



## **2023 PRIOR AUTHORIZATION CRITERIA**

UCare Individual & Family Plans UCare Individual & Family Plans with M Health Fairview

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.

Last updated: 12/1/2023

#### **Notice of Nondiscrimination**

UCare complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. UCare does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

We provide <u>aids and services at no charge to people with disabilities</u> to communicate effectively with us, such as TTY line, or written information in other formats, such as large print.

If you need these services, contact us at 612-676-3200 (voice) or toll free at 1-800-203-7225 (voice), 612-676-6810 (TTY), or 1-800-688-2534 (TTY).

We provide <u>language</u> services at no charge to people whose primary <u>language</u> is not <u>English</u>, such as qualified interpreters or information written in other <u>languages</u>.

If you need these services, contact us at the number on the back of your membership card or 612-676-3200 or toll free at 1-800-203-7225 (voice); 612-676-6810 or toll free at 1-800-688-2534 (TTY).

If you believe that UCare has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file an oral or written grievance.

#### Oral grievance

If you are a current UCare member, please call the number on the back of your membership card. Otherwise please call **612-676-3200** or toll free at **1-800-203-7225** (voice); **612-676-6810** or toll free at **1-800-688-2534** (TTY). You can also use these numbers if you need assistance filing a grievance.

#### Written grievance

Mailing Address

**UCare** 

Attn: Appeals and Grievances

PO Box 52

Minneapolis, MN 55440-0052

Email: <a href="mailto:cag@ucare.org">cag@ucare.org</a>
Fax: 612-884-2021

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 1-800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 612-676-3200/1-800-203-7225 (TTY: 612-676-6810/1-800-688-2534).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 612-676-3200/1-800-203-7225 (TTY: 612-676-6810/1-800-688-2534).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 612-676-3200/1-800-203-7225 (TTY: 612-676-6810/1-800-688-2534).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 612-676-3200/1-800-203-7225 (TTY: 612-676-6810/1-800-688-2534).

注意: 如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 612-676-3200/1-800-203-7225(TTY: 612-676-6810/1-800-688-2534)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 612-676-3200/1-800-203-7225 (телетайп: 612-676-6810/1-800-688-2534).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 612-676-3200/1-800-203-7225 (TTY: 612-676-6810/1-800-688-2534).

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 612-676-3200/1-800-203-7225 (መስማት ለተሳናቸው: 612-676-6810/1-800-688-2534).

ဟ်သူဉ်ဟ်သး-နမ့်္။ကတိုး ကညီ ကိုဂ်အယိ, နမၤန့်၊ ကိုဂ်အတါမၤစာၤလ၊ တလက်ဘူဉ်လက်စ္၊ နီတမံးဘဉ်သံ့နှဉ်လီး ကိုး 612-676-3200/1-800-203-7225 (TTY: 612-676-6810/1-800-688-2534).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 612-676-3200/1-800-203-7225 (TTY: 612-676-6810/1-800-688-2534).

ប្រយ័ក្ន៖ បើសិនជាអ្នកនិយា ភាសារ័ខ្ចរ, រសវាជំនួយរ័ជ្នកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរវីអ្នក។ ចូរ ទូរស័ព្ទ 612-676-3200/1-800-203-7225 (TTY: 612-676-6810/ 1-800-688-2534)។

ملحوظة :إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان اتصل برقم ملحوظة :إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان اتصل برقم 612-676-6810/1-800-203-7225).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 612-676-3200/1-800-203-7225 (ATS : 612-676-6810/1-800-688-2534).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 612-676-3200/1-800-203-7225 (TTY: 612-676-6810/1-800-688-2534) 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 612-676-3200/1-800-203-7225 (TTY: 612-676-6810/1-800-688-2534).

# **Abiraterone**

## **Products Affected**

• abiraterone oral tablet 250 mg, 500 mg

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

# PA Criteria Criteria Details 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

## **Actemra**

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Polymyalgia Rheumatica.  |
| Exclusion<br>Criteria              | Concurrent Use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD. Crohn's disease. COVID-19.                             |
| Required<br>Medical<br>Information | Diagnosis and other medications tried for the diagnosis provided  |
| Age<br>Restrictions                | PJIA/SJIA - 2 years of age and older. All other conditions - 18 years of age and older.   |
| Prescriber<br>Restrictions         | RA/PJIA/SJIA/PMR/GCA - Prescribed by or in consultation with a rheumatologist. ILD - Prescribed by or in consultation with a rheumatologist or a pulmonologist. |
| Coverage<br>Duration               | ILD - 1 yr. RA/GCA/PMR/PJIA/SJIA - 6 mo. Continuation - 1 yr.   |

#### PA Criteria Criteria Details Other Criteria Giant Cell Arteritis (GCA) - approve if pt has tried one systemic corticosteroid (e.g. prednisone). Interstitial Lung Disease Associated with Systemic Sclerosis (ILD) - approve if pt has elevated acute phase reactants (C-reactive protein (CRP) greater than 6 mg/mL, erythrocyte sedimentation rate (ESR) greater than 28 mm/h, or platelet count greater than 330 x 109/L), forced vital capacity (FVC) is greater than 55% of the predicted value, and diagnosis is confirmed by high-resolution computed tomography. Polyarticular Juvenile Idiopathic Arthritis (PJIA) - approve if the patient will be starting on Actemra subcutaneous concurrently with methotrexate, sulfasalazine, or leflunomide (or has a contraindication) or has aggressive disease AND has tried adalimumab, Enbrel, an infliximab product, or Simponi Aria or the pt has heart failure or a previously treated lymphoproliferative disorder. Arthritis (RA) - approve if the patient has tried adalimumab. Cimzia, Enbrel, an infliximab product, or Simponi OR the pt has heart failure or a previously treated lymphoproliferative disorder. Systemic Juvenile Idiopathic Arthritis (SJIA) - approve if the patient has tried ONE other systemic agent for this condition (e.g., a corticosteroid, a conventional synthetic DMARD, or a 1-month trial of an NSAID). Polymyalgia Rheumatica (PMR) - approve if the patient has tried one systemic corticosteroid (e.g., prednisone). 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. Covid-19 - Hospitalized patient: all requests reviewed by Medical Director. Indicated if pt is receiving systemic

corticosteroids and requires supplemental oxygen, mechanical ventilation or extracorporeal membrane oxygenation (ECMO).

## **Acthar**

## **Products Affected**

• ACTHAR

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.                            |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                | Infantile Spasms - Younger than 2 years of age                                  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist.                            |
| Coverage<br>Duration               | Infantile Spasms - 1 month  |
| Other Criteria                     | Infantile spasms - Approve. Other indications are not recommended for approval. |

## **Adalimumab**

- HADLIMA
- HADLIMA PUSHTOUCH
- HADLIMA(CF)
- HADLIMA(CF) PUSHTOUCH
- HUMIRA PEN
- HUMIRA PEN CROHNS-UC-HS START
- HUMIRA PEN PSOR-UVEITS-ADOL HS
- HUMIRA SUBCUTANEOUS SYRINGE KIT HUMIRA(CF) PEN PEDIATRIC UC 40 MG/0.8 ML

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

| 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<br>Criteria              | Concurrent use with biologic DMARD or targeted synthetic DMARD (does not include methotrexate, hydroxychloroquine, sulfasalazine, and leflunomide). Polymyalgia rheumatica.  |
| Required<br>Medical<br>Information | Diagnosis, previous medications tried  |
| Age<br>Restrictions                | CD - 6 years or older. PP - 18 years or older. UC - 5 years or older   |
| Prescriber<br>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<br>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 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. 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 arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet and has tried at least |
|                | 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.  |

# **Aimovig**

## **Products Affected**

• AIMOVIG AUTOINJECTOR

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Combination use with other prophylactic CGRP agents or Nurtec ODT. Acute treatment of migraines. Cluster headache. Hemiplegic migraine.  |
| Required<br>Medical<br>Information | Diagnosis, number of migraine headaches per month, prior therapies tried   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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 Aimovig, the pt has had a significant clinical benefit from the medication as determined by the prescriber. |

# **Ajovy**

- AJOVY AUTOINJECTOR
- AJOVY SYRINGE

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Combination use with other prophylactic CGRP agents or Nurtec ODT. Acute treatment of migraines. Cluster headache.   |
| Required<br>Medical<br>Information | Diagnosis, number of migraine headaches per month, prior therapies tried   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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 mettastatic disease or the tumor is inoperable. |

# **Alunbrig**

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

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Erdheim-Chester Disease. Inflammatory Myofibroblastic Tumor (IMT).   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. |

# **Anabolic Steroids**

## **Products Affected**

• ANADROL-50

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. Girls w/ Turner's Syndrome or Ullrich-Turner Syndrome (oxandrolone only), management of protein catabolism w/ burns or burn injury (oxandrolone only), AIDS wasting and cachexia. |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information |  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | Authorization will be for 12 months, unless otherwise specified.   |
| Other Criteria                     |  |

## **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<br>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<br>Medical<br>Information | Diagnosis, lab results, other therapies tried  |
| Age<br>Restrictions                | Anemia due to MDS - 18 years or older  |
| Prescriber<br>Restrictions         | Anemia due to MDS/Anemia due to Myelofibrosis - prescribed by or in consultation with a hematologist or oncologist.  |
| Coverage<br>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. 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.

# Arcalyst

## **Products Affected**

ARCALYST

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Concurrent use with other biologic therapies for an inflammatory condition. COVID-19  |
| Required<br>Medical<br>Information | Diagnosis, genetic testing  |
| Age<br>Restrictions                | CAPS/Pericarditis - 12 years and older  |
| Prescriber<br>Restrictions         | CAPS - Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. IL-1 RA-Prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders. |
| Coverage<br>Duration               | Initial - 6 months. Continuation - 1 year.  |

| PA Criteria    | Criteria Details   |
|----------------|--|
| Other Criteria | Cryopyrin-Associated Periodic Syndromes (CAPS) [Familial Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease or chronic infantile neurological cutaneous and articular syndrome]- Initial - Approve. Deficiency of Interleukin-1 Receptor Antagonist (IL-1 RA)- Initial - approve if pt is greater than 10 kg (22 lbs) AND genetic testing has confirmed a mutation in the IL1RN gene and according to the prescriber, patient has demonstrated a clinical benefit with Kineret. Pericarditis - Approve if pt has recurrent pericarditis with a history of at least three episodes of pericarditis in the past AND pt is currently receiving standard treatment or standard treatment is contraindicated. Continuation for all - Approve it pt has been established on therapy for 6 months and, when compared to baseline, pt has experienced a beneficial clinical response as assessed by at least one objective measure or improvement in at least one symptom. |

# Aubagio

## **Products Affected**

• teriflunomide

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA approved indications not otherwise excluded   |
| Exclusion<br>Criteria              | Non-relapsing forms of MS. Concurrent use of other disease-modifying agents used for MS (examples include interferon beta 1a, interferon beta 1b, glatiramer, peginterferon beta-1a, fingolimod, cladribine, siponomid, dimethyl fumarate DR, ocrelizumab, natalizumab, and alemtuzumab)  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

## **Austedo**

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

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis and previous medications tried   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         | Chorea - Prescribed by or in consultation with a neurologist.  Dyskinesia - Prescribed by or in consultation with a neurologist or psychiatrist.   |
| Coverage<br>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. |

## **Avonex**

#### **Products Affected**

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

• AVONEX INTRAMUSCULAR SYRINGE **KIT** 

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis.  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

# **Ayvakit**

## **Products Affected**

AYVAKIT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA approved indications not otherwise excluded from coverage. Myeloid/Lymphoid Neoplasms with Eosinophilia.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies, test results   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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**

- BENLYSTA INTRAVENOUS
- BENLYSTA SUBCUTANEOUS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Concurrent use with other biologics or Lupkynis (voclosporin capsules). Rheumatoid Arthritis.  |
| Required<br>Medical<br>Information | Diagnosis, lab results, other therapies tried  |
| Age<br>Restrictions                | Subcutaneous - 18 years or older, IV - 5 years or older  |
| Prescriber<br>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<br>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 immunosuppressive 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. |

## **Betaseron**

- BETASERON SUBCUTANEOUS KIT
- BETASERON SUBCUTANEOUS RECON SOLN

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA approved indications not otherwise excluded from coverage.                                      |
| Exclusion<br>Criteria              | Concurrent use of other disease-modifying agent used for multiple sclerosis. Non-relapsing forms of MS. |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or after consultation with a neurologist or an MS specialist.                             |
| Coverage<br>Duration               | 3 Years   |
| Other Criteria                     | Multiple Sclerosis - pt has a relapsing form of MS.   |

# **Bexarotene capsule**

## **Products Affected**

• bexarotene

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, other therapies tried  |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | prescribed by or in consultation with an oncologist or dermatologist  |
| Coverage<br>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 generic 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 serious adverse reaction. |

## **Bexarotene Gel**

## **Products Affected**

• bexarotene

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.                    |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | prescribed by or in consultation with an oncologist or dermatologist    |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Cutaneous T-Cell Lymphoma - Approve if pt has cutaneous manifestations. |

## **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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies   |
| Age<br>Restrictions                | CML - 1 year or older. Others - 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 ORAL CAPSULE 50 MG, 75 MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Plus Colon or Rectal Cancer.   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. Non-Small Cell Lung Cancer - approve if pt has BRAF V600E mutation-positive metastatic disease and Braftovi will be taken in combination with Mektovi. |

## **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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, prior treatments  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, concurrent medications  |
| Age<br>Restrictions                | 18 years and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a hematologist   |
| Coverage<br>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, cyclosporine, 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<br>Criteria              | Metastatic Castration-Resistant Prostate Cancer   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried, mutation status  |
| Age<br>Restrictions                | HCC/RCC/Endometrial carcinoma/GIST/NSCLC - 18 years or older. Thyroid carcinoma - 12 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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**

• CALQUENCE (ACALABRUTINIB MAL)

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. Marginal Zone Lymphoma. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | diagnosis, prior treatments  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, LVOT gradient, LVEF, LV wall thickness    |
| Age<br>Restrictions                | 18 years or older                                    |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Differentiated Thyroid Carcinoma.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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. |

