive disease.

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metered-dose pump 10 mg/0.5
gram /actuation, 12.5 mg/ 1.25
gram (1 %), 20.25 mg/1.25 gram
(1.62 %)
testosterone transdermal gel in
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