

PRIOR AUTHORIZATION CRITERIA

This list is current as of December 1, 2019 and pertains to the following formularies:

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| 2019 Pharmacy Benefit Dimensions PDP offered by Niagara County Formulary – D0122 | Version 33 |
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Pharmacy Benefit Dimensions requires you (or your physician) to get prior authorization for certain drugs listed on the formularies above. This means that you will need to get approval from us before you fill your prescriptions. If you do not get approval, we may not cover the drug. These drugs are listed with a “PA” in the Requirements/Notes column on the formularies. This document contains the Prior Authorization requirements that are associated with the formularies listed above.

If you have any questions, please contact our Medicare Member Services Department at 1-800-667-5936 or, for TTY users 711, October 1st – March 31st: Monday through Sunday from 8 a.m. to 8 p.m., April 1st – September 30th: Monday through Friday from 8 a.m. to 8 p.m.

Pharmacy Benefit Dimensions is a subsidiary of Independent Health. Independent Health is a PDP with a Medicare contract. Enrollment in Pharmacy Benefit Dimensions PDP depends on contract renewal between Independent Health and CMS.

The formulary may change at any time. You will receive notice when necessary.

ABILIFY MYCITE (aripiprazole with sensor)

Products Affected

- ABILIFY MYCITE ORAL TABLET 10 MG, 15 MG, 2 MG, 20 MG, 30 MG, 5 MG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Dementia-related psychosis |
| Required Medical Information | Diagnosis of covered use, documentation of previous aripiprazole use (see Other Criteria). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. For approval, the patient must have documentation of at least a one-month trial of generic aripiprazole solution, tablets, or orally-disintegrating tablets. |

ACTIMMUNE (interferon gamma-1b)

Products Affected

- ACTIMMUNE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

ADCIRCA (tadalafil)

Products Affected

- *alyq*
- *tadalafil 20 mg oral tablet (pah)*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Diagnosis of severe (Child-Pugh class C) hepatic impairment, creatinine clearance below 30 mL/min or on hemodialysis |
| Required Medical Information | Diagnosis of covered use, submission of patient weight and serum creatinine (to calculate estimated creatinine clearance). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to cardiology and pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ADEMPAS (riociguat)

Products Affected

- ADEMPAS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy, severe (Child-Pugh class C) hepatic impairment, creatinine clearance below 15 mL/min or on dialysis, concurrent use with nitrates or nitric oxide donors in any form, concurrent use with phosphodiesterase inhibitors |
| Required Medical Information | Diagnosis of covered use, submission of negative pregnancy test result for female patients of childbearing age, submission of patient weight and serum creatinine (to calculate estimated creatinine clearance). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to cardiology and pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ADENOSINE DEAMINASE DEFICIENCY

Products Affected

- REVCOVI

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe thrombocytopenia |
| Required Medical Information | Diagnosis of covered use, submission of plasma ADA activity and platelet count. |
| Age Restrictions | For Adagen, 18 years of age or younger |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

AFINITOR (everolimus)

Products Affected

- AFINITOR
- AFINITOR DISPERZ

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. For renal cell carcinoma, documented prior use of sunitinib or sorafenib. For postmenopausal women with advanced hormone receptor-positive, HER-2 negative breast cancer, documentation of treatment failure with letrozole or anastrozole and confirmation drug is being used in combination with exemestane. |
| Age Restrictions | 1 year of age or older |
| Prescriber Restrictions | Restricted to hematology, neurology, and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

AIMOVIG (erenumab-aooe)

Products Affected

- AIMOVIG (140 MG DOSE)
- AIMOVIG SUBCUTANEOUS SOLUTION AUTO-INJECTOR 140 MG/ML, 70 MG/ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of migraine days per month from medical chart, documentation patient has tried and failed or has a contraindication to at least two preferred alternatives such as propranolol, timolol, topiramate, and valproic acid. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | Initially 3 months, then 1 year |
| Other Criteria | PA applies to all. Continuation requires documentation of clinically relevant response to therapy. |

AKYNZEO (netupitant/palonosetron)

Products Affected

- AKYNZEO ORAL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, confirmation patient will receive concurrent dexamethasone therapy as indicated based on level of chemotherapy regimen emetogenicity. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. If the medication is being administered related to cancer treatment and is a full replacement for intravenous administration of antiemetic therapy within 48 hours of cancer treatment, it is covered as a Part B benefit. To be eligible for Part B coverage, the prescribing physician must indicate this on the prescription. Otherwise it may be covered as a Part D benefit. |

ALECENSA (alectinib)

Products Affected

- ALECENSA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of baseline ALT, AST, bilirubin, and CPK levels. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | Initially 3 months, then 1 year |
| Other Criteria | PA applies to new starts only. Submission of liver function tests, CPK, and documented response to treatment are required for continuation of approval. |

ALPHA-1-PROTEINASE INHIBITORS

Products Affected

- ARALAST NP INTRAVENOUS SOLUTION RECONSTITUTED
- RECONSTITUTED 1000 MG, 500 MG
- GLASSIA
- PROLASTIN-C INTRAVENOUS SOLUTION
- ZEMAIRA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Individuals with immunoglobulin A (IgA) deficiency who have known antibodies against IgA |
| Required Medical Information | Diagnosis of covered use, confirmation that patient has clinically evident emphysema secondary to congenital alpha-1-PI deficiency by submission of pulmonary function testing (e.g., spirometry or body plethysmography), X-ray radiography, or diffusing capacity of the lung for carbon monoxide (DLCO). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

ALUNBRIG (brigatinib)

Products Affected

- ALUNBRIG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation that patient has progressed on or has a documented intolerance to crizotinib. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

AMANTADINE EXTENDED-RELEASE PRODUCTS

Products Affected

- GOCOVRI
- OSMOLEX ER ORAL TABLET EXTENDED RELEASE 24 HOUR 129 MG, 193 MG, 258 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | End stage renal disease (creatinine clearance below 15 mL/min) |
| Required Medical Information | Diagnosis of covered use, documentation patient tried and failed immediate-release amantadine. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

AMBISOME (amphotericin B liposomal injection)