## Chenodal

#### **Products Affected**

• CHENODAL

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Cerebrotendinous Xanthomatosis.   |
| Exclusion<br>Criteria              | Combination Therapy with Cholbam (cholic acid).  |
| Required<br>Medical<br>Information | Diagnosis, previously tried therapies  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | CX - prescribed by or in consultation with a metabolic specialist who treats patients with CX  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Gallstones - Approve if pt has previously tried or is currently using an ursodiol product. Cerebrotendinous Xanthomatosis (CX)- Approve. |

# Cibinqo

#### **Products Affected**

• CIBINQO

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Concurrent use with a biologic or with a targeted synthetic DMARD, Biologic Immunomodulator, JAK inhibitor, or other potent immunosuppressants. COVID-19.  |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried  |
| Age<br>Restrictions                | 12 years or older  |
| Prescriber<br>Restrictions         | prescribed by or in consultation with an allergist, immunologist, or dermatologist.  |
| Coverage<br>Duration               | AD: initial - 3mo, cont - 1 year   |
| Other Criteria                     | Atopic Dermatitis (AD) - Approve if pt has had a 3 month trial of at least one traditional systemic therapy, 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. |

## Cimzia

#### **Products Affected**

- CIMZIA
- CIMZIA POWDER FOR RECONST
- CIMZIA STARTER KIT

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA approved indications. Spondyloarthritis (SpA), Other subtypes.   |
| Exclusion<br>Criteria              | Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).  |
| Required<br>Medical<br>Information | diagnosis, medication history  |
| Age<br>Restrictions                | CD/PP - 18 years and older   |
| Prescriber<br>Restrictions         | AS/nr-axSpA/RA/SpA - prescribed by or in consultation with a rheumatologist. CD - prescribed by or in consultation with a gastroenterologist. PP - prescribed by or in consultation with a dermatologist. PsA - prescribed by or in consultation with a rheumatologist or a dermatologist. |
| Coverage<br>Duration               | AS/CD/nf-axSpA/PsA/RASpA - 6 mo. PP - 3 mo. Continuation - 1 yr.   |

| PA Criteria    | Criteria Details  |
|----------------|---|
| Other Criteria | Ankylosing Spondylitis (AS) - approve if pt has tried two of Enbrel, adalimumab, Rinvoq, or Taltz. Crohn's disease (CD) - approve if pt has tried adalimumab. Non-Radiographic Axial Spondyloarthritis (nr-axSpA) - approve if pt has C-reactive protein (CRP) elevated beyond the upper limit of normal OR sacroiliitis reported on magnetic resonance imaging (MRI). Plaque Psoriasis (PP) - approve if pt has tried two of Enbrel, adalimumab, Otezla, Skyrizi, Stelara subcutaneous, Taltz, and Tremfya. Psoriatic Arthritis (PsA) - approve if pt has tried two of Enbrel, adalimumab, Otezla, Stelara subcutaneous, Taltz, Tremfya, Skyrizi, and Xeljanz/XR. Rheumatoid Arthritis (RA) - approve if pt has tried two of Actemra subcutaneous, Enbrel, adalimumab, Rinvoq, and Xeljanz/XR. 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 disease-modifying antirheumatic drug (DMARD). 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. |

## Cometriq

#### **Products Affected**

• COMETRIQ

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Non-Small Cell Lung Cancer. Differentiated Thyroid Carcinoma.  |
| Exclusion<br>Criteria              | Metastatic Castration-Resistant Prostate Cancer   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | Differentiated Thyroid Carcinoma - 12 years or older. Medullary Thyroid Carinoma/NSCLC - 18 years or older  |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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). |

## **Continuous Glucose Monitors**

#### **Products Affected**

- DEXCOM G6 RECEIVER
- DEXCOM G6 SENSOR
- DEXCOM G6 TRANSMITTER
- DEXCOM G7 RECEIVER
- DEXCOM G7 SENSOR

- FREESTYLE LIBRE 14 DAY READER
- FREESTYLE LIBRE 14 DAY SENSOR
- FREESTYLE LIBRE 2 READER
- FREESTYLE LIBRE 2 SENSOR
- FREESTYLE LIBRE 3 SENSOR

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | Diabetes Mellitus   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, insulin use  |
| Age<br>Restrictions                | Freestye Libre - 18 years of age or older. Freestyle Libre 2 - 4 years of age or older. Dexcom - 2 years of age or older.   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 3 years   |
| Other Criteria                     | Diabetes type 1 - Approve. Other Diabetes Types - Approve if patient is injecting insulin three times per day or using an insulin pump AND insulin dose requires frequent adjustment, per provider. |

## Copiktra

#### **Products Affected**

COPIKTRA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Marginal Zone Lymphoma.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Central Nervous System Cancer. Histiocytic Neoplasm.  |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis. Mutation results. Other therapies tried.  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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<br>Criteria              | Chronic Kidney Disease (CKD), Severe Renal Impairment or End<br>Stage Renal Disease, Epidermal Nevus Syndrome |
| Required<br>Medical<br>Information | Diagnosis, lab values   |
| Age<br>Restrictions                | TIO - 2 years or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a endocrinologist or nephrologist                                       |
| Coverage<br>Duration               | X-linked Hypophosphotemia - 1 year, Tumor-induced<br>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 tumorinduced 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**

#### **Products Affected**

• dalfampridine

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, ambulation evaluation measures   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.  |
| Coverage<br>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 ORAL TABLET 100 MG, 25 MG

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

## **Diacomit**

#### **Products Affected**

• DIACOMIT

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. Treatment-Refractory Seizures/Epilepsy (i.e., Lennox-Gastaut Syndrome, infantile spasms, tuberous sclerosis complex, Sturge-Weber syndrome, Doose syndrome, infection-related or anoxo-ischemic epilepsy syndromes, cortical malformation/dysplasia, epileptic encephalopathies associated with sodium channel mutations, and epilepsy with myoclonic absences).  |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, previous therapies  |
| Age<br>Restrictions                | 2 years and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Dravet Syndrome, Initial- approve if the patient weighs 7 kg or more and is taking concomitant clobazam OR the patient is unable to take clobazam due to adverse events as determined by the prescribing physician. Treatment-Refractory Seizures/Epilepsy, Initial - approve if the patient weighs 7 kg or more and if the patient has tried at least two other antiseizure medications. Continuation- approve if the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescribing physician. |

## **Dimethyl Fumarate**

#### **Products Affected**

• dimethyl fumarate

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA approved indications not otherwise excluded   |
| Exclusion<br>Criteria              | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis.  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.  |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

## **Dupixent**

#### **Products Affected**

• DUPIXENT PEN SUBCUTANEOUS PEN INJECTOR 200 MG/1.14 ML, 300 MG/2 MI

SYRINGE 100 MG/0.67 ML, 200 MG/1.14 ML, 300 MG/2 ML

• DUPIXENT SYRINGE SUBCUTANEOUS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Concurrent use with another Monoclonal Antibody Therapy or JAK inhibitor   |
| Required<br>Medical<br>Information | Diagnosis, prescriber specialty, other medications tried and length of trials.   |
| Age<br>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<br>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<br>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 8 weeks of PPI and tried dietary modifications unless inappropriate per provider. Cont. - approve if 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 previous 2

| 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**

#### **Products Affected**

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

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>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<br>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**

#### **Products Affected**

- EMGALITY PEN
- EMGALITY SYRINGE

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Combination use with other prophylactic CGRP agents or Nurtec ODT. Acute treatment of migraines.   |
| Required<br>Medical<br>Information | Diagnosis, number of migraine headaches per month, prior therapies tried   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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<br>Criteria              | Concurrent use with Soliris or Ultomiris   |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a hematologist   |
| Coverage<br>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**

#### **Products Affected**

- ENBREL MINI
- 25 MG (1 ML)
- ENBREL SUBCUTANEOUS SOLUTION

25 MG/0.5 ML

- ENBREL SUBCUTANEOUS RECON SOLN ENBREL SUBCUTANEOUS SYRINGE 25 MG/0.5 ML (0.5), 50 MG/ML (1 ML)
  - ENBREL SURECLICK

| 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<br>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<br>Medical<br>Information | Diagnosis, previous therapies tried  |
| Age<br>Restrictions                | PP - 4 years or older  |
| Prescriber<br>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<br>Duration               | AS/JIA/PsA/RA/SpA/SD - 6 mo. PP/BD -3mo GVHD-1mo PG-<br>4mo. Cont GVHD - 3 mo. Cont all others - 1 yr  |

#### PA Criteria Criteria Details Other Criteria Ankylosing Spondylitis (AS) - Approve. Juvenile Idopathic Arthritis (JIA) - Approve if pt has tried one other systemic agent for this condition, pt will be starting on Enbrel concurrently with methotrexate (MTX), sulfasalazine, or leflunomide, pt has an absolute contraindication to MTX, sulfasalazine, or leflunomide, or pt has aggressive disease, as determined by the prescribing physician. Plague Psoriasis (PP) - Approve if pt has tried at least one traditional systemic agent for psoriasis or a biologic for at least 3 months, unless intolerant. Psoriatic Arthritis (PsA) - Approve. Rheumatoid Arthritis (RA) - Pt has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) or biologic for at least 3 months. Behcet's Disease (BD) - Approve if pt has tried at least one conventional therapy or biologic. Graft vs. Host Disease (GVHD) - Approve if pt has tried one conventional treatment. 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 (SD) - Approve if pt has tried one corticosteroid and one conventional synthetic DMARD for at least 2 months or was 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.

## **Epidiolex**

#### **Products Affected**

• EPIDIOLEX

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. Treatment-Refractory Seizures/Epilepsy [specific rare conditions] (i.e. CDKL5 deficiency disorder, Dup15q, Aicardi, or Doose syndromes, febrile infection-related epilepsy syndromes, Sturge-Weber syndrome, lissencephaly, cortical malformation/dysplasia, and epilepsy with myoclonic absences).   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, previous therapies  |
| Age<br>Restrictions                | 1 year and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Dravet Syndrome - Approve if pt has tried or is concomitantly receiving two other antiseizure medications or one of Diacomit, Fintepla, or clobazam. Lennox-Gaustaut Syndrome - Approve if pt has tried or is concomitantly receiving two other antiseizure medications. Tuberous Sclerosis Complex - approve if pt has tried or is concomitantly receiving two other antiseizure medications. Treatment Refractory Seizures/Epilepsy - approve if pt has tried or is concomitantly receiving two other antiseizure medications. Continuation therapy - approve if pt is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber. |

## **Erivedge**

#### **Products Affected**

• ERIVEDGE

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. Central Nervous System Cancer.   |
| Exclusion<br>Criteria              | Basal Cell Carcinoma (Locally advanced or metastatic) that progressed while on Odomzo. Metastatic Colorectal Cancer. Ovarian Cancer.  |
| Required<br>Medical<br>Information | Diagnosis. Mutation results. Other therapies tried.   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, other therapies  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 oral tablet 100 mg, 150 mg, 25 mg

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Bone Cancer. Renal Cell Carcinoma. Vulvar Cancer.  |
| Exclusion<br>Criteria              | Breast Cancer. Colorectal Cancer, Advanced. Glioblasatoma<br>Multiforme. Head and Neck Cancer, Squamous Cell, Recurrent<br>and/or Metastatic. Hepatocellular Carcinoma (HCC), Advanced.<br>Renal Cell Carcinoma (RCC), Advanced - Clear Cell Histology.   |
| Required<br>Medical<br>Information | Diagnosis, mutation results, previous therapies tried   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 nonclear 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. |

## **Esbriet**

#### **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<br>Criteria              | Concomitant use with Ofev.  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         | prescribed by or in consultation with a pulmonologist.  |
| Coverage<br>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). |

# **Everolimus (antineoplastic)**

#### **Products Affected**

• everolimus (antineoplastic)

| 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. Meningioma. Soft Tissue Sarcoma. Thymomas and Thymic Carcinomas. Differentiated Thyroid Carcinoma. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL). |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, hormone receptor status, prior therapies   |
| Age<br>Restrictions                | Breast cancer/NE tumors/RCC/TC/EC/GIST/CHL/HN/US/STS/TTC/WM/LPL - 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. Differentiated Thyroid Carcinoma -Approve if refractory to radioactive iodine therapy. Endometrial Carcinoma - 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 pt has

| 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. |

## **Everolimus (immunosuppressant)**

#### **Products Affected**

• everolimus (immunosuppressive)

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA approved indications not otherwise excluded   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Liver Transplant Rejection, Prophylaxis - Approve if everolimus will be used in combination with other medications for this indication. Renal Transplant Rejection, Prophylaxis, Low to Moderate Risk - Approve if everolimus will be used in combination with other medications for this indication. |

## **Exkivity**

#### **Products Affected**

• EXKIVITY

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results, previous therapies tried   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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**

#### **Products Affected**

- FASENRA
- FASENRA PEN

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | COPD. Concurrent use of Fasenra with another monoclonal antibody therapy. Hypereosinophilic Syndrome. |
| Required<br>Medical<br>Information | Diagnosis, labs, previous and current medications, spirometry results                                 |
| Age<br>Restrictions                | 12 years or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an allergist, immunologist, or pulmonologist                    |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>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<br>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. |

# **Fingolimod**

### **Products Affected**

• fingolimod

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis (MS). Non-relapsing forms of MS.   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                | 10 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

# **Fintepla**

#### **Products Affected**

• FINTEPLA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                | 2 years and older (initial therapy)   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an neurologist (initial therapy)  |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Dravet Syndrome - Approve if pt has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving clobazam, Epidiolex, or Diacomit. Continuation - Approve if the pt is responding to therapy as determined by the prescriber. Lennox-Gastaut Syndrome - Approve if pt has tried or is concomitantly receiving at least two other antiepileptic drugs. Continuation - Approve if the pt is responding to therapy as determined by the prescriber. |

# **Fotivda**

#### **Products Affected**

• FOTIVDA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded  |
| Exclusion<br>Criteria              | Diagnosis, other therapies   |
| Required<br>Medical<br>Information |  |
| Age<br>Restrictions                | 18 years and older   |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                | NSCLC-18 years or older, Thyroid Cancers-12 years or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist   |
| Coverage<br>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 disease 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 disease. Medullary Thyroid Cancer - Approve if patient has unresectable, recurrent, or metastatic disease and rearranged during transfection (RET)- fusion positive disease or RET-mutation-positive disease and the pt. is continuing therapy with Gavreto. |

# **Gilotrif**

#### **Products Affected**

• GILOTRIF

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Head and Neck Cancer.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results, previous therapies tried  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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. |

## **Glatiramer**

#### **Products Affected**

• glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Concurrent use with other disease-modifying agents used for multiple sclerosis (MS). Non-relapsing forms of MS.   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.  |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

# Glatopa

#### **Products Affected**

• GLATOPA SUBCUTANEOUS SYRINGE 20 MG/ML, 40 MG/ML

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Non-relapsing forms of MS. Concurrent use of other disease-modifying agents used for MS (examples include interferon beta 1a, interferon beta 1b, glatiramer, peginterferon beta-1a, fingolimod, cladribine, siponomid, dimethyl fumarate DR, ocrelizumab, natalizumab, and alemtuzumab)  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

### **Glucagon-Like Peptide -1 Agonists**

#### **Products Affected**

- BYDUREON BCISE
- BYDUREON SUBCUTANEOUS PEN INJECTOR
- BYETTA
- MOUNJARO
- OZEMPIC SUBCUTANEOUS PEN INJECTOR 0.25 MG OR 0.5 MG (2 MG/3 ML), 0.25 MG OR 0.5 MG(2

MG/1.5 ML), 1 MG/DOSE (2 MG/1.5 ML), 1 MG/DOSE (4 MG/3 ML), 2 MG/DOSE (8 MG/3 ML)

- RYBELSUS
- SOLIQUA 100/33
- TRULICITY
- VICTOZA 2-PAK
- VICTOZA 3-PAK

| PA Criteria                        | Criteria Details                                     |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. |
| Exclusion<br>Criteria              | Type 1 diabetes. Weight loss treatment.              |
| Required<br>Medical<br>Information |  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 3 years  |
| Other Criteria                     | Diabetes type 2 - Approve.                           |

### **Growth Hormone**

#### **Products Affected**

- GENOTROPIN
- GENOTROPIN MINIQUICK
- NORDITROPIN FLEXPRO
- ZORBTIVE

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Short Bowel Syndrome in Adults.   |
| Exclusion<br>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<br>Medical<br>Information | Diagnosis, lab results [documentation required], vitals  |
| Age<br>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<br>Restrictions         | GHD, Noonan, PWS, SHOX, born small - eval by endocrinologist.<br>CKD - eval by endocrinologist or a nephrologist.  |
| Coverage<br>Duration               | NGHDSS (initial) - 6 months. SBS (initial and cont) - 1 mo. All others - 1 year  |

#### PA Criteria Criteria Details

#### **Other Criteria**

GHD-Child/Adolescent - 2 GH tests with inadequate reponse OR 1 GH test with inadequate response and at least 1 risk factor for GHD, undergone brain radiation or tumor resection and either 1 GH test with an inadequate response or deficiency in at least 1 other pituitary hormone, pt has congenital hypopituitarism and either 1 GH test with an inadequate response, deficiency in at least 1 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 inadequate response, or hypophysectomy. Short Stature - at least 5 yo, ht below 1.2% or SDS -2.25, velocity below 4cm/vr or below 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 has doubled.GHD in Adult/Transition Adolescent - Not used for antiaging therapy or athletic ability or body building, doc. of childhood onset, adult onset from hypopituitarism, pt has known 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 negative response to GH stim test or transition adolescent pt has been off somatropin for 1 month and has inadequate GH stim test (see policy). CKD Child/Adolescent- GFR less than 60 and baseline ht is less than 5th percentile and ht velocity is below 25th perentile over 3 months in infants or 6 months in children. Noonan-Baseline ht is less than 5th percentile, dx confirmed by genetic test or clinical diagnosis if genetic test is not definitive. Prader-Willi Syndromedx confirmed by genetic testing. Short Stature Homeobox (SHOX) - pt has SHOX deficiency on chromosome analysis, epiphyses open, and ht below 5th percentile. Born Small/Silver-Russell Syndrome - Approve if pt was born 2 SD below mean birth wt/ht and did not have catch-up growth before age 2-4 and epiphyses open and height remains below 5th percentile. Turner Syndrome - dx confirmed by karyotypoe analysis and

| PA Criteria | Criteria Details   |
|-------------|--|
|             | baseline ht below 5th percentile. Short Bowel Syndrome - pt dependent on parenteral nutrition. Cont - Approve if prescriber attests to response. HIV w/ wasting or cachexia - unintention wt loss of 10% or more from baseline or wt less than 90% of lower limit of IBW or BMI 20 or less and pt has wasting or cachexia, has been antiretroviral tx for 30 days or more and will continue, not being use solely for tx of alteration in body fat distribution and pt has tried 1 appetite stimulant unless contraindicated. Cont (CKD, Noonan, PWS,SHOX,Born Small,Turner) - height increased by 2 cm/hr and epiphyses open. Cont (CHD, CKD, SS w/ tx longer than 10mo) - Ht has increased by 2cm/yr, if greater than 11 yo epiphysis open, and if 18yo, mid parental height not obtained. |

# Haegarda

#### **Products Affected**

• HAEGARDA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Concomitant use with other HAE prophylactic therapies. Patients may concomitantly use medications for the treatment of acute HAE attacks.   |
| Required<br>Medical<br>Information | diagnosis, lab values   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders.  |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Hereditary Angioedema (HAE) - HAE type 1 or type 2 as 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. [documentation required] Continuation therapy - patient is currently receiving Haegarda for HAE type 1 or type 2 prophylaxis AND according to the prescriber, the patient has had a favorable clinical response (e.g., decrease in number of HAE acute attack frequency, decrease in HAE attack severity, decrease in duration of HAE attacks) since initiating Haegarda prophylactic therapy compared with baseline. |

## Hemlibra

#### **Products Affected**

• HEMLIBRA

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

#### **PA** Criteria Criteria Details Other Criteria Hemophilia A with Factor VIII Inhibitors - Approve if pt is using Hemlibra 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. Presciber 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 damage, has experienced a joint bleed, or has a specific 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 bleeding/bleeding risk in which the prescriber determines the use of Hemlibra is warranted. Prescriber also attests that 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.

# Hetlioz

#### **Products Affected**

• tasimelteon

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA approved indications not otherwise excluded from coverage.  |
| Exclusion<br>Criteria              | Insomnia (Primary), Nighttime Sleep Disturbances in Smith-<br>Magenis Syndrome (SMS), Concomitant use with other<br>medications for sleep (ex. ramelteon, sedative hypnotics or<br>benzodiazepines). Other types of sleep-related disorders |
| Required<br>Medical<br>Information | Diagnosis, previous medications   |
| Age<br>Restrictions                | 18 years and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a physician who specializes in the treatment of sleep disorders.  |
| Coverage<br>Duration               | Initial - 6 Months. Continuation - 1 Year   |

#### PA Criteria Criteria Details

#### **Other Criteria**

Non-24-Hour Sleep Wake Disorder (Non-24) (Initial Therapy) -Pt is totally blind with no perception of light, AND Diagnosis of Non-24 is confirmed by meeting ONE of the following conditions (a or b): a) Assessment of at least one physiologic circadian phase marker, Note: Examples of physiologic circadian phase markers include measurement of urinary melatonin levels, dim light melatonin onset (as measured in blood or saliva), and assessment of core body temperature. OR b) If assessment of at least one physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for greater than or equal to 1 week plus evaluation of sleep logs recorded for greater than or equal to 1 month, AND Patient meets BOTH of the conditions: Patient has received at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with melatonin under the guidance of a physician who specializes in the treatment sleep disorders AND Patient had inadequate efficacy with melatonin therapy according to the prescriber, Note: Examples of efficacy with melatonin therapy include entrainment, clinically meaningful or significant increases in nighttime sleep, and clinically meaningful or significant decreases in daytime sleep. Non-24-Hour Sleep Wake Disorder (Non-24) (Continuation of Therapy): Patient is totally blind with no perception of light, AND Patient meets both of the conditions: Patient has received at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with melatonin under the guidance of a physician who specializes in the treatment sleep disorders, AND Patient had inadequate efficacy with melatonin therapy according to the prescriber Note: Examples of efficacy with melatonin therapy include entrainment, clinically meaningful or significant increases in nighttime sleep, and clinically meaningful or significant decreases in daytime sleep. AND Patient meets both of the conditions (a and b): a) Patient has received at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with Hetlioz under the guidance of a physician who specializes in the treatment of sleep disorders Note:

| PA Criteria | Criteria Details   |
|-------------|--|
|             | Patients who have not received at least 6 months of continuous Hetlioz therapy, or if the therapy has not been continuous (i.e., 6 consecutive months of daily treatment), should follow criteria 1 (initial therapy). And b) Patient has achieved adequate results with Hetlioz therapy according to the prescriber. Note: Examples of adequate results with Hetlioz therapy include entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep. |

# **Hycamtin**

### **Products Affected**

• HYCAMTIN ORAL

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded from Part D. All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | diagnosis  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Small Cell Carcinoma of Lung - Approve if pt has relapsed disease with a prior complete or partial response and is at least 45 days from the end of first-line chemotherapy. |

# **Hydroxyurea**

### **Products Affected**

• hydroxyurea

| PA Criteria                        | Criteria Details                                     |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. |
| Exclusion<br>Criteria              | COVID-19   |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     |  |

# Hyqvia

### **Products Affected**

• HYQVIA

| PA Criteria                        | Criteria Details                                     |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | diagnosis  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Primary Immunoglobulin Deficiency - Approve.         |

## **Ibandronate**

#### **Products Affected**

• ibandronate intravenous

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Osteoporosis prevention. Concurrent use of ibandronate injectinon with other medications for osteoprosis.  |
| Required<br>Medical<br>Information | Diagnosis, lab results   |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Osteoporosis, Treatment for a Postmenopausal Patient - Approve if pt has had a T-score (current or at any time in the past) at or below -2.5 at the lumbar spine, femoral neck, total hip and/or 33% (one-third) radius (wrist), has had an osteoporotic fracture or a fragility fracture, or pt has low bone mass and is at high risk for fracture, according to the prescriber, and meets one of the following: 1) has tried ibandronate injection (Boniva) or zoledronic acid injection (Reclast), 2) cannot take an oral bisphosphonate due to difficulty swallowing, inability to remain in an upright position post oral bisphosphonate administration, 3) has tried and failed tried at least one oral bisphosphonate or oral bisphosphonate-containing product due to inadequate efficacy after 12 months, experienced an osteoporotic fracture or a fragility fracture while receiving oral bisphosphonate therapy, or experienced significant intolerance to an oral bisphosphonate, or 4) has had an osteoporotic fracture or a fragility fracture. |

### **Ibrance**

#### **Products Affected**

• IBRANCE

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All-FDA approved indications not otherwise excluded. Liposarcoma. |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, hormone receptor status, concurrent therapies          |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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). |

# **Icatibant**

#### **Products Affected**

• icatibant

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded  |
| Exclusion<br>Criteria              | HAE Prophylaxis  |
| Required<br>Medical<br>Information | Diagnosis, lab results   |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an allergist/immunologist or a physican that specializes in the treatment of HAE or related disorders.   |
| Coverage<br>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 1 or 2 as confirmed 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. A diagnosis of HAE with normal C1-INH (also referred to as HAE type III) does NOT satisfy this requirement. [documentation required] Continuation - Approve if 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. |

# **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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, previous therapies  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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 from coverage.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis. Mutation results.   |
| Age<br>Restrictions                | ASM/DP/HS/MMD/KS/MC - 18 or older.   |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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 plateletderived growth factor receptor (PDGFR) gene rearrangements. Chordoma - Approve. Desmoid Tumors (aggressive fibromatosis) - 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
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET

| 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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies   |
| Age<br>Restrictions                | GVHD - 1 year or older, All other indications - 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. |

# **Immune Globulin**

#### **Products Affected**

- FLEBOGAMMA DIF
- GAMASTAN S/D
- GAMMAGARD LIQUID
- GAMUNEX-C

- PRIVIGEN
- XEMBIFY

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | For Vivaglobin, Hizentra prescribed with one of the following physician specialists: an allergist/immunologist, immunologist, otolaryngologist (ear nose and throat [ENT] physician), pulmonologist, or an infectious disease specialist |
| Coverage<br>Duration               | Authorization will be for 12 months.   |

#### PA Criteria Criteria Details Other Criteria For Gammunex-C, Gammaked, Gammagard liquid given SC and Vivaglobin, Hizentra, needs to be used for the treatment of a primary humoral or combined immune deficiency, which includes common variable immunodeficiency (CVID), X-linked agammaglobulinemia, severe combined immunodeficiencies (SCID), Wiskott-Aldrich syndrome, hyper-IgM syndromes (Xlinked or autosomal recessive), other combined immunodeficiencies with significant hypogammaglobulinemia or antibody production defect, and unspecified hypogammaglobulinemia. For Gammunex-C, Gammked, Gammagard, other IVIG given IV, need documented diagnosis, prescriber specialty. For Vivaglobin, Hizentra, diagnoses Common variable immunodeficiency (CVID) and Unspecified hypogammaglobulinemia patient has documented history of significant recurrent or persistent, severe bacterial infections (such as recurrent pneumonias, frequent episodes of bacterial infections such as sinusitis, otitis, bronchitis, skin structure infections, or infections of the gastrointestinal tract) according to the prescribing physician that are not responding to antibiotics or prophylactic antibiotics or member has interfering hypersensitivities, other disorders increasing susceptibility to infection need to have been sought out and treated if exist, patient has reduced IgG level or reduced IgG1 and IgG3 levels or IgG1 reduction. Other immune deficiencies for Hizentra, Vivaglobin, patient has frequent and severe infections.