Products Affected

- ABELCET
- AMBISOME
- AMPHOTERICIN B INJECTION
- AMPHOTERICIN B INTRAVENOUS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to infectious diseases |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

AMPYRA (dalfampridine)

Products Affected

- *dalfampridine er*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | History of seizure, moderate or severe renal impairment (CrCl less than or equal to 50 mL/min) |
| Required Medical Information | Diagnosis of covered use, submission of serum creatinine, patient weight, and objective measurement of walking speed, confirmation that patient is able to walk. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | Initially 3 months, then 1 year |
| Other Criteria | PA applies to all. Re-authorization contingent upon documentation the patient has demonstrated an improvement in walking speed from baseline measure (or maintenance of improvement if patient has been on long-term therapy) since starting medication. |

ANADROL-50 (oxymetholone)

Products Affected

- ANADROL-50

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Carcinoma of the prostate or breast in male patients, carcinoma of the breast in females with hypercalcemia, women who are or may become pregnant, nephrosis or the nephrotic phase of nephritis, severe hepatic dysfunction |
| Required Medical Information | Diagnosis of covered use, submission of CBC and liver function tests. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 6 months |
| Other Criteria | PA applies to new starts only. |

ARCALYST (rilonacept)

Products Affected

- ARCALYST

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Active or chronic infection |
| Required Medical Information | Diagnosis of covered use, TB skin test result obtained within the past 12 months. |
| Age Restrictions | 12 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

ARIKAYCE (amikacin inhalation)

Products Affected

- ARIKAYCE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Non-refractory Mycobacterium avium complex (MAC) lung disease |
| Required Medical Information | Diagnosis of covered use, submission of clinical rationale describing patient's lack of or limited treatment options for MAC which may include documentation of failure of 6 consecutive months' treatment using standard multidrug therapy. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | This medication is covered as a Part B benefit except for enrollees residing in a long-term care facility. PA applies to all when covered as a Part D benefit. |

BALVERSA (erdafitinib)

Products Affected

- BALVERSA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of FDA-approved companion test showing susceptible FGFR2 or FGFR3 genetic alterations, prior chemotherapy regimen(s) used. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

BENLYSTA (belimumab)

Products Affected

- BENLYSTA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe active lupus nephritis, severe active central nervous system lupus, patients using other biologic medications or intravenous cyclophosphamide |
| Required Medical Information | Diagnosis of covered use, confirmation that the patient is taking standard therapy defined as at least one of the following: corticosteroids, NSAIDs, antimalarials, or immunosuppressants. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

BENZNIDAZOLE

Products Affected

- BENZNIDAZOLE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 2 years of age through 12 years of age |
| Prescriber Restrictions | Restricted to infectious diseases |
| Coverage Duration | 60 days |
| Other Criteria | PA applies to all. |

BOSULIF (bosutinib)

Products Affected

- BOSULIF

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of renal function testing. For accelerated or blast phase Ph+ CML, documentation of resistance or intolerance to at least one of the following prior therapies: imatinib, dasatinib, or nilotinib. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

BRAFTOVI/MEKTOVI (encorafenib/binimetinib)

Products Affected

- BRAFTOVI
- MEKTOVI

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation, serum potassium, and serum magnesium, confirmation that encorafenib and binimetinib will be co-administered. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

BRIVIACT (brivaracetam)

Products Affected

- BRIVIACT ORAL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 4 years of age or older |
| Prescriber Restrictions | PA not required for neurology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

BUTALBITAL-CONTAINING PRODUCTS IN OLDER PATIENTS

Products Affected

- *ascomp-codeine*
- BUPAP ORAL TABLET 50-300 MG
- *butalbital-acetaminophen oral tablet*
- *butalbital-apap-caff-cod*
- *butalbital-apap-caffeine oral capsule*
- *butalbital-apap-caffeine oral tablet 50-325-40 mg*
- *butalbital-asa-caff-codeine*
- *butalbital-aspirin-caffeine oral capsule*
- ESGIC ORAL TABLET
- FIORICET ORAL CAPSULE
- FIORICET/CODEINE ORAL CAPSULE 50-300-40-30 MG
- FIORINAL
- FIORINAL/CODEINE #3
- *phrenilin forte oral capsule 50-300-40 mg*
- TENCON ORAL TABLET 50-325 MG
- VANATOL LQ
- *zebutal oral capsule 50-325-40 mg*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | All 4 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, (3) documentation that the benefits of the drug outweigh the potential risks to the patient, and (4) documentation patient has tried and failed or have a contraindication to a preferred alternative such as ibuprofen or rizatriptan. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

C1 ESTERASE INHIBITORS (for hereditary angioedema)

Products Affected

- BERINERT
- CINRYZE
- HAEGARDA
- RUCONEST

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of documentation that epinephrine will be immediately available in the event of an acute severe hypersensitivity reaction. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

CABLIVI (caplacizumab-yhdp)

Products Affected

- CABLIVI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to cardiology, hematology, and immunology |
| Coverage Duration | 3 months |
| Other Criteria | PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

CABOMETYX (cabozantinib)

Products Affected

- CABOMETYX

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

CALQUENCE (acalabrutinib)

Products Affected

- CALQUENCE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Patients on proton pump inhibitors |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

CAPRELSA (vandetanib)

Products Affected

- CAPRELSA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Congenital long QT syndrome, moderate or severe hepatic impairment, QTcF interval greater than 450 msec |
| Required Medical Information | Diagnosis of covered use, submission of baseline serum potassium, calcium, magnesium, ALT, AST, bilirubin, TSH, creatinine clearance (or serum creatinine plus current patient weight), and ECG. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

CARBAGLU (carglumic acid)

Products Affected

- CARBAGLU

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of plasma ammonia level. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

CASTRATION-RESISTANT PROSTATE CANCER (PBD)

Products Affected

- ERLEADA
- NUBEQA
- XTANDI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology, oncology, and urology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

CERDELGA (eliglustat)

Products Affected

- CERDELGA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Patients who are extensive or intermediate CYP2D6 metabolizers taking a strong CYP2D6 inhibitor with a strong or moderate CYP3A inhibitor, intermediate and poor CYP2D6 metabolizers taking a strong CYP3A inhibitor |
| Required Medical Information | Diagnosis of covered use, submission of CYP2D6 metabolizer status as detected by an FDA-cleared test for determining CYP2D6 genotype. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