# Inlyta

#### **Products Affected**

• INLYTA ORAL TABLET 1 MG, 5 MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                | ARCC/DTC/STS - 18 years or older  |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Chronic Myelomonocytic Leukemia - Approve. Myelodysplastic<br>Syndrome - Approve. Myelodysplastic<br>Syndrome/Myeloproliferative Neoplasm Overlap Neoplasms -<br>Approve |

## **Inrebic**

#### **Products Affected**

• INREBIC

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded from coverage. Myeloid/Lymphoid neoplasms with Eosinophilia.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Myelofibrosis (MF), including Primary MF, Post-Polycythemia<br>Vera MF, and Post-Essential Thrombocythemia MF - Approve if<br>pt has intermediate-2 or high-risk disease. Myeloid/Lymphoid<br>neoplasms - Approve if the pt has eosinophilia and tumor has a<br>JAK2 rearrangement. |

### **Iressa**

### **Products Affected**

• gefitinib

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 oral tablet
- 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<br>Criteria              |  |
| Required<br>Medical<br>Information | diagnosis, serum ferritin level  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a hematologist   |
| Coverage<br>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. |

# **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<br>Criteria              | Coronavirus disease 2019 (COVID-19)   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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<br>Criteria              |  |
| Required<br>Medical<br>Information | Previous therapies tried. Mutation results.  |
| Age<br>Restrictions                | GVHD - 12 years or older. MF/PV/CML-2/ET/MLN - 18 years or older. ALL - 21 years or older.   |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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 eosinophliia 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.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information |   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Concurrent use of Samsca. Hyponatremia.   |
| Required<br>Medical<br>Information | Diagnosis, renal function   |
| Age<br>Restrictions                | 18 years and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a nephrologist  |
| Coverage<br>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). |

# **Kalydeco**

### **Products Affected**

• KALYDECO

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>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<br>Medical<br>Information | Diagnosis, specific CFTR gene mutations  |
| Age<br>Restrictions                | 1 month and older  |
| Prescriber<br>Restrictions         | Must be prescribed by or in consultation with a pulmonologist or physician or specializes in the treatment of CF   |
| Coverage<br>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. |

# Kesimpta

### **Products Affected**

KESIMPTA PEN

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA approved indications not otherwise excluded from coverage.  |
| Exclusion<br>Criteria              | Concurrent use with other disease modifying agents used for multiple sclerosis. Non-relapsing forms of multiple sclerosis.  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.  |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

# Kisqali

- KISQALI FEMARA CO-PACK ORAL TABLET 200 MG/DAY(200 MG X 1)-2.5 MG, 400 MG/DAY(200 MG X 2)-2.5 MG, 600 MG/DAY(200 MG X 3)-2.5 MG
- KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Breast cancer in men. |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | diagnosis, hormone receptor status, concurrent therapies                   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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 Kisgali 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 Kisgali 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 HER2negative breast cancer and pt is receiving a gonadotropinreleasing hormone (GnRH) AND Kisgali will be used in combination with anastrozole, exemestane, letrozole, or fulvestrant.

# Koselugo

### **Products Affected**

• KOSELUGO

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Circumscribed Glioma. Langerhans Cell Histiocytosis.  |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                | NT1 - 2 years or older. PA - 3 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results, prior therapies tried  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. |

# **Kynmobi**

### **Products Affected**

 KYNMOBI SUBLINGUAL FILM 10 MG, 10-15-20-25-30 MG, 15 MG, 20 MG, 25 MG, 30 MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Concurrent Use with a Serotonin 5-HT3 Antagonist   |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist.   |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Parkinson's Disease - Approve if the pt is diagnosed with advanced Parkinsons disease, is experiencing "off" episodes (such as muscle stiffness, slow movements or difficulty starting movements), is currently receiving carbidopa/levodopa, and has previously tried one other treatment for off episodes to which the pt had significant intolerance to or inadequate efficacy from, according to the prescriber. |

# Ledipasvir-Sofosbuvir

### **Products Affected**

• ledipasvir-sofosbuvir

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Recurrent HCV post-liver transplant.  |
| Exclusion<br>Criteria              | Combination use with other direct acting antivirals, excluding ribavirin.  |
| Required<br>Medical<br>Information | Genotype, prescriber specialty, other medications tried or those that will be used in combination with requested medication, cirrhosis status. |
| Age<br>Restrictions                | 3 years or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD.  |
| Coverage<br>Duration               | Approval duration will be applied consistent with AASLD/ISDA guidance  |
| Other Criteria                     | Criteria will be applied consistent with current AASLD/IDSA guidance   |

### 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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Medullary thyroid carcinoma. Thymic Carcinoma. |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 tried at least one systemic therapy. Melanoma - 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 |

# **Letairis/Tracleer**

### **Products Affected**

bosentan

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | The patient has a diagnosis of PAH (WHO Group 1)   |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | For Pulmonary Arterial Hypertension (PAH) or Chronic Thromboembolic Pulmonary Hypertension (CTEPH) must be prescribed by or in consultation with a cardiologist or a pulmonologist |
| Coverage<br>Duration               | Authorization will be for 12 months.   |

| PA Criteria    | Criteria Details   |
|----------------|--|
| Other Criteria | For PAH patient must have had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). For Digital Ulcers/Systemic Sclerosis approve if patient has tried two other therapies for this condition such as calcium channel blockers (CCBs) [e.g., amlodipine, felodipine, nifedipine], alphaadrenergic blockers (e.g., prazosin), nitroglycerin, phosphodiesterase type 5 (PDE5) inhibitors (e.g., sildenafil tablets, Levitra [vardenafil tablets]), or angiotensin converting enzyme (ACE) inhibitors OR the patient has tried one vasodilator/prostanoid therapy (e.g., epoprostenol injection, alprostadil injection). For Chronic Thromboembolic Pulmonary Hypertension (CTEPH) approve if he patient meets ONE of the following: The patient has tried Adempas OR The patient has a specific contraindication to use of Adempas according to the prescribing physician (e.g., the patient is receiving nitrates or nitric oxide donors, the patient is receiving a phosphodiesterase inhibitor [e.g., Revatio, Adcirca], the patient is hypotensive or is at risk for hypotension) OR The patient is currently receiving Tracleer for CTEPH. |

# **Livtencity**

### **Products Affected**

• LIVTENCITY

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, weight   |
| Age<br>Restrictions                | 12 years or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center  |
| Coverage<br>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**

#### **Products Affected**

- BELBUCA
- buprenorphine
- buprenorphine hcl buccal film 750 mcg, 900 mcg
- fentanyl transdermal patch 72 hour mcg/hr, 75 mcg/hr
- methadone oral concentrate
- methadone oral solution 10 mg/5 ml, 5

mg/5 ml

- methadone oral tablet 10 mg, 5 mg
- morphine oral capsule, extend. release pellets 100 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg
- 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 morphine oral tablet extended release 100 mg, 15 mg, 200 mg, 30 mg, 60 mg

| 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 diagnosis, patients in a hospice program/end-of-life care/palliative care. |
| Exclusion<br>Criteria              | Acute (ie, non-chronic) pain  |
| Required<br>Medical<br>Information | Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies.  |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |

| PA Criteria    | Criteria Details   |
|----------------|--|
| Other Criteria | For pain severe enough to require daily, around-the-clock, long-term opioid treatment (with no cancer diagnosis and not in hospice), approve if all of the following criteria are met: 1) patient is not opioid naive (buprenorphine products are excluded from this requirement), 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 discussed risks (e.g., addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 4) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (i.e., FDA labeled use) prior to reviewing for quantity exception. For pain severe enough to require daily, around-the-clock, long-term opioid treatment with cancer or sickle cell diagnosis or in hospice, end-of-life care, or palliative care program - Approve. |

### Lonsurf

### **Products Affected**

• LONSURF

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, mutation results   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 ORAL TABLET 100 MG, 25 MG

| 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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results, previous therapies   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indication not otherwise excluded. Pancreatic Adenocarcinoma   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist                                     |
| Coverage<br>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

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

• LUPRON DEPOT (6 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<br>Criteria              | Hirsutism. Menstrual Migraine. Premenstrual Syndrome (PMS). Polycystic Ovarian Syndrome (PCOS).  |
| Required<br>Medical<br>Information | Diagnosis, concurrent medications  |
| Age<br>Restrictions                |  |
| Prescriber<br>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<br>Duration               | Endometriosis/Cx/Ovarian/Bleeding Cx/Gender/CPP - 1 year.<br>Leiomyomata - 3 mo. Uterine Bleeding - 6  |

| 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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results, other therapies tried   |
| Age<br>Restrictions                | 18 years or older                                    |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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 epiderm |
|                | BRCA2-altered disease and has tried one systemic regimen.  |

# **Lysosomal Storage Disease Enzyme Replacement Therapies**

- ALDURAZYME
- CEREZYME INTRAVENOUS RECON SOLN 400 UNIT
- ELAPRASE
- ELELYSO

- FABRAZYME
- LUMIZYME
- VIMIZIM
- VPRIV

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, confirmatory testing results  |
| Age<br>Restrictions                | Acid alpha-glucosidase deficiency (Pompe disease) - 8 years or older   |
| Prescriber<br>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<br>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 deficient 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 N-acetylgalactosamine-6-sulfatase gene mutation. |

# Lytgobi

### **Products Affected**

• LYTGOBI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results, previous therapies tried   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 previously treated with at least one systemic regimen. |

### Makena

- 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<br>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<br>Medical<br>Information |   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. |

# **Mavyret**

- MAVYRET ORAL PELLETS IN PACKET
- MAVYRET ORAL TABLET 100-40 MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. Criteria will be applied consistent with current AASLD/IDSA guidance and, if not available, FDA labeling. HCV Genotype Unknown/Undetermined.                          |
| Exclusion<br>Criteria              | HCV with moderate or severe hepatic impairment. Concomitant use with any other direct-acting antiviral. Life expectancy less than 1 year due to non-liver related comorbidities. Pediatric patients less than 3 years old. |
| Required<br>Medical<br>Information | Genotype, prescriber specialty, other medications tried or used in combination with requested medication   |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician   |
| Coverage<br>Duration               | Criteria will be applied consistent with current AASLD/IDSA guidance or FDA label  |
| Other Criteria                     | Criteria will be applied consistent with current AASLD/IDSA guidance and, if not available, FDA labeling.  |

# **Mayzent**

- MAYZENT
- MAYZENT STARTER(FOR 1MG MAINT)
- MAYZENT STARTER(FOR 2MG MAINT)

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA approved indications not otherwise excluded   |
| Exclusion<br>Criteria              | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis.  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.  |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

# Megestrol

### **Products Affected**

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

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.           |
| Exclusion<br>Criteria              | Coverage is not provided for weight gain for cosmetic reasons. |
| Required<br>Medical<br>Information |  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 12 months  |
| Other Criteria                     |  |

## **Mekinist**

### **Products Affected**

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

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

## Mektovi

### **Products Affected**

MEKTOVI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, BRAF V600 mutations  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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). Non-Small Cell Lung Cancer - approve if pt has BRAF V600E mutation-positivve metastatic disease and Mektovi will be taken in combination with Braftovi. |

# **Natpara**

### **Products Affected**

NATPARA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Acute post-surgical hypoparathyroidism. Hypoparathyroidism Caused by Calcium-Sensing Receptor Mutations   |
| Required<br>Medical<br>Information | Diagnosis, lab results  |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist.   |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, HER2 status, other therapies tried   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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**

### **Products Affected**

• 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<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, previous therapies tried, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 relapsed 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 azacytidine 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. |

## **Nexletol**

### **Products Affected**

NEXLETOL

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Primary Hyperlipidemia (PH). |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | lab results, prior therapies tried  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |

### PA Criteria Criteria Details Other Criteria Atherosclerotic Cardiovascular Disease (ASCVD) Initial -approve if pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND pt has tried a high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly for greater than or equal to 8 continuous weeks and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Heterozygous Familial Hypercholesterolemia (HeFH) Initial - approve if pt meets one of the following - The patient has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL OR the patient has genetic confirmation of HeFH by mutations in the lowdensity lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 or low-density lipoprotein receptor adaptor protein 1 gene OR the patient has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds - the prescriber used the Dutch Lipid Network criteria and the patient has a score greater than 5 OR the prescriber used the Simon Broome criteria and the patient met the threshold for definite or possible familial hypercholesterolemia OR the patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus

cornea, tuberous xanthomas or xanthelasma) AND the pt tried ONE high intensity statin AND ezetimibe concomitantly for

greater than or equal to 8 continuous weeks and LDL-C remains

determined to be statin intolerant defined by experiencing statin

muscle symptoms while receiving separate trials of atorvastatin

greater than or equal to 70 mg/dL unless the patient is

related rhabdomyolysis or pt experienced skeletal-related

| PA Criteria | Criteria Details  |
|-------------|---|
|             | and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Primary Hyperlipidemia (PH) Initial - approve if pt has coronary artery Ca or calcification score of 300 or more and tried a high intensity statin AND ezetimibe concomitantly for 8 continuous weeks or longer and LDL-C remains 70 mg/dL or more unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Continuation - Approve if according to the prescriber, the patient has experienced a response. |

# Nexviazyme

### **Products Affected**

• NEXVIAZYME

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indication not otherwise excluded.   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, lab or mutation results confirming diagnosis   |
| Age<br>Restrictions                | 1 year or older   |
| Prescriber<br>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<br>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. |

# **Nilutamide**

### **Products Affected**

• nilutamide

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Prostate Cancer - Approve if nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist. |

## **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<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, other medication use   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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   |
|------------------------------------|--|
| Covered Uses                       | All FDA approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, concurrent therapies  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Atopic dermatitis. COPD. Concurrent use with another monoclonal antibody therapy. Eosinophilic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis.  |
| Required<br>Medical<br>Information | Diagnosis, lab results, previous medication use   |
| Age<br>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<br>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<br>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 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-PDGFRanegative 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 level of greater than 1,000 cells per mL prior to treatment with any monoclonal antibody therapy that may lower blood eosinophil levels AND pt has tried at least one other treatment for hypereosinophilic syndrome for a minimum of 4 weeks. Nasal Polyps (NP) - Approve if pt has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan and has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell. Pt has receiv |
|                | 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<br>Criteria              | Heroin detoxification. Levodopa-Induced Dyskinesia in Parkinson's Disease. Neuropathic Pain. Psychosis-Related Aggression. Treatment-Resistant Depression. |
| Required<br>Medical<br>Information | diagnosis  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist.   |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Treatment of Pseudobulbar Affect - Approve if pt has pseudobulbar affect associated with a chronic neurological condition.                                 |

# **Nuplazid**

### **Products Affected**

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA approved indication not otherwise excluded  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist.  |
| Coverage<br>Duration               | 1 Year  |
| Other Criteria                     | Parkinsons Disease Psychosis - Approve if pt has hallucinations and delusions associated with Parkinsons disease psychosis and pt does not have dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis. |

## **Nurtec ODT**

### **Products Affected**

NURTEC ODT

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Combination therapy with Aimovig, Ajovy, Emgality, Vyepti, Nurtec ODT, and Qulipta if Nurtec is being taken for the preventive treatment of episodic migraine.   |
| Required<br>Medical<br>Information | Diagnosis, other therapies used  |
| Age<br>Restrictions                | 18 years and older   |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Migraine, acute treatment - Pt has tried at least one triptan therapy or has a contraindication to triptans according to the prescriber. Preventive Treatment of Episodic Migraine - Approve if pt has at least 4 but less than 15 migraine headache days per month, AND has tried at at least two standard prophylactic pharmacologic therapies, each from a different pharmacologic class, but had inadequate efficacy or experienced adverse effects severe enough to warrant discontinuation, or pt is currently taking Nurtec ODT and has had a significant clinical benefit from the medication as determined by the prescriber. |

# **Ocaliva**

### **Products Affected**

• OCALIVA

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Alcoholic liver disease. Nonalcoholic Fatty Liver Disease, including Nonalcoholic Fatty liver or Nonalcoholic Steatohepatitis.   |
| Required<br>Medical<br>Information | Diganosis, lab results, prior therapies  |
| Age<br>Restrictions                | 18 years and older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician  |
| Coverage<br>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. |

### **Ocrevus**

### **Products Affected**

• OCREVUS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Concurrent Use with Other Disease-Modifying Agents Used for Multiple Sclerosis.  |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Multiple Sclerosis, Relapsing Forms - Approve if pt has a relapsing form of multiple sclerosis (e.g. clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease). Continuation- less than 1 year of Ocrevus therapy - Approve if pt. has relapsing form of MS. Continuation-1 year or more of Ocrevus therapy - Approve if pt has relapsing form of MS and pt experienced a beneficial clinical response when assessed by at least 1 objective measure or pt experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. Multiple Sclerosis, Primary Progressive - Approve. |

## **Odomzo**

### **Products Affected**

• ODOMZO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA approved indication not otherwise excluded  |
| Exclusion<br>Criteria              | Basal Cell Carcinoma (Locally advanced or metastatic) that progressed while on Erivedge   |
| Required<br>Medical<br>Information | Diagnosis, previous treatments  |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Basal Cell Carcinoma, Locally Advanced - Approve if pt has recurrent basal cell carcinoma following surgery or radiation therapy OR Patient is not a candidate for surgery and according to the prescriber, the patient is not a candidate for radiation therapy. Continuation - Approve. Basal Cell Carcinoma, Metastatic - Approve if the disease is limited to nodal metastases. |

# Ofev

### **Products Affected**

• OFEV

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Combination use with pirfenidone (Esbriet).   |
| Required<br>Medical<br>Information | diagnosis   |
| Age<br>Restrictions                | 18 years of age or older  |
| Prescriber<br>Restrictions         | IPF/ILDCF - prescribed by or in consultation with a pulmonologist. ILDSS - prescribed by or in consultation with a pulmonologist or a rheumatologist  |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Idiopathic Pulmonary Fibrosis (IPF) - Approve if pt has forced vital capacity (FVC) greater than or equal to 40 percent of the predicted value AND diagnosis must be confirmed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or a surgical lung biopsy demonstrating UIP. Interstitial Lung Disease, Chronic Fibrosing with a Progressive Phenotype (ILDCF) - approve if the FVC is greater than or equal to 40% 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. Interstitial Lung Disease Associated with Systemic Sclerosis (ILDSS) - approve if FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by HRCT. Continuation (all) - approve if pt has experienced a beneficial response to therapy over the last year while receiving Ofev. |

# **Omnipod**

#### **Products Affected**

- OMNIPOD 5 G6 INTRO KIT (GEN 5)
- OMNIPOD 5 G6 PODS (GEN<sup>5</sup>)
- OMNIPOD CLASSIC PDM KIT(GEN 3)
- OMNIPOD CLASSIC PODS (GEN 3)
- OMNIPOD DASH INTRO KIT (GEN 4)
- OMNIPOD DASH PODS (GEN 4)

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | Diabetes mellitus, type 1. Diabetes mellitus, type 2, insulin dependent.  |
| Exclusion<br>Criteria              | Omnipod 5 - Type 2 DM   |
| Required<br>Medical<br>Information | diagnosis, insulin use  |
| Age<br>Restrictions                | Omnipod 5 - age 6 and older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 3 years   |
| Other Criteria                     | Diabetes mellitus, type 1 - Approve (Omnipod 5 only - pt must<br>be using at least 6 units of insulin daily). Diabetes mellitus,<br>type 2, insulin dependent - Approve if pt is using at least three<br>injections of insulin per day. Continuation - Approve. |

# **Ongentys**

### **Products Affected**

• ONGENTYS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.                                   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | diagnosis  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | prescribed by or in consultation with a neurologist                                    |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Parkinson's Disease - approve if pt is currently receiving carbidopa/levodopa therapy. |

# **Onureg**

### **Products Affected**

• ONUREG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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. |

# **Orencia SC**

### **Products Affected**

- ORENCIA
- ORENCIA CLICKJECT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Concurrent use with Biologic or Targeted Synthetic DMARDs.<br>Ankylosing Spondylitis. Inflammatory Bowel Disease. Psoriasis.                |
| Required<br>Medical<br>Information | Diagnosis, other therapies tried  |
| Age<br>Restrictions                | JIA: 2 years and older. RA/PsA: 18 years or older   |
| Prescriber<br>Restrictions         | RA/JIA: Prescribed by or in consultation with a rheumatologist PsA: Prescribed by or in consultation with a rheumatologist or dermatologist |
| Coverage<br>Duration               | Initial - 6 months. Continuation - 1 year   |

### PA Criteria Criteria Details Other Criteria Rheumatoid Arthritis (RA)- Approve if pt has tried 1 conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months, unless contraindicated or the pt has already tried a biologic for 3 months and The pt has tried 2 of Actemra, Enbrel, adalimumab, Rinvog, Xeljanz/XR, Cimzia, infliximab product, Kevzara or Simponi [documentation required] or the pt has heart failure, previously treated for lymphoproliferative disorder, a previous serious infection, or a demyelinating disorder. Juvenile Idiopathic Arthritis (JIA) -Approve if pt has tried 1 other agent for this condition or will be starting on therapy concurrently with methotrexate, sufasalazine or lefunomide or has an absolute contraindication to methotrexate, sulfasalazine or lefunomide or pt has aggressive disease AND pt has tried 2 of Actemra, Enbrel, adalimumab, Xeljanz, Orencia IV, infliximab product or Simponi Aria, or the pt has heart failure, previously treated for lymphoproliferative disorder, a previous serious infection, or a demyelinating disorder. Psoriatic Arthritis (PsA) - Approve if pt has tried 2 of Enbrel, adalimumab, Otezla, Rinvog, Skyrizi SC, Stelara SC, Taltz, Tremfya, Xeljanz/XR, Cimzia, infliximab product or Simponi [documentation required] or pt has heart failure, a previously treated lymphoproliferative disorder, previous serious infection, or demyelinating disorder. 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 1 objective measure or patient experienced an improvement in at least 1 symptom.

# Orgovyx

### **Products Affected**

ORGOVYX

| PA Criteria                        | Criteria Details                                     |
|------------------------------------|--|
| Covered Uses                       | All FDA approved indications not otherwise excluded. |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                | 18 years or older                                    |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 Year   |
| Other Criteria                     | Prostate Cancer - Approve.                           |

## Oriahnn

### **Products Affected**

• ORIAHNN

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded   |
| Exclusion<br>Criteria              | Heavy Menstrual Bleeding not associated with Uterine Fibroids   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies, test results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an obstetrician-<br>gynecologist or a health care practitioner who specializes in the<br>treatment of women's health  |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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

### **Products Affected**

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Cystic Fibrosis heterozygous for the F508del Mutation.<br>Combination use with Kalydeco, Symdeko, or Trikafta.  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                | 1 year or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of CF.  |
| Coverage<br>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). |

## Orserdu

### **Products Affected**

• ORSERDU ORAL TABLET 345 MG, 86 MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information |  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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. |

### Otezla

### **Products Affected**

• OTEZLA

(4)-30 MG(19)

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

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Concurrent use with a biologic DMARD or targeted synthetic DMARD. Ankylosing spondylitis. Rheumatoid arthritis.  |
| Required<br>Medical<br>Information | Diagnosis, previous medications tried  |
| Age<br>Restrictions                | 18 years and older   |
| Prescriber<br>Restrictions         | Behcet's/PsA - prescribed by or in consultation with a rheumatologist or a dermatologist. PP - prescribed by or in consultation with a dermatologist.  |
| Coverage<br>Duration               | Behcet's/PP - 4 months. PsA - 6 months. Continuation - 1 year.   |
| Other Criteria                     | Behcet's Disease - Approve if pt has oral ulcers or other mucocutaneous involvement and has tried at least one systemic therapy. Plaque Psoriasis (PP) - Approve if patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant or the pt has a contraindication to MTX, as determined by the prescribing physician. Psoriatic Arthritis (PsA)- Approve. 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. |

## **Oxervate**

### **Products Affected**

• OXERVATE

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Treatment duration of greater than 16 weeks   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an ophthalmologist or an optometrist.   |
| Coverage<br>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  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Lab results   |
| Age<br>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<br>Restrictions         | Prescribed by or in consultation with an allergist or immunologist  |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, lab results  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a metabolic disease specialist  |
| Coverage<br>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 pretreatment baseline AND pt is not receiving concomitant therapy with sapropterin (Kuvan, generic). |

# **Pegfilgrastim**

### **Products Affected**

- NEULASTA
- NEULASTA ONPRO
- UDENYCA
- UDENYCA AUTOINJECTOR

• ZIEXTENZO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. Peripheral Blood Progenitor Cell Transplantation in Patients with Cancer.  |
| Exclusion<br>Criteria              | Myelodysplastic Syndrome.   |
| Required<br>Medical<br>Information | Diagnosis, other therapies  |
| Age<br>Restrictions                |   |
| Prescriber<br>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<br>Duration               | Cancer pts receiving chemo - 6 months, RS - 1 month, PBPC - 1 dose  |

| 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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, prior therapies  |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, other therapies tried  |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Wilson's disease - Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.   |
| Coverage<br>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 prescience 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. |

# **Piqray**

### **Products Affected**

• PIQRAY

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA approved indications not otherwise excluded from coverage.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, prior therapies  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. |

## **Plegridy**

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

| D4 G '1 '                          |   |
|------------------------------------|---|
| PA Criteria                        | Criteria Details  |
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis.  |
| Required<br>Medical<br>Information | diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.  |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

## **Pomalyst**

### **Products Affected**

• POMALYST

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded from Part D. All FDA-approved indications not otherwise excluded. Central Nervous System Lymphoma. POEMS Syndrome. Systemic Light Chain Amyloidosis.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | diagnosis, other therapies tried   |
| Age<br>Restrictions                | KS/MM/POEMS/SLCA - 18 years or older   |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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**

### **Products Affected**

• PROMACTA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Thrombocytopenia in Myelodysplastic Syndrome (MDS)   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, lab results  |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | AA/IT - Prescribed by or in consultation with a hematologist. THCV - prescribed by or in consultation with a gastroenterologist, hepatologist, or ID. TMDS - prescribed by or in consultation with a hematologist or an oncologist. |
| Coverage<br>Duration               | THCV - 1 year. AA - 4 months. IT, TMDS - 3 months. Continuation (all) - 1 year.   |

| PA Criteria    | Criteria Details  |
|----------------|---|
| Other Criteria | Aplastic Anemia (AA) - approve if the pt has low platelet counts at baseline (e.g., less than 30,000/mL) AND the patient has tried one immunosuppressant therapy OR pt will be using Promacta in combination with standard immunosuppressive therapy. Immune Thrombocytopenia (IT) - Approve if pt meets both 1) pt has a platelet count of less than 30,000/mL or less than 50,000/mL and pt is at risk for bleeding according to prescriber. 2) Pt has tried at least one other therapy or has undergone splenectomy. Thrombocytopenia in Patients with Chronic Hepatitis C (THCV) - approve if pt has low platelet count at baseline (e.g. less than 75,000/mL) AND pt will be receiving interferon-based therapy for HCV. TMDS - Approve if pt has low to intermediate risk MDS and pt either has platelet count of less than 30,000/mL or less than 50,000/mL and pt is at risk for bleeding according to prescriber. AA Continuation - approve if pt demonstrates a beneficial clinical response according to prescriber. CIT, TMDS Cont approve if pt demonstrates a beneficial clinical response according to prescriber and pt remains at risk for bleeding complications. |

## **Pulmonary Arterial Hypertension Agents**

- ambrisentan
- OPSUMIT ORAL TABLET 10 MG
- sildenafil (pulm.hypertension) oral tablet
- tadalafil (pulm. hypertension)
- UPTRAVI ORAL TABLET 1,000 MCG,
- 1,200 MCG, 1,400 MCG, 1,600 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG
- UPTRAVI ORAL TABLETS, DOSE PACK 200 MCG (140)- 800 MCG (60)

| 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<br>Criteria              | Erectile Dysfunction.   |
| Required<br>Medical<br>Information | diagnosis, other therapies tried, right heart catheterization results   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Pulmonary Arterial Hypertension/Chronic Thromboembolic Pulmonary Hypertension - prescribed by or in consultation with a cardiologist or a pulmonologist.  |
| Coverage<br>Duration               | 3 years   |

| PA Criteria    | Criteria Details  |
|----------------|---|
| 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. If requesting coverage for Uptravi, pt has also tried a phosphodiesterase type 5 inhibitor or endothelin receptor antagonist for at least 60 days. 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. |

# Qinlock

### **Products Affected**

• QINLOCK

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Menalnoma, Cutatneous.  |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, other therapies tried   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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. |

### **Rebif**

- REBIF (WITH ALBUMIN)REBIF REBIDOSE
- REBIF TITRATION PACK

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis.  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.  |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

# Repatha

- REPATHA SURECLICK
- REPATHA SYRINGE

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Concurrent use of Leqvio, Juxtapid, Praluent.   |
| Required<br>Medical<br>Information | diagnosis, lab values, other therapies tried  |
| Age<br>Restrictions                | ASCVD/Primary Hyperlipidemia - 18 years or older, HoFH/HeFH - 10 years or older   |
| Prescriber<br>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<br>Duration               | 3 years   |
| 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. |

## **Retacrit**

### **Products Affected**

• RETACRIT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. Anemia due to myelodysplastic syndrome (MDS). Anemia Associated with Myelofibrosis.  |
| Exclusion<br>Criteria              | Anemia associated with cancer in patinets 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<br>Medical<br>Information | Diagnosis, lab values   |
| Age<br>Restrictions                | Anemia due to MDS - 18 years or older   |
| Prescriber<br>Restrictions         | Anemia due to MDS/Anemia due to Myelofibrosis - prescribed by or in consultation with a hematologist or oncologist.   |
| Coverage<br>Duration               | CKD dialysis-3 yrs. CKD/MDS/HIV-1 yr. Chemo-6 months. Myelofibrosis-3 mo, cont1 yr. Surgery-1 mo  |

#### PA 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 11.5 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 recieving myelosuppressive chemotherapy 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 recieving 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 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.

### **RETEVMO**

### **Products Affected**

• RETEVMO ORAL CAPSULE 40 MG, 80 MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Histiocytic Neoplasm  |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results  |
| Age<br>Restrictions                | Thyroid Cancer-12 years or older. All others - 18 years or older.  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, baseline labs or genetic testing results   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | prescribed by or in consultation with an immunologist, hematologist/oncologist, or physician that specializes in ADA-SCID or related disorders  |
| Coverage<br>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   |
|------------------------------------|--|
| 1 A Criteria                       |  |
| 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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried, other medications, lab results  |
| Age<br>Restrictions                | FL/MCL/MZL/MM/MDS/BCL/CHL/MF/PTCL/POEMS/SLCA/TCL - 18 years or older   |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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 - approve if pt has relapsed/refractory or progressive disease. Central Nervous System Lymphoma - approve if prescriber attests that pt has relapsed or refractory disease. Classical 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 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. 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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                | 12 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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. |

## Rinvoq

#### **Products Affected**

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

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Concurrent use with a biologic or with a targeted synthetic DMARD, Biologic Immunomodulator, JAK inhibitor, or other potent immunosuppressants. COVID-19.   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried   |
| Age<br>Restrictions                | AD - 12 or older. AS/PsA/RA/UC/CD - 18 years or older   |
| Prescriber<br>Restrictions         | AD - prescribed by or in consultation with an allergist, immunologist, or dermatologist. PsA - Prescribed by or in consultation with a rheumatologist or dermatologist. AS/RA/NRAS - Prescribed by or in consultation with a rheumatologist. UC/CD- Prescribed by or in consultation with a gastroenterologist. |
| Coverage<br>Duration               | AD initial - 3 mo. AS/NRAS/PsA/RA/UC/CD initial - 6 mo. Continuation - 1 yr.  |

| PA Criteria    | Criteria Details  |
|----------------|---|
| Other Criteria | Ankylosing Spondylitis (AS) - Approve if pt has had a 3 month trial of adalimumab, Enbrel, Cimzia, an infliximab product, or Simponi, unless intolerant. Atopic Dermatitis (AD) - Approve if pt has had a 3 month trial of at least one traditional systemic therapy, unless intolerant. Crohn's Disease (CD) - Approve if pt has had a 3 mo. trial of at least one tumor necrosis factor inhibitor unless able to tolerate. Non-Radiographic Axial Spondyloarthritis (NRAS) - Approve if pt has objective signs of inflammation defined as C-reactive protein elevated beyond the upper limit of normal or sacroiliitis reported on MRI and the pt has had a 3 month trial of Cimzia, Enbrel, an adalimumab product, an infliximab product or Simponi unless intolerant. Psoriatic Arthritis (PsA) - Approve if pt has tried adalimumab, Enbrel, Cimzia, an infliximab product, or Simponi for at least 3 months, unless intolerant. Rheumatoid Arthritis (RA) - Approve if pt has tried adalimumab, Enbrel, Cimzia, an infliximab product, or Simponi for at least 3 months, unless intolerant. Ulcerative Colitis - Approve if pt has had at least a 3 month trial of adalimumab, an infliximab product, or Simponi SC or was unable to tolerate. 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. |

# 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<br>Criteria              | Granulomatosis with Polyangiitis (Wegener's granulomatosis) or Microscopic Polyangiitis. Pemphigus Vulgaris. Rheumatoid Arthritis.                                 |
| Required<br>Medical<br>Information | Diagnosis, previous rituximab use  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist.   |
| Coverage<br>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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Pediatric Diffuse High-Grade Gliomas   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, mutation results   |
| Age<br>Restrictions                | NSCLC/PDHGG - 18 year or older. Solid Tumors - 12 years or older  |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, mutation results, previous therapies tried   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. |

## Rufinamide

### **Products Affected**

• rufinamide

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Treatment-Refractory Seizures/Epilepsy  |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                | 1 year or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Lennox-Gastaut Syndrome - Approve if pt has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Treatment-Refractory Seizures/Epilepsy - Approve if pt has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Continuation (all) - Approve if pt is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber. |

# Rydapt

### **Products Affected**

RYDAPT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Myeloid or Lymphoid Neoplasms.   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 ORAL TABLET 20 MG, 40 MG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results, previous therapies tried   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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<br>Criteria              |  |
| Required<br>Medical<br>Information |  |
| Age<br>Restrictions                | 18 years and older (initial therapy)   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome (initial therapy)   |
| Coverage<br>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. |

## Skyrizi

- SKYRIZI INTRAVENOUS
- SKYRIZI SUBCUTANEOUS PEN INJECTOR
- SKYRIZI SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.83 ML
- SKYRIZI SUBCUTANEOUS SYRINGE KIT
- SKYRIZI SUBCUTANEOUS WEARABLE INJECTOR 360 MG/2.4 ML (150 MG/ML)

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)  |
| Required<br>Medical<br>Information | Diagnosis, Previous medication use  |
| Age<br>Restrictions                | PP - 18 years or older  |
| Prescriber<br>Restrictions         | CD - prescribed by or in consultation with a gastroenterologist PP- prescribed by or in consultation with a dermatologist. PsA - prescribed by or in consultation with a rheumatologist or a dermatologist. |
| Coverage<br>Duration               | PP initial - 3 mo. CD/PsA initial - 6 mo. Continuation - 1 yr.  |

| PA Criteria    | Criteria Details  |
|----------------|---|
| Other Criteria | Crohn's Disease (CD) - Approve Skyrizi On-Body if pt has tried or is currently taking corticosteroids unless contraindicated or pt has tried one other conventional systemic therapy (Examples of conventional systemic therapy: azathioprine, 6-mercaptopurine, methotrexate) or patient has already tried at least one biologic or pt has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, or pt had ileocolonic resection and according to the prescriber the pt will receive induction dosing with Skyrizi intravenous within 3 months of initiating therapy with Skyrizi subcutaneous. Plaque Psoriasis (PP) - Approve Skyrizi SC if pt has tried at least one traditional systemic agent or a biologic for at least 3 months, unless intolerant or has a contraindication to MTX as determined by prescriber. Psoriatic Arthritis (PsA) - Approve Skyrizi SC. 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. |

# **Sodium Phenylbutyrate**

### **Products Affected**

• sodium phenylbutyrate

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information |  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | Authorization will be for 1 year                                 |
| Other Criteria                     |  |

# **Sofosbuvir-Velpatasvir**

### **Products Affected**

• sofosbuvir-velpatasvir

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Combination use with other direct acting antivirals, excluding ribavirin. Life expectancy less than 12 months due to non-liver related comorbidities. |
| Required<br>Medical<br>Information | Genotype, prescriber specialty, other medications tried or used in combination with requested medication.   |
| Age<br>Restrictions                | 3 years or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician              |
| Coverage<br>Duration               | Criteria will be applied consistent with current AASLD/IDSA guidance.   |
| Other Criteria                     | Criteria will be applied according to AASLD guidelines.   |

### **Solaraze**

### **Products Affected**

• diclofenac sodium topical gel 3 %

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Actinic Cheilitis. Disseminated Superficial Actinic Porokeratosis.   |
| Exclusion<br>Criteria              | Osteoarthritis  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 6 months  |
| Other Criteria                     | Actinic Keratoses - Approve. Actinic Cheilitis (Actinic Keratoses of the Lips) - Approve. Disseminated Superficial Actinic Porokeratosis - Approve if pt has tried 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. |

## **Somatuline Depot**

### **Products Affected**

• SOMATULINE DEPOT

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Pheochromocytoma and Paraganglioma.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previous treatments/therapies  |
| Age<br>Restrictions                |   |
| Prescriber<br>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<br>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. |

### **Somavert**

### **Products Affected**

• SOMAVERT

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Treatment of Excess Growth Hormone Associated with McCune-Albright Syndrome (MAS)  |
| Required<br>Medical<br>Information | Diagnosis, previous therapy, concomitant therapy   |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an endocrinologist   |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Acromegaly - approve if pt 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 is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND patient has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender for the reporting laboratory. |

## Sotyktu

### **Products Affected**

• SOTYKTU

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Concurrent use with Biologic or Targeted Synthetic DMARDs. Concurrent use with other potent immunosuppressants, including methotrexate.  |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried  |
| Age<br>Restrictions                | PP - 18 years of age and older   |
| Prescriber<br>Restrictions         | PP - prescribed by or in consultation with a dermatologist.  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Plaque Psoriasis (PP) - Approve if pt has tried at least one traditional systemic agent for psoriasis for at least 3 months unless intolerant or pt has a contraindication to methotrexate AND pt has tried 3 of Enbrel, an adalimumab product, Otezla, Skyrizi SC, Stelara SC, Taltz, and Tremfya. Continuation - Approve if pt has tried 3 of Enbrel, an adalimumab product, Otezla, Skyrizi SC, Stelara SC, Taltz, and Tremfya OR pt has been established on Sotyktu for at least 90 days and at least a 90 day supply has been dispensed in the last 130 days and pt has experienced a beneficial clinical response defined as improvement from baseline in estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis AND pt experienced improvement in at least one symptom such as decreased pain, itching, and/or burning. |

## **Spravato**

### **Products Affected**

• SPRAVATO

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, prior therapies tried   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         | Prescribed by a psychiatrist   |
| Coverage<br>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 ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

| 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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, previous therapies  |
| Age<br>Restrictions                | Bone Cancer, Gastrointestinal Stromal Tumor, Melanoma<br>Cuatneous, Meyloid/Lymphoid Neoplasms with Eosinophilia - 18<br>years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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. |

### **Stelara**

#### **Products Affected**

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5 ML
- STELARA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Concurrent use of another biologic or targeted synthetic DMARD. Ankylosing Spondylitis.  |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried.   |
| Age<br>Restrictions                | PP, PsA- 6 years or older.   |
| Prescriber<br>Restrictions         | PP - prescribed by or in consultation with a dermatologist. PsA - prescribed by or in consultation with a rheumatologist or dermatologist. CD/UC - prescribed by or in consultation with a gastroenterologist. |
| Coverage<br>Duration               | CD/PsA/UC - 6 months. PP - 3 months. Continuation - 1 year.  |

#### PA Criteria Criteria Details Other Criteria Crohn's Disease (CD) - Approve if pt has received a single induction dose with Stelara IV within 2 months of initiating therapy with Stelara SC and meets one of the following: pt has tried or is currently taking corticosteroids or corticosteroids are contraindicated, the pt has tried one conventional systemic therapy for Crohns disease, pt has already tried a biologic, pt has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, or pt had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). Plaque Psoriasis (PP) - Approve if pt has tried at least at least one traditional systemic agent for psoriasis for at least 3 months unless intolerant, the pt has already tried a biologic for 3 months, or the pt has a contraindication to methotrexate, as determined by the prescribing physician. Psoriatic Arthritis (PsA) - Approve. Ulcerative Colitis (UC) - Approve if pt has had a trial of one systemic agent for UC or pt has pourchitis and has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema and will receive a single induction dose with Stelara IV within 2 months of initiating therapy with Stelara SC. 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.

# Stivarga

### **Products Affected**

• STIVARGA

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

| PA Criteria    | Criteria Details  |
|----------------|---|
| Other Criteria | Colon, Rectal and Appendiceal 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. |

# **Strensiq**

### **Products Affected**

• STRENSIQ

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, genetic testing results   |
| Age<br>Restrictions                |  |
| Prescriber<br>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<br>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<br>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<br>Medical<br>Information | Diagnosis, previously tried therapies   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         | Narcolepsy - prescribed by or in consultation with a sleep specialist physician or a neurologist  |
| Coverage<br>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. |

# Supprelin LA

### **Products Affected**

• SUPPRELIN LA

| PA Criteria                        | Criteria Details                                     |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information |  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     |  |

### **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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results, previous therapies tried   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. |

## **Sylatron**

### **Products Affected**

• SYLATRON

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Systemic mastocytosis, myeloproliferative neoplasms   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an oncologist  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Melanoma-approve if the patient has microscopic or gross nodal involvement and has had a complete lymphadenectomy within the past 84 days. Systemic mastocytosis-approve if the patient has aggressive systemic mastocytosis OR systemic mastocytosis with an associated hematologic malignancy OR osteopenia/osteoporosis with refractory bone pain and/or decreasing bone mineral density on bisphosphonate therapy. Myeloproliferative neoplasms-approve if the patient has symptomatic low-risk myelofibrosis or polycythemia vera or essential thrombocythemia. |

### **Tabrecta**

### **Products Affected**

• TABRECTA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Histiocytic Neoplasm |
| Exclusion<br>Criteria              | Colon or Rectal Cancer  |
| Required<br>Medical<br>Information | Diagnosis, mutation results, other therapies tried                        |
| Age<br>Restrictions                | LGG, ST- 1 year and older. All others - 6 years and older                 |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 therapy. 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   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Other therapies tried and mutation results   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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. |

### **Taltz**

#### **Products Affected**

- TALTZ AUTOINJECTOR
- TALTZ AUTOINJECTOR (2 PACK)
- TALTZ AUTOINJECTOR (3 PACK)
- TALTZ SYRINGE

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Concurrent use of biologic or targeted synthetic DMARDS. Inflammatory bowel disease (Crohn's, ulcerative colitis).   |
| Required<br>Medical<br>Information | Diagnosis and previous therapies tried   |
| Age<br>Restrictions                | PP- 6 years or older.  |
| Prescriber<br>Restrictions         | AS/NRAS - prescribed by or in consultation with a rheumatologist. PP- prescribed by or in consultation with a dermatologist. PsA- prescribed by or in consultation with a rheumatologist or dermatologist.   |
| Coverage<br>Duration               | AS/NRAS/PsA - 6 months. PP - 3 months. Continuation - 1 year   |
| Other Criteria                     | Ankylosis Spondylitis (AS) - Approve. Non-Radiographic Axial Spondyloarthritis (NRAS) - Approve if pt has objective signs of inflammation (elevated CRP, sacroiliitis on MRI). Plaque Psoriasis (PP) - Approve if pt has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant OR the pt has a contraindication to methotrexate, as determined by prescriber. Psoriatic Arthritis (PsA) - Approve. 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. |

### **Talzenna**

### **Products Affected**

• TALZENNA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, BRCA mutation status, HER2 status  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. |

# **Tasigna**

### **Products Affected**

• TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG

| 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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried   |
| Age<br>Restrictions                | Acute Lymphoblastic Leukemia, Gastrointestinal Stromal Tumor,<br>Melanoma Cutaneous, Meyloid/Lymphoid Neoplasms with<br>Eosinophilia - 18 years or older  |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded from coverage.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried, mutation results   |
| Age<br>Restrictions                | Epitheliod Sarcoma - 16 and older. Follicular Lymphoma - 18 and older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Epitheliod 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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. |

# **Teriparatide**

### **Products Affected**

• teriparatide

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

## **Testosterone (Topical)**

#### **Products Affected**

- ANDRODERM
- testosterone transdermal gel
- testosterone transdermal gel in metered-dose pump 10 mg/0.5 gram /actuation, 12.5 mg/ 1.25 gram (1 %), • testosterone transdermal solution in 20.25 mg/1.25 gram (1.62 %)
- testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram), 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)
  - 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<br>Criteria              | Not covered if used to enhance athletic performance.  |
| Required<br>Medical<br>Information | Diagnosis, lab values   |
| Age<br>Restrictions                |   |
| Prescriber<br>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<br>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. |

## **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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, genetic testing results   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         | CHD/HD/TS - prescribed by or in consultation with a neurologist. TD - prescribed by or in consultation with a neurologist or psychiatrist.   |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Chorea associated with Huntington's Disease (CHD) - approve if 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

| 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<br>Criteria              | Cancer Cachexia. Crohn's Disease.   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried, other medications, lab results   |
| Age<br>Restrictions                | Multiple Myeloma, Myelofibrosis - 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 multicentric 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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Bone Cancer. Central Nervous System Cancer.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years and older  |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 |

# **Tobramycin (nebulized)**

#### **Products Affected**

- tobramycin in 0.225 % nacl
- tobramycin inhalation
- tobramycin with nebulizer

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Bronchiectasis, Non-Cystic Fibrosis.  |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | diagnosis, pathology results   |
| Age<br>Restrictions                | Bronchiectasis - 18 years or older   |
| Prescriber<br>Restrictions         | CF - prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis. Bronchiectasis - prescribed by or in consultation with a pulmonologist. |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Cystic Fibrosis (CF) - Approve if pt has Pseudomonas aeruginosa in culture of the airway. Bronchiectasis, Non-Cystic Fibrosis - Approve if pt has Pseudomonas aeruginosa in culture of the airway.     |

## **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<br>Criteria              | Acute pain. Postoperative pain.  |
| Required<br>Medical<br>Information | diagnosis  |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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. |

### **Trelstar**

#### **Products Affected**

• TRELSTAR INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.                                |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prostate cancer - Prescribed by or in consultation with an oncologist or urologist. |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Advanced Prostate Cancer - Approve.   |

## **Tremfya**

#### **Products Affected**

• TREMFYA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded from coverage.  |
| Exclusion<br>Criteria              | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)  |
| Required<br>Medical<br>Information | Diagnosis, Previous medication use  |
| Age<br>Restrictions                | PP - 18 years of age and older  |
| Prescriber<br>Restrictions         | PP- Prescribed by or in consultation with a dermatologist. PsA - Prescribed by or in consultation with a rheumatologist or dermatologist.   |
| Coverage<br>Duration               | PP - 3 months. PsA - 6 months. Continuation - 1 year  |
| Other Criteria                     | Plaque Psoriasis (PP) - Approve if patient has tried at least one traditional or biologic systemic agent for psoriasis for at least 3 months unless intolerant, or the patient has a contraindication to methotrexate, as determined by the prescriber. Psoriatic Arthritis (PsA) - Approve. 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. |

## **Trikafta**

#### **Products Affected**

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

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

#### **Products Affected**

- LUPRON DEPOT-PED
- LUPRON DEPOT-PED (3 MONTH)
- 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<br>Criteria              | Peripheral Precocious Puberty (Also Known as GnRH-Independent Puberty)  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Gender dysphoria - Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.                              |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Central Precocious Puberty - Approve. Gender-<br>Dysphoric/Gender-Incongruent Persons, Persons Undergoing<br>Gender Reassignment (Female-To-Male or Male-To-Female) -<br>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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Cholangiocarcinoma - Approve if pt is currently receiving 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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA approved indications not otherwise excluded from coverage   |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, other therapies used   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 ORAL CAPSULE 125 MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. Histiocytic Neoplasms.  |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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<br>Criteria              | Cervical Cancer. Gastric, Esophageal, or Gastroesophageal<br>Adenocarcinoma Cancer. Head and Neck, Squamous Cell<br>Carcinoma. Renal Cell Carcinoma (RCC). Urothelial Carcinoma. |
| Required<br>Medical<br>Information | Diagnosis, hormone receptor status   |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 year   |

#### PA Criteria Criteria Details Other Criteria Breast Cancer, Human Epidermal Growth Factor Receptor 2 Positive (HER2+) - approve if pt has advanced or metastatic breast cancer and the following criteria are met: pt has received prior therapy with trastuzumab AND the medication will be used in combination with capecitabine OR the medication will be used in combination with trastuzumab OR approve if pt has hormone receptor-positive (estrogen- and/or progesterone-positive) metastatic breast cancer and the following criteria are met: pt is a postmenopausal woman, a premenopausal or perimenopausal woman and 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) agonist AND the medication will be used in combination with an aromatase inhibitor (e.g. letrozole, anastrozole, or exemestane). Bone Cancer - Chordoma - approve if pt 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 and with wild-type RAS AND the medication is used as subsequent therapy in combination with trastuzumab AND pt has not been previously treated with a HER2-inhibitor (e.g. traztuzumab, Nerlyx, Kadcyla, Perjeta).

## **Tymlos**

#### **Products Affected**

• TYMLOS

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              | Concurrent use with other medications for osteoporosis (Prolia , oral bisphosphonates, intravenous bisphosphonates , calcitonin nasal spray, teriparatide, and Evenity) except calcium and Vitamin D. Osteoporosis Prevention. |
| Required<br>Medical<br>Information | diagnosis, BMD results   |
| Age<br>Restrictions                |  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | Up to 2 years (total)  |

| PA Criteria    | Criteria Details  |
|----------------|---|
| Other Criteria | Osteoporosis Treatment for a Postmenopausal or Male Patient - 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 pt only) or zoledronic acid injection OR has tried at least one oral bisphosphonate or oral bisphosphonate-containing product and experienced inadequate efficacy such as experiencing an osteoporotic fracture or fragility fracture while receiving oral bisphosphonate therapy during a trial duration of 12 months according to 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. |

## **Tysabri**

#### **Products Affected**

• TYSABRI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Concurrent Use of Tysabri with an Immunosuppressant Agent in Patients with Crohn's Disease. Concurrent Use of Tysabri with Other Disease-Modifying Agents used for MS. Non-relapsing forms of Multiple Sclerosis. Ulcerative Colitis. |
| Required<br>Medical<br>Information | Diagnosis, other therapies tried  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         | MS - Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of MS. CD - Prescribed by or in consultation with a gastroenterologist.  |
| Coverage<br>Duration               | MS - 1 year. CD - 6 mo. continuation - 1 year.  |

#### PA Criteria Criteria Details Other Criteria Multiple Sclerosis (MS) - Approve if pt has a relapsing form of multiple sclerosis AND according to the prescriber the patient has experienced inadequate efficacy or significant intolerance to one disease-modifying agent used for MS OR according to the prescriber the patient has highly-active or aggressive multiple sclerosis by meeting one of the following: rapidly-advancing deterioration(s) in physical functioning [documentation required], disabling relapse(s) with suboptimal response to systemic corticosteroids [documentation required], magnetic resonance imaging (MRI) findings suggest highly-active or aggressive multiple sclerosis [documentation required], or manifestations of multiple sclerosis-related cognitive impairment [documentation required]. Continuation - If pt has been receiving Tysabri for less than 1 year approve if pt has relapsing form of MS. If pt has been receiving Tysabri for more than 1 year approve if pt has relapsing form of MS and pt has experienced a beneficial clinical response when assessed by at least 1 objective measure or pt experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. Crohn's Disease (CD) - Approve if pt has moderately to severely active CD and pt has tried at least two biologics for CD (not including the requested biologic or a biosimilar of the requested biologic). Continuation - Approve if pt has received at least 6 months of Tysabri and has experience a beneficial clinical response from baseline in at least 1 objective measure or an improvement in at least 1 symptom such as decrease pain, fatigue, stool frequency, or blood in stool.

# Ukoniq

#### **Products Affected**

• UKONIQ

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, other therapies tried.   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 3 years   |
| Other Criteria                     | Follicular Lymphoma - Approve if pt has received at least three prior lines of systemic therapy. Marginal Zone Lymphoma - Approve if pt has received at least one prior anti-CD20-based regimen. Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma - Approve if pt has received at least one prior anti-CD20-based regimen and either has gastric MALT or non-gastric/non-cutaneous MALT. |

## **Valchlor**

#### **Products Affected**

• VALCHLOR

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. T-cell leukemia/lymphoma. Langerhans Cell Histiocytosis.  |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis  |
| Age<br>Restrictions                | Cutaneous lymphomas - 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Cutaneous Lymphomas (includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders) - Approve. Adult T-Cell Leukemia/Lymphoma - Approve if pt has chronic/smoldering subtype of adult T-cell leukemia/lymphoma. Langerhans Cell Histiocytosis - Approve if pt has unifocal Langerhans cell histiocytosis with isolated skin disease. |

### **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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previously tried therapies, mutation status  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, previously tried therapies, mutation status   |
| Age<br>Restrictions                | 4 years or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with an ophthalmologist or an optometrist.  |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, hormone receptor status, concurrent therapies                        |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 4 or more 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 receptor posi |
|                | 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.  |

## Viberzi

#### **Products Affected**

• VIBERZI

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA approved indications not otherwise excluded from coverage |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                | 18 years and older  |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 Year  |
| Other Criteria                     | Irritable bowel syndrome with diarrhea - Approve.                 |

## Vijoice

#### **Products Affected**

 VIJOICE ORAL TABLET 125 MG, 250 MG/DAY (200 MG X1-50 MG X1), 50 MG

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results  |
| Age<br>Restrictions                | 2 years and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a physician that specializes in treatment of genetic disorders |
| Coverage<br>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 manifestation of PROS (Note: Examples of 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 ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, NTRK gene fusion status  |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, tumor mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, lab results  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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. |

### Vosevi

#### **Products Affected**

VOSEVI

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded. Chronic Hepatitis C Virus Genotype 1b, 2, 4, 5, or 6. Patients already started on Vosevi.   |
| Exclusion<br>Criteria              | Combination with any other Direct-Acting Antivirals (DAAs). Life Expectancy Less than 12 months due to non-liver related comorbidities   |
| Required<br>Medical<br>Information | Genotype, prescriber specialty, other medications tried or used in combination with requested medication   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician   |
| Coverage<br>Duration               | 12 weeks   |
| Other Criteria                     | Chronic Hepatitis C Virus (HCV) Genotype 1b, 2, 4, 5, or 6 - Approve if pt either does not have cirrhosis or has compensated cirrhosis AND pt had a prior null response, prior partial response, or relapse after prior treatment with an HCV direct-acting antiviral (DAA) regimen containing either an NS5A inhibitor or Sovaldi + a non-NS5a inhibitor. Chronic HCV, Genotype 1a or 3 - Approve if pt either does not have cirrhosis or has compensated cirrhosis AND pt had a prior null response, prior partial response, or relapse after prior treatment with an HCV direct-acting antiviral regimen containing an NS5A inhibitor or had a prior null response, prior partial response, or relapse after prior treatment with an HCV DAA regimen containing Sovaldi + a non-NS5A inhibitor. |