CESAMET (nabilone)

Products Affected

- CESAMET

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of documentation that patient has tried and failed to adequately respond to at least one conventional antiemetic therapy. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. If the medication is being administered related to cancer treatment and is a full replacement for intravenous administration of antiemetic therapy within 48 hours of cancer treatment, it is covered as a Part B benefit. To be eligible for Part B coverage, the prescribing physician must indicate this on the prescription. Otherwise it may be covered as a Part D benefit. |

CGRP INHIBITORS

Products Affected

- AJOVY
- EMGALITY
- EMGALITY (300 MG DOSE)

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of headache days per month from medical chart. For migraine, documentation patient has tried and failed or has a contraindication to at least two preferred alternatives such as propranolol, timolol, topiramate, and valproic acid. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | Initially 3 months, then 1 year |
| Other Criteria | PA applies to all. Continuation requires documentation of clinically relevant response to therapy. |

CHENODAL (chenodiol)

Products Affected

- CHENODAL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy, known hepatocyte dysfunction, bile duct abnormalities such as intrahepatic cholestasis, primary biliary cirrhosis, or sclerosing cholangitis, radiopaque stones, nonvisualizing gallbladder confirmed as nonvisualizing after 2 consecutive single doses of dye, compelling reasons for gallbladder surgery |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 24 months |
| Other Criteria | PA applies to all. |

CHOLBAM (cholic acid)

Products Affected

- CHOLBAM

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to hepatology, gastroenterology, and pediatric gastroenterology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

COMETRIQ (cabozantinib)

Products Affected

- COMETRIQ (100 MG DAILY DOSE)
- COMETRIQ (140 MG DAILY DOSE)
- COMETRIQ (60 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment |
| Required Medical Information | Diagnosis of covered use, baseline oral examination results. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

COPIKTRA (duvelisib)

Products Affected

- COPIKTRA ORAL CAPSULE 15 MG, 25 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of at least two prior therapies tried and failed. Additionally, if being given to a female of reproductive potential, documentation of a negative pregnancy prior to initiation and that the patient has been counseled to use effective contraception during treatment and for at least 1 month after the last dose. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology or oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

CORLANOR (ivabradine)

Products Affected

- CORLANOR ORAL SOLUTION
- CORLANOR ORAL TABLET

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Acute decompensated heart failure, blood pressure less than 90/50 mmHg, resting heart rate less than 60 bpm prior to treatment, severe hepatic impairment, pacemaker dependence (heart rate maintained exclusively by the pacemaker), or sick sinus syndrome, sinoatrial block, or 3rd degree AV block unless a functioning demand pacemaker is present |
| Required Medical Information | Diagnosis of covered use described as is indicated (1) to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use or (2) for stable symptomatic heart failure due to dilated cardiomyopathy in patients who are in sinus rhythm with an elevated heart rate, submission of current baseline blood pressure reading, confirmation that patient does not have any of the following: (1) acute decompensated heart failure, (2) sick sinus syndrome, sinoatrial block, or 3rd degree AV block, unless a functioning demand pacemaker is present, (3) resting heart rate less than 60 bpm prior to treatment, (4) severe hepatic impairment, (5) pacemaker dependence (heart rate maintained exclusively by the pacemaker). |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to cardiology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation requires documentation of clinically relevant response to therapy. |

COTELLIC (cobimetinib)

Products Affected

- COTELLIC

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation, submission of left ventricular ejection fraction. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

CUPRIMINE (penicillamine)

Products Affected

- *penicillamine oral*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy unless being treated for Wilson's disease or certain patients with cystinuria, rheumatoid arthritis patients with a history or other evidence of renal insufficiency |
| Required Medical Information | Diagnosis of covered use, laboratory analysis applicable to indication for use, documentation that patient has tried and failed or had an intolerance to penicillamine tablets. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

CYSTARAN (cysteamine)

Products Affected

- CYSTARAN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

DAURISMO (glasdegib)

Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, confirmation patient will also be receiving cytarabine as part of chemotherapeutic regimen. If patient is under 75 years of age, documentation of comorbidities that preclude use of intensive induction chemotherapy. Additionally, if being given to a female of reproductive potential, documentation of a negative pregnancy prior to initiation and that the patient has been counseled to use effective contraception during treatment and for at least 30 days after the last dose. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

DEFERASIROX

Products Affected

- *deferasirox oral tablet soluble*
- JADENU
- JADENU SPRINKLE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Creatinine clearance less than 40 mL per min or serum creatinine more than 2 times the age-adjusted upper limit of normal, platelet count below $50 \times 10^9/L$ |
| Required Medical Information | Diagnosis of covered use, submission of CBC, LFTs, serum creatinine, ferritin, and urine protein values, submission of patient weight, documentation that member has had yearly ophthalmic and auditory testing. |
| Age Restrictions | 2 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 3 months |
| Other Criteria | PA applies to all. For continuation, documentation of ferritin level within last 3 months and CBC, LFT, serum creatinine, urine protein value, patient weight, and ophthalmic and auditory testing have been performed within the last year. |

DENOSUMAB

Products Affected

- PROLIA
- XGEVA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Hypocalcemia. For Prolia, pregnancy. |
| Required Medical Information | Diagnosis of covered use. For Prolia, "high risk for fracture" is defined as (1) a history of osteoporotic fracture or (2) multiple risk factors for fracture or (3) patients who have failed or are intolerant of other available osteoporosis therapies, confirmation of osteoporosis diagnosis either through densitometry (T-score less than or equal to -2.5 at the total hip, femoral neck, or lumbar spine) or clinically (documented presence of fragility fracture). |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

DIACOMIT (stiripentol)

Products Affected

- DIACOMIT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Moderate or severe renal impairment, moderate or severe hepatic impairment |
| Required Medical Information | Diagnosis of covered use, confirmation patient is also receiving clobazam. |
| Age Restrictions | 2 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. Monotherapy requests for Dravet syndrome will not be approved as there are no clinical data to support using stiripentol in this manner. |