### **Votrient**

#### **Products Affected**

- pazopanib 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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, previously tried therapies  |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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). |

## Voxzogo

#### **Products Affected**

VOXZOGO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>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<br>Medical<br>Information | Diagnosis, genetic testing results  |
| Age<br>Restrictions                | 5-17 years old  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a pediatric endocrinologist   |
| Coverage<br>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 epipihyses 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 criteira and pts most recent annualized growth velocity continues to be above their baseline annualized growth velocity value prior to starting on Voxzogo. |

## **Vumerity**

#### **Products Affected**

• VUMERITY

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Non-relapsing forms of multiple sclerosis. Concurrent use of other disease-modifying agents used for multiple sclerosis.  |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.  |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Multiple Sclerosis - Approve if pt has a relapsing form of multiple sclerosis. Continuation - aprove if patient has experienced a beneficial clinical response when assessed by at least one objective measure or experienced stabilization, slowed progreession or improvement in at least one symtom such as motor function, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. |

## Welireg

#### **Products Affected**

• WELIREG

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

## Xalkori

#### **Products Affected**

• XALKORI

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Histiocytic Neoplasms, Cutaneous Melanoma, NSCLC with MET Mutation.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results  |
| Age<br>Restrictions                | ALCL/IMT - 1 year or older. All others - 18 years or older.  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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 rearragement 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 and advanced, recurrent or metastatic disease OR the tumor is inoperable. Melanoma, cutaneous - Approve if pt has ALK positive disease or ROS1 fustion disease. |

# Xeljanz

#### **Products Affected**

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET
- XELJANZ XR

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

| PA Criteria    | Criteria Details   |
|----------------|--|
| Other Criteria | Ankylosing Spondylitis (AS) -Approve if pt has had a 3 month trial of adalimumab, Enbrel, Cimzia, an infliximab product, or Simponi, unless intolerant. Juvenile Idiopathic Arthritis (JIA) - Approve if pt has had a 3 month trial of adalimumab, Enbrel, an infliximab product, or Simponi, unless intolerant. Psoriatic Arthritis (PSA) -Approve if pt has had a 3 month trial of adalimumab, Enbrel, Cimzia, an infliximab product, or Simponi, unless intolerant, 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 adalimumab, Enbrel, Cimzia, an infliximab product, or Simponi, unless intolerant. Ulcerative Colitis (UC) - Approve if pt has had a 3 month trial of adalimumab, an infliximab product, or Simponi, 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. |

## Xermelo

#### **Products Affected**

• XERMELO

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | diagnosis, previous therapies tried   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Carcinoid Syndrome Diarrhea - Approve if pt has been on a long-acting somatostatin analog (SSA) therapy for at least 3 consecutive months, and while on a SSA, the patient continues to have at least four bowel movements per day, and Xermelo will be used concomitantly with a SSA. Continuation - Approve if the pt is continuing to take Xermelo concomitantly with a long-acting somatostatin analog therapy for carcinoid syndrome diarrhea. |

### Xifaxan

#### **Products Affected**

• XIFAXAN

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Helicobacter Pylori Infection   |
| Required<br>Medical<br>Information | other medications used  |
| Age<br>Restrictions                | Hepatic Encephalopathy/IBSD - 18 years or older. Traveler's Diarrhea - 12 years or older.   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | Hepathic Encephalopathy - 6 mo. IBSD/SIBO - 14 days.<br>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 SUBCUTANEOUS RECON SOLN
- XOLAIR SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.5 ML

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>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<br>Medical<br>Information | Diagnosis, other medications tried.   |
| Age<br>Restrictions                | Asthma - 6 years and older. Urticaria - 12 years and older.<br>Nasal Polyps - 18 years and older.   |
| Prescriber<br>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<br>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 longacting beta2-agonists, inhaled longacting 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 asthma that 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 AND has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal

| 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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Myeloid/Lymphoid Neoplasms.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 ORAL TABLET 100 MG/WEEK (50 MG X 2), 40 MG/WEEK (40 MG X 1), 40MG TWICE WEEK (40 MG X 2), 60 MG/WEEK (60 MG X 1), 60MG TWICE WEEK (120 MG/WEEK), 80 MG/WEEK (40 MG X 2), 80MG TWICE WEEK (160 MG/WEEK)

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, Prior therapies  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, other therapies  |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Uterine Leiomyosarcoma.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previous therapies tried, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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 disase 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<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results, other therapies tried   |
| Age<br>Restrictions                | 18 years or older  |
| Prescriber<br>Restrictions         |  |
| Coverage<br>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 combination 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.

## **Zileuton**

#### **Products Affected**

• zileuton

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA approved indication not otherwise excluded  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previous medication tried  |
| Age<br>Restrictions                | 12 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Prophylaxis and Chronic Treatment of Persistent Asthma - Approve if pt is using in combination with an orally inhaled corticosteroid and patient has experienced treatment failure or has a contraindication/intolerance to both montelukast and zafirlukast. |

# Zokinvy

#### **Products Affected**

ZOKINVY

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.  |
| Exclusion<br>Criteria              | Progeroid Laminopathies. Other Progeroid Syndromes.   |
| Required<br>Medical<br>Information | Diagnosis, test results   |
| Age<br>Restrictions                | 1 year and older  |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a geneticist or pediatric cardiologist  |
| Coverage<br>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. |

## Zolinza

#### **Products Affected**

• ZOLINZA

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.                              |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis   |
| Age<br>Restrictions                |   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Cutaneous T-Cell Lymphoma including Mycosis<br>Fungoides/Sezary Syndrome- Approve |

# **Ztalmy**

#### **Products Affected**

• ZTALMY

| PA Criteria                        | Criteria Details   |
|------------------------------------|--|
| Covered Uses                       | All FDA-approved indications not otherwise excluded.   |
| Exclusion<br>Criteria              |  |
| Required<br>Medical<br>Information | Diagnosis, mutation results  |
| Age<br>Restrictions                | 2 years or older   |
| Prescriber<br>Restrictions         | Prescribed by or in consultation with a neurologist  |
| Coverage<br>Duration               | 1 year   |
| Other Criteria                     | Sieizures associated with cyclin-dependentt Kinase-Like 5 (CDKL5) Deficiency Disorder - Approve if pt has molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene and has tried or is concomitantly receiving at least 2 other antiepileptic drugs. |

# Zydelig

#### **Products Affected**

• ZYDELIG

| PA Criteria                        | Criteria Details  |
|------------------------------------|---|
| <b>Covered Uses</b>                | All FDA-approved indications not otherwise excluded. Marginal Zone Lymphoma.  |
| Exclusion<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, previously tried therapies   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>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<br>Criteria              |   |
| Required<br>Medical<br>Information | Diagnosis, mutation results   |
| Age<br>Restrictions                | 18 years or older   |
| Prescriber<br>Restrictions         |   |
| Coverage<br>Duration               | 1 year  |
| Other Criteria                     | Non-Small Cell Lung Cancer - Approve 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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|                                  |                                     |

| SKYRIZI SUBCUTANEOUS               | testosterone transdermal gel in      |       |
|------------------------------------|--------------------------------------|-------|
| WEARABLE INJECTOR 360 MG/2.4       | packet 1 % (25 mg/2.5gram), 1 %      |       |
| ML (150 MG/ML)211                  | (50 mg/5 gram), 1.62 % (20.25        |       |
| sodium phenylbutyrate213           | mg/1.25 gram), 1.62 % (40.5          |       |
| sofosbuvir-velpatasvir             | mg/2.5 gram)                         | 242   |
| SOLIQUA 100/3378                   | testosterone transdermal solution in |       |
| SOMATULINE DEPOT216                | metered pump w/app                   |       |
| SOMAVERT 217                       | tetrabenazine                        |       |
| sorafenib148                       | THALOMID                             |       |
| SOTYKTU218                         | TIBSOVO                              |       |
| SPRAVATO219                        | tobramycin in 0.225 % nacl           |       |
| SPRYCEL ORAL TABLET 100 MG, 140    | tobramycin inhalation                |       |
| MG, 20 MG, 50 MG, 70 MG, 80 MG 220 | tobramycin with nebulizer            |       |
| STELARA SUBCUTANEOUS               | TRELSTAR INTRAMUSCULAR               | ,     |
| SOLUTION 45 MG/0.5 ML221           | SUSPENSION FOR RECONSTITUTION        | V     |
| STELARA SUBCUTANEOUS SYRINGE       |                                      |       |
| 45 MG/0.5 ML, 90 MG/ML221          | TREMFYA                              |       |
| STIVARGA223                        | TRIKAFTA ORAL GRANULES IN            |       |
| STRENSIQ                           | PACKET, SEQUENTIAL                   | 251   |
| sunitinib malate oral capsule 12.5 | TRIKAFTA ORAL TABLETS,               |       |
| mg, 25 mg, 37.5 mg, 50 mg 228      | SEQUENTIAL                           | 251   |
| SUNOSI226                          | TRIPTODUR                            |       |
| SUPPRELIN LA227                    | TRULICITY                            |       |
| SYLATRON                           | TRUSELTIQ ORAL CAPSULE 100           |       |
| TABRECTA                           | MG/DAY (100 MG X 1), 125             |       |
| tadalafil (pulm. hypertension)189  | MG/DAY(100 MG X1-25MG X1), 50        |       |
| TAFINLAR ORAL CAPSULE              | MG/DAY (25 MG X 2), 75 MG/DAY        |       |
| TAFINLAR ORAL TABLET FOR           | (25 MG X 3)                          | 254   |
| SUSPENSION232                      | TUKYSA ORAL TABLET 150 MG, 50        |       |
| TAGRISSO 234                       | MG                                   | .255  |
| TALTZ AUTOINJECTOR235              | TURALIO ORAL CAPSULE 125 MG          |       |
| TALTZ AUTOINJECTOR (2 PACK) 235    | TYMLOS                               | . 259 |
| TALTZ AUTOINJECTOR (3 PACK) 235    | TYSABRI                              | 261   |
| TALTZ SYRINGE235                   | UDENYCA                              | .180  |
| TALZENNA 236                       | UDENYCA AUTOINJECTOR                 | 180   |
| TASIGNA ORAL CAPSULE 150 MG,       | UKONIQ                               | .263  |
| 200 MG, 50 MG 237                  | UPTRAVI ORAL TABLET 1,000 MCG,       |       |
| tasimelteon85                      | 1,200 MCG, 1,400 MCG, 1,600 MCG      | ,     |
| TAZVERIK238                        | 200 MCG, 400 MCG, 600 MCG, 800       |       |
| TEPMETKO239                        | MCG                                  | .189  |
| teriflunomide17                    | UPTRAVI ORAL TABLETS, DOSE PACE      |       |
| teriparatide240                    | 200 MCG (140)- 800 MCG (60)          | 189   |
| testosterone transdermal gel 242   | VALCHLOR                             | 264   |
| testosterone transdermal gel in    | VENCLEXTA ORAL TABLET 10 MG,         |       |
| metered-dose pump 10 mg/0.5        | 100 MG, 50 MG                        |       |
| gram /actuation, 12.5 mg/ 1.25     | VENCLEXTA STARTING PACK              | 265   |
| gram (1 %), 20.25 mg/1.25 gram     | VERKAZIA                             | .266  |
| (1.62 %)                           | VERZENIO                             | 267   |
|                                    |                                      |       |

| VIBERZI                          | 269                      |
|----------------------------------|--------------------------|
| VICTOZA 2-PAK                    | 78                       |
| VICTOZA 3-PAK                    |                          |
| VIJOICE ORAL TABLET 125 MG, 250  |                          |
| MG/DAY (200 MG X1-50 MG X1), 50  |                          |
| MG                               | 270                      |
| VIMIZIM                          | 136                      |
| VITRAKVI ORAL CAPSULE 100 MG,    |                          |
| 25 MG                            | 272                      |
| VITRAKVI ORAL SOLUTION           | 272                      |
| VIZIMPRO                         | 273                      |
| VONJO                            | 274                      |
| VOSEVI                           | 275                      |
| VOTRIENT                         | 276                      |
| VOXZOGO                          | 278                      |
| VPRIV                            |                          |
| VUMERITY                         | 279                      |
| WELIREG                          | 280                      |
| XALKORI                          |                          |
| XELJANZ ORAL SOLUTION            |                          |
| XELJANZ ORAL TABLET              |                          |
| XELJANZ XR                       |                          |
| XEMBIFY                          |                          |
| XERMELO                          |                          |
| XIFAXAN                          | 285                      |
| XOLAIR SUBCUTANEOUS RECON        |                          |
|                                  | 286                      |
| XOLAIR SUBCUTANEOUS SYRINGE      |                          |
| 150 MG/ML, 75 MG/0.5 ML          |                          |
| XOSPATA                          |                          |
| XPOVIO ORAL TABLET 100 MG/WEEK   |                          |
| (50 MG X 2), 40 MG/WEEK (40 MG X |                          |
| 1), 40MG TWICE WEEK (40 MG X 2), | ,                        |
| 60 MG/WEEK (60 MG X 1), 60MG     |                          |
| TWICE WEEK (120 MG/WEEK), 80     |                          |
| MG/WEEK (40 MG X 2), 80MG        | 200                      |
| TWICE WEEK (160 MG/WEEK)         |                          |
| XTANDI ORAL CAPSULE              |                          |
| XTANDI ORAL TABLET 40 MG, 80 MG  |                          |
| ZARXIO                           |                          |
| ZEJULA ORAL CAPSULE              |                          |
|                                  | つへつ                      |
| 7FILLA ODAL TARLET               |                          |
| ZEJULA ORAL TABLET               | 292                      |
| ZELBORAF                         | 292<br>293               |
| ZELBORAFZIEXTENZO                | 292<br>293<br>180        |
|                                  | 292<br>293<br>180<br>295 |

| ZORBTIVE | 79  |
|----------|-----|
| ZTALMY   | 298 |
| ZYDELIG  | 299 |
| ZYKADIA  | 300 |