DICLOFENAC 1% GEL

Products Affected

- *diclofenac sodium transdermal gel*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery |
| Required Medical Information | Diagnosis of covered use, including the relief of pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Not evaluated for use on joints of the spine, hip, or shoulder and therefore requests for use on these areas will not be approved. |

DICLOFENAC 3% GEL

Products Affected

- *diclofenac sodium transdermal gel*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to dermatology |
| Coverage Duration | 90 days |
| Other Criteria | PA applies to all. |

DIFICID (fidaxomicin)

Products Affected

- DIFICID

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 10 days |
| Other Criteria | PA applies to all. |

DIGOXIN IN OLDER PATIENTS

Products Affected

- *digitek oral tablet 250 mcg*
- *digox oral tablet 250 mcg*
- *digoxin oral solution*
- *digoxin oral tablet 250 mcg*
- LANOXIN ORAL TABLET 187.5 MCG, 250 MCG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Current diagnosis of atrial fibrillation or congestive heart failure, submission of patient's current CrCl (mL/min) or current weight and serum creatinine level for the purposes of calculating CrCl with result greater than or equal to 30 mL/min. Patient must have tried and failed to respond adequately to 0.125 mg of digoxin. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. PA not required for doses less than or equal to 0.125 mg per day. |

DUOBRII (halobetasol/tazarotene)

Products Affected

- DUOBRII

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of covered use, submission of negative pregnancy test result for female patients of childbearing age, documentation patient tried and failed augmented betamethasone dipropionate, clobetasol, fluocinonide 0.1%, halobetasol, or another Class I ultra-high potency topical steroid. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to dermatology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

DUOPA (carbidopa/levodopa enteral suspension)

Products Affected

- DUOPA ENTERAL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Patients taking non-selective monoamine oxidase inhibitors |
| Required Medical Information | Diagnosis of covered use, confirmation patient has a naso-jejunal tube for short-term administration or a PEG-J for long-term administration. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

DUPIXENT (dupilumab)

Products Affected

- DUPIXENT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. For atopic dermatitis, documentation of treatment with at least a moderate strength topical corticosteroid for at four weeks or have a contraindication to their use or therapy is not otherwise advisable. For moderate-to-severe asthma, either (1) documentation of eosinophilic subtype via serum or sputum eosinophil count or lung biopsy or (2) documentation asthma is moderate or severe and requires daily oral corticosteroid for control. |
| Age Restrictions | 12 years of age or older based on indication |
| Prescriber Restrictions | Restricted to allergy, immunology, dermatology, and pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation requires documentation of a positive response to therapy. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

EGRIFTA (tesamorelin)

Products Affected

- EGRIFTA SUBCUTANEOUS SOLUTION
RECONSTITUTED 1 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy, active malignancy, disruption of HPA axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation, or head trauma, use for weight loss |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation of therapy requests require confirmation that the patient has demonstrated a clinical improvement (or maintenance of improvement once achieved) from baseline. |

EMFLAZA (deflazacort)

Products Affected

- EMFLAZA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation of treatment failure with or intolerance to prednisone. |
| Age Restrictions | 2 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

EMSAM (selegiline transdermal)

Products Affected

- EMSAM

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pheochromocytoma |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ENDOTHELIN RECEPTOR ANTAGONISTS

Products Affected

- *ambrisentan*
- *bosentan*
- OPSUMIT
- TRACLEER ORAL TABLET SOLUBLE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | For all referenced medications, pregnancy. For ambrisentan only, idiopathic pulmonary fibrosis. |
| Required Medical Information | For all referenced medications, diagnosis of covered use, submission of negative pregnancy test result for female patients of childbearing age, submission of baseline AST, ALT, and bilirubin. For ambrisentan and macitentan only, submission of baseline hemoglobin level. |
| Age Restrictions | For ambrisentan and macitentan, 18 years of age or older. For bosentan, 3 years of age or older. |
| Prescriber Restrictions | Restricted to cardiology and pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

EPCLUSA (sofosbuvir/velpatasvir)

Products Affected

- EPCLUSA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) infection, submission of baseline HCV RNA level, documentation of whether cirrhosis is present or not and whether it is compensated or decompensated, confirmation that patients with decompensated cirrhosis will receive concomitant ribavirin therapy unless ribavirin therapy is otherwise clinically not indicated, submission of eGFR (safety and efficacy of Eplclusa has not been established in patients with eGFR less than 30 mL/min/1.73 m ²), confirmation a test for HBV infection (HBsAg and anti-HBc) was completed. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 12 weeks |
| Other Criteria | PA applies to all. |

EPIDIOLEX (cannabidiol)

Products Affected

- EPIDIOLEX

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 2 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ERIVEDGE (vismodegib)

Products Affected

- ERIVEDGE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, pregnancy status for female patients. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ERYTHROPOIETINS

Products Affected

- ARANESP (ALBUMIN FREE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 300 MCG/ML, 40 MCG/ML, 60 MCG/ML
- ARANESP (ALBUMIN FREE) INJECTION SOLUTION PREFILLED SYRINGE
- EPOGEN INJECTION SOLUTION 10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML
- PROCRT
- RETACRIT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of hemoglobin or hematocrit level, serum iron, total iron-binding capacity (TIBC), and transferrin within 30 days of request date, documentation that the patient does not have uncontrolled hypertension. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | For non-ESRD-related conditions: 90 days. For ESRD-related conditions: 1 year. |
| Other Criteria | A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

ESTROGENS IN OLDER PATIENTS

Products Affected

- ALORA
- *amabelz*
- ANGELIQ
- CLIMARA PRO
- COMBIPATCH
- DEPO-ESTRADIOL
- DIVIGEL
- DOTTI
- DUAVEE
- ELESTRIN
- ESTRACE ORAL
- *estradiol oral*
- *estradiol transdermal*
- *estradiol-norethindrone acet*
- *estropipate oral tablet 0.75 mg*
- EVAMIST
- *fyavolv*
- *jinteli*
- *lopreeza*
- MENEST ORAL TABLET 0.3 MG, 0.625 MG, 1.25 MG
- MENOSTAR
- *mimvey*
- *mimvey lo*
- MINIVELLE
- *norethindrone-eth estradiol*
- PREFEST
- PREMARIN ORAL
- PREMPHASE
- PREMPRO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | All 5 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation the provider is aware of the associated risks including breast and endometrial cancer and an increased risk of clot formation, (3) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, (4) documentation that the benefits of the drug outweigh the potential risks to the patient, and (5) for all indications except treatment of vasomotor symptoms of menopause, documentation of a trial and failure or contraindication to two preferred alternatives is required (for vulvar/vaginal atrophy, topical estradiol and conjugated estrogens, for osteoporosis, alendronate, ibandronate, and raloxifene). |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | PA not required for gynecology |

| PA Criteria | Criteria Details |
|--------------------------|---|
| Coverage Duration | 1 year |
| Other Criteria | A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

EUCRISA (crisaborole)

Products Affected

- EUCRISA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 2 years of age or older |
| Prescriber Restrictions | Restricted to dermatology |
| Coverage Duration | Initially 30 days, then 1 year |
| Other Criteria | PA applies to all. Continuation requires documentation of a positive response to therapy. |

FARYDAK (panobinostat)

Products Affected

- FARYDAK

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment, recent myocardial infarction or unstable angina |
| Required Medical Information | Diagnosis of covered use, documentation that the patient has received at least 2 prior regimens including bortezomib and an immunomodulatory agent, submission of baseline ECG documenting QTcF is less than 450 msec prior to initiation, submission of baseline serum electrolytes including potassium and magnesium, submission of baseline CBC documenting platelet count is at least $100 \times 10^9/L$ and absolute neutrophil count is at least $1.5 \times 10^9/L$, submission of baseline liver function tests including AST, ALT, and total bilirubin. For multiple myeloma, confirmation drug will be given with dexamethasone and bortezomib. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | Initially 8 cycles. An additional 8 cycles if clinical benefit seen. |
| Other Criteria | PA applies to new starts only. |

FENTANYL TRANSMUCOSAL

Products Affected

- ABSTRAL
- *fentanyl citrate buccal lozenge on a handle*
- *fentanyl citrate buccal tablet*
- LAZANDA
- SUBSYS SUBLINGUAL LIQUID 100 MCG, 1200 (600 X 2) MCG, 1600 (800 X 2) MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Patients not tolerant to the effects of a chronic opioid, treatment of acute or postoperative pain including headache, migraines, or dental pain |
| Required Medical Information | Diagnosis of covered use, verified claim or documentation of patient's morphine-equivalent opioid dose. |
| Age Restrictions | For the buccal film or tablet, sublingual spray or tablet, intranasal spray, 18 years of age or older. For the lozenge or lollipop, 16 years of age or older. |
| Prescriber Restrictions | PA not required for oncology |
| Coverage Duration | 1 Year |
| Other Criteria | PA applies to all except oncology. |

FERRIPROX (deferiprone)

Products Affected

- FERRIPROX

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of serum ferritin levels, CBC, ANC, platelet count, and serum ALT. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

FIRAZYR (icatibant)

Products Affected

- *icatibant acetate*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

FIRDAPSE (amifampridine)

Products Affected

- FIRDAPSE
- RUZURGI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | History of seizure |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

FIRVANQ (vancomycin oral solution)

Products Affected

- FIRVANQ

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | PA does not apply to gastroenterology or infectious diseases. |
| Coverage Duration | 10 days |
| Other Criteria | PA applies to all except gastroenterology and infectious diseases. |

FLECTOR (diclofenac epolamine) PATCH

Products Affected

- *diclofenac epolamine*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery, use on non-intact or damaged skin resulting from any etiology including exudative dermatitis, eczema, infection lesions, burns, or wounds, pregnancy after 30 weeks gestation |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 3 months |
| Other Criteria | PA applies to all. Product is approved for acute pain, defined as short-term pain not lasting longer than a 3-month period. |

FORTEO (teriparatide)

Products Affected

- FORTEO SUBCUTANEOUS SOLUTION 600 MCG/2.4ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, postmenopausal status, submission of serum calcium level, documentation that other treatment options have failed (or are contraindicated), submission of a value, condition, or past medical history that assesses fracture risk (e.g., DEXA scan results or prior fracture), submission of number of total months of all prior use of parathyroid hormone analogs and parathyroid hormone related peptides. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 2 years maximum dependent on patient's prior use of all PTH analogs and PTH-related peptides |
| Other Criteria | PA applies to all. Use of parathyroid hormone analogs and/or parathyroid hormone related peptides for more than 2 years during a patient's lifetime is not recommended and requests for therapy with any of these agents for a combined total of greater than 2 years will not be approved. |

GALAFOLD (migalastat)

Products Affected

- GALAFOLD

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe renal impairment (eGFR less than 30 mL/min/1.73 m ²) or end stage renal disease requiring dialysis |
| Required Medical Information | Diagnosis of covered use, documentation that the patient has an amenable galactosidase alpha gene variant (see section 12.1, table 2 of package insert for full list) based on in vitro assay data as interpreted by a clinical genetics professional. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

GATTEX (teduglutide)

Products Affected

- GATTEX

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of documentation that a colonoscopy (or alternate imaging) of the entire colon with polyp removal was performed within 6 months prior to starting treatment, submission of baseline laboratory values including bilirubin, alkaline phosphatase, lipase, and amylase obtained within 6 months prior to starting therapy. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation of therapy requires a colonoscopy result within 6 months of PA expiration. |

GILOTRIF (afatinib)

Products Affected

- GILOTRIF

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. For non-small cell lung cancer, submission of positive FDA-approved test for non-resistant epidermal growth factor receptor mutations. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

GnRH ANTAGONISTS

Products Affected

- ELIGARD
- FIRMAGON
- *leuprolide acetate injection*
- LUPANETA PACK
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- LUPRON DEPOT-PED (1-MONTH)
INTRAMUSCULAR KIT 11.25 MG, 15 MG
- LUPRON DEPOT-PED (3-MONTH)
INTRAMUSCULAR KIT 30 MG (PED)
- TRELSTAR MIXJECT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of covered use, documentation of a negative pregnancy test in women of childbearing potential. For prostate cancer, documentation of baseline prostate-specific antigen and serum testosterone level. |
| Age Restrictions | For Eligard, Firmagon, Lupaneta, Lupron Depot, and Trelstar, 18 years of age or older. |
| Prescriber Restrictions | Restricted to hematology, oncology, endocrinology, gynecology, and urology |
| Coverage Duration | For endometriosis and uterine fibroids, up to 6 months. For all other indications, 1 year. |
| Other Criteria | PA applies to new starts only. Re-treatment for endometriosis is not recommended because safety data are not available. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

GROWTH HORMONE

Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- NORDITROPIN FLEXPPO
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20
- NUTROPIN AQ NUSPIN 5
- OMNITROPE
- SAIZEN
- SAIZENPREP
- ZOMACTON

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation of growth failure, submission of IGF-1 levels, height, weight, creatinine clearance (or serum creatinine), fasting blood glucose, and bone age if applicable based on patient age and diagnosis. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to endocrinology and nephrology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Requests for continuation of therapy require annual submission of updated IGF-1 level, bone age if applicable based on patient age and diagnosis, height, weight, creatinine clearance (or serum creatinine), and fasting glucose. |

H.P. ACTHAR (corticotropin)

Products Affected

- ACTHAR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Request for IV administration, treatment of patients under 2 years of age in whom congenital infections are suspected, patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, a history of or presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin |
| Required Medical Information | Diagnosis of covered use, submission of blood pressure reading and baseline serum sodium and potassium levels. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

HARVONI (ledipasvir/sofosbuvir)

Products Affected

- HARVONI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) genotype 1a, 1b, 4, 5, or 6 infection, submission of baseline HCV RNA level, documentation of whether cirrhosis is present or not and whether or not it is compensated or decompensated, confirmation of whether patient is treatment-naive or treatment-experienced, submission of eGFR, confirmation a test for HBV infection (HBsAg and anti-HBc) was completed. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Treatment-experienced pts w/genotype 1 and compensated cirrhosis, 24 weeks. All others, 12 weeks. |
| Other Criteria | PA applies to all. For treatment-naive patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL, 8 weeks of therapy may be considered by the provider. |

HEMANGEOL (propranolol oral solution)

Products Affected

- HEMANGEOL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Premature infant with corrected age less than 5 weeks, body weight less than 2 kg, asthma or history of bronchospasm, bradycardia (less than 80 beats per minute), greater than first degree heart block, decompensated heart failure, blood pressure less than 50/30 mmHg, pheochromocytoma |
| Required Medical Information | Diagnosis of covered use, submission of current weight. |
| Age Restrictions | 5 weeks of age up to 1 year of age |
| Prescriber Restrictions | Restricted to otolaryngology, pediatric otolaryngology, and pediatric ophthalmology |
| Coverage Duration | 6 months |
| Other Criteria | PA applies to all. Treatment must be initiated between the ages of 5 weeks and 5 months. |

HETLIOZ (tasimelteon)

Products Affected

- HETLIOZ

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology and sleep specialty |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

HIGH-RISK DRUGS IN OLDER PATIENTS

Products Affected

- *benztropine mesylate oral*
- BUTISOL SODIUM ORAL TABLET 30 MG
- *chlordiazepoxide hcl*
- *chlorpropamide*
- *dipyridamole oral*
- *disopyramide phosphate oral*
- *glyburide oral*
- *guanfacine hcl er*
- *guanfacine hcl oral*
- INDOCIN ORAL
- *indomethacin er*
- *indomethacin oral*
- INTUNIV
- *ketorolac tromethamine oral*
- *meprobamate*
- *methyldopa oral*
- *methyldopa-hydrochlorothiazide*
- *nifedipine oral*
- NORPACE
- NORPACE CR
- *phenobarbital oral elixir*
- *phenobarbital oral tablet*
- SPRIX
- *thioridazine hcl oral*
- *trihexyphenidyl hcl*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | All 3 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, and (3) documentation that the benefits of the drug outweigh the potential risks to the patient. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | |

HYALURONATES

Products Affected

- EUFLEXXA INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE
- GEL-ONE INTRA-ARTICULAR PREFILLED SYRINGE
- GELSYN-3
- GENVISC 850
- HYALGAN
- HYMOVIS
- MONOVISC
- ORTHOVISC INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE
- SUPARTZ FX
- SYNVISC INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE
- SYNVISC ONE INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Patient diagnosed with osteoarthritis of the knee joint and has tried and failed to respond to conservative non-pharmacologic therapy (exercise, physical therapy, weight loss) and simple analgesics (oral salicylates, non-steroidal anti-inflammatory drugs, and acetaminophen) within the previous 18 months. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Injection is being administered by an orthopedic surgeon, rheumatologist, physiatrist, or physician who has completed a formal sports medicine fellowship and is fully knowledgeable about the differential diagnosis of knee pain, is able to perform microscopic analysis of synovial fluid, and can recognize conditions such as pseudogout. |
| Coverage Duration | 1 treatment cycle |

| PA Criteria | Criteria Details |
|-----------------------|---|
| Other Criteria | A maximum of 1 injection of Synvisc-One, Gel-One, or Monovisc, 3 injections of Euflexxa or Synvisc, 4 injections of Orthovisc, or 5 injections of Hyalgan per knee joint may be authorized per treatment cycle. Retreatment may be authorized, provided (1) previous treatment cycle was administered at least 6 months ago, (2) treating physician submits documentation of a favorable patient response including pain relief derived of more than 3 months in duration, (3) patient has demonstrated a reduction in analgesic use or increase in functional capacity, and (4) patient's progress and results of hyaluronate therapy is fully documented in the patient's record. |

HYDROXYZINE IN OLDER PATIENTS

Products Affected

- *hydroxyzine hcl oral tablet*
- *hydroxyzine pamoate oral*
- VISTARIL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | All 3 of the following criteria must be met: (1) diagnosis of anxiety or pruritus, (2) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, and (3) documentation that the benefits of the drug outweigh the potential risks to the patient. For pruritus, documentation patient has tried and had an inadequate response to a second-generation antihistamine. For anxiety, documentation patient has tried and failed or had an inadequate response to at least 2 other FDA-approved products for the management of anxiety OR documentation medication is being used as a sedative before and after general anesthesia. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

IBRANCE (palbociclib)

Products Affected

- IBRANCE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of documentation confirming HER2-negative status, confirmation that the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant, submission of baseline CBC. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ICLUSIG (ponatinib)

Products Affected

- ICLUSIG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Newly diagnosed chronic phase CML |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

IDHIFA (enasidenib)

Products Affected

- IDHIFA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of positive FDA-approved test for isocitrate dehydrogenase-2 mutation, baseline CBC and bilirubin. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

IDIOPATHIC PULMONARY FIBROSIS TREATMENTS

Products Affected

- ESBRIET
- OFEV

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | For Esbriet, patients with end stage renal disease on dialysis |
| Required Medical Information | Diagnosis of covered use. Submission of baseline AST, ALT, and bilirubin. For Esbriet, submission of patient's current weight and serum creatinine level for the purposes of calculating creatinine clearance. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

ILARIS

Products Affected

- ILARIS SUBCUTANEOUS SOLUTION

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Positive TB test |
| Required Medical Information | Diagnosis of covered use, submission of TB skin test result obtained within past 12 months, documentation that patient has received all recommended vaccinations as appropriate including pneumococcal vaccine and inactivated influenza vaccine prior to initiation of therapy. For CAPS, confirmed diagnosis including genetic testing for variant FCAS or MWS and documentation patient is not receiving concomitant TNF inhibitor therapy. For SJIA, submission of CBC including platelet count and confirmed diagnosis defined by prominence of systemic and inflammatory features including spiking fevers, rash, swelling and inflammation of lymph nodes, liver, and spleen, and high white blood cell and platelet counts. |
| Age Restrictions | 2 years of age or older |
| Prescriber Restrictions | For SJIA, restricted to rheumatology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation of therapy requires submission of updated TB skin test result obtained within the past 12 months and objective documentation of positive patient response or maintenance of response. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

IMATINIB

Products Affected

- GLEEVEC
- *imatinib mesylate*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of baseline LFTs and renal function testing. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

IMBRUVICA (ibrutinib)

Products Affected

- IMBRUVICA ORAL CAPSULE
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG, 560 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment (Child-Pugh class C) |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology, oncology, and transplant specialty |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

IMIQUIMOD

Products Affected

- *imiquimod external*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | PA not required for dermatology, obstetrics/gynecology, colorectal surgery, or oncology |
| Coverage Duration | For AK and genital and perianal warts, 16 weeks. For superficial basal cell carcinoma, 6 weeks. |
| Other Criteria | PA applies to new starts only. |

IMMUNE GLOBULIN

Products Affected

- BIVIGAM GM/100ML, 10 GM/200ML, 20 GM/200ML,
- CARIMUNE NF INTRAVENOUS SOLUTION RECONSTITUTED 12 GM, 6 GM 20 GM/400ML, 5 GM/100ML, 5 GM/50ML
- FLEBOGAMMA DIF
- GAMASTAN S/D
- GAMMAGARD
- GAMMAGARD S/D LESS IGA
- GAMMAKED
- GAMMAPLEX INTRAVENOUS SOLUTION 10
- GAMUNEX-C
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 10 GM/100ML, 10 GM/200ML, 2 GM/20ML, 2.5 GM/50ML, 20 GM/200ML, 25 GM/500ML, 5 GM/100ML, 5 GM/50ML
- PRIVIGEN

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | IgA-deficient patients with antibodies against IgA and a history of hypersensitivity. For IM forms, severe thrombocytopenia or coagulation disorder that would contraindicate an IM injection. |
| Required Medical Information | Diagnosis of covered use. For ITP, submission of platelet count. For CLL, IgG level less than 600 mg/dL and recent history of serious bacterial infection requiring either oral or IV antibiotic therapy. For CIDP, unequivocal diagnosis and documentation patient is refractory or intolerant to prednisone or azathioprine given in therapeutic doses over at least 3 months. For passive immunization against varicella, confirmation that the patient is immunosuppressed and cannot receive varicella-zoster immune globulin. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | For acute conditions/new starts, 3 months. For renewal of chronic conditions, 1 year. |
| Other Criteria | PA applies to all. For continuation of any diagnosis, documentation of the clinical response to therapy must be submitted. Covered as a Part B benefit if administered in the home for the treatment of primary immune deficiency, covered as a Part D benefit for all other indications when administered in the home. For all indications, if administered in the physician office or infusion center it is covered as a Part B benefit. |

INBRIJA (levodopa inhalation)

Products Affected

- INBRIJA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Currently on nonselective monoamine oxidase inhibitor or has taken one within last 2 weeks, asthma, COPD, or other chronic underlying lung disease |
| Required Medical Information | Diagnosis of covered use, prescription claim or documentation from physician showing patient is currently taking carbidopa/levodopa, documentation of at least one other medication used for "off" episodes (see Other Criteria). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. For approval, the patient must have documentation of a trial of at least one other medication for the treatment of "off" episodes including a dopamine agonist (e.g., pramipexole, ropinirole), a COMT inhibitor (e.g., entacapone), or a monoamine oxidase B inhibitor (e.g., rasagiline, selegiline). |

INJECTABLE TESTOSTERONE

Products Affected

- DEPO-TESTOSTERONE INTRAMUSCULAR SOLUTION
- *testosterone cypionate intramuscular solution 100 mg/ml, 200 mg/ml*
- *testosterone enanthate intramuscular solution*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of serum testosterone level, documentation that patient has been evaluated for the presence of breast and prostate cancer prior to initiation of therapy. |
| Age Restrictions | |
| Prescriber Restrictions | PA not required for urology or endocrinology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all except when prescribed by urology or endocrinology. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

INLYTA (axitinib)

Products Affected

- INLYTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment (Child-Pugh class C), uncontrolled hypertension |
| Required Medical Information | Diagnosis of covered use, documentation of one prior systemic therapy failure, submission of laboratory values including baseline ALT, AST, bilirubin, TSH, urine protein values, submission of baseline blood pressure reading. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

INREBIC (fedratinib)

Products Affected

- INREBIC

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment, unavoidable concomitant use of moderate or strong CYP3A4 inducers or dual CYP3A4/CYP2C19 inhibitors |
| Required Medical Information | Diagnosis of covered use, submission of thiamine level and platelet count. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. For approval, the patient must have tried and failed to have an adequate response to or had an intolerance to ruxolitinib. |

INTERLEUKIN-5 ANTAGONISTS (severe eosinophilic asthma)

Products Affected

- FASENRA
- FASENRA PEN
- NUCALA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. For eosinophilic asthma, documentation that patient's symptoms are poorly controlled with inhaled corticosteroids, submission of pulmonary function test results including FEV1, frequency of inhaled short-acting beta2-agonist therapy, frequency of daily and nighttime symptoms and exacerbations, and effect of exacerbations on activity. For Nucala (eosinophilic asthma diagnosis only), submission of blood eosinophil count documenting 150 cells/mcL obtained within 6 weeks of therapy initiation or 300 cells/mcL within 12 months of therapy initiation. For Fasenra, submission of laboratory confirmation of eosinophilic asthma diagnosis (serum eosinophil count, sputum eosinophil count, or lung biopsy). |
| Age Restrictions | 12 years of age or older |
| Prescriber Restrictions | Restricted to allergy, pulmonology, and immunology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

INTRON A (interferon alfa-2b)

Products Affected

- INTRON A

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Autoimmune hepatitis, decompensated liver disease |
| Required Medical Information | Diagnosis of covered use, submission of triglyceride levels, hemoglobin, complete and differential white blood cell counts, platelet count, serum electrolytes, ALT, serum bilirubin level, serum albumin level, and TSH. For malignant melanoma, submission of the date of surgical treatment. For AIDS-related Kaposi's sarcoma, submission of total CD4 count. For chronic hepatitis C, submission of HCV RNA, prothrombin time, baseline serum creatinine level, and laboratory confirmation of hepatitis C virus, and documentation of previous response to therapy if applicable. For chronic hepatitis B, submission of prothrombin time and documentation patient has been serum HBsAG positive for at least 6 months with evidence of HBV replication. |
| Age Restrictions | For hairy cell leukemia, malignant melanoma, follicular lymphoma, condylomata acuminata, or AIDS-related Kaposi's sarcoma, 18 years of age or older. For chronic hepatitis C, 3 years of age or older. For chronic hepatitis B, 1 year of age or older. |
| Prescriber Restrictions | |
| Coverage Duration | Up to 1 year depending on covered use. See "Other Criteria" section. |

| PA Criteria | Criteria Details |
|-----------------------|---|
| Other Criteria | <p>PA applies to new starts only. For hairy cell leukemia, up to 6 months. For condylomata acuminata, up to 3 weeks per course, and at least 12 weeks must pass in between multiple courses in order to be reauthorized. For Kaposi's sarcoma, up to 16 weeks. For hepatitis B infection, up to 24 weeks. For all other indications/uses, up to 1 year. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.</p> |

INVEGA TRINZA (paliperidone 3-month injectable suspension)

Products Affected

- INVEGA TRINZA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Dementia-related psychosis |
| Required Medical Information | Diagnosis of covered use, documentation of at least 4 months' treatment with 1-month paliperidone palmitate extended-release injectable suspension. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

IRESSA (gefitinib)

Products Affected

- IRESSA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, confirmation of EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ITRACONAZOLE

Products Affected

- *itraconazole oral*
- TOLSURA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, fungal culture result identifying causative organism or positive KOH result. |
| Age Restrictions | |
| Prescriber Restrictions | PA not required for infectious diseases |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

JAKAFI (ruxolitinib)

Products Affected

- JAKAFI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | For myelofibrosis, a platelet count less than $50 \times 10^9/L$ with either concomitant estimated creatinine clearance between 15 and 59 mL/min, end stage renal disease not on dialysis, or any degree of hepatic impairment |
| Required Medical Information | Diagnosis of covered use, submission of baseline platelet count, ALT, AST, and bilirubin, submission of creatinine clearance or current body weight with serum creatinine for calculation of estimated creatinine clearance. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

JUXTAPID (lomitapide)

Products Affected

- JUXTAPID

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy, moderate or severe hepatic impairment (Child-Pugh class B or C), active liver disease |
| Required Medical Information | Diagnosis of covered use, submission of baseline lab values including ALT, AST, alkaline phosphatase, total bilirubin, baseline LDL-C, total cholesterol (TC), apoB, and non-HDL-C, documentation of negative pregnancy test result in females of reproductive potential, submission of renal indices, documentation of contraindication to or treatment failure with evolocumab. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to cardiology, lipidology, and endocrinology with experience in and a focus on lipid management |
| Coverage Duration | Initially 6 months, then 1 year |
| Other Criteria | PA applies to all. Submission of LDL level documenting clinically significant response to therapy will be required for reauthorization. |

JYNARQUE (tolvaptan)

Products Affected

- JYNARQUE ORAL TABLET 15 MG, 30 MG
- JYNARQUE ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | History of signs or symptoms of significant liver impairment or injury (not including uncomplicated polycystic liver disease), uncorrected abnormal blood sodium concentrations, inability to sense or respond to thirst, hypovolemia, uncorrected urinary outflow obstruction, anuria |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to nephrology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

KALYDECO (ivacaftor)

Products Affected

- KALYDECO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of cystic fibrosis mutation test result and baseline ALT and AST. |
| Age Restrictions | 6 months of age or older |
| Prescriber Restrictions | Restricted to pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

KETOCONAZOLE ORAL

Products Affected

- *ketoconazole oral*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Acute or chronic liver disease, treatment of fungal meningitis or fungal infections of the skin or nails |
| Required Medical Information | Ketoconazole is being requested for the treatment of one of the following culture-proven, systemic fungal infections in patients who have failed or who are intolerant to other therapies: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis, submission of baseline ALT, AST, total bilirubin, alkaline phosphatase, prothrombin time and INR, confirmation from the prescriber that the potential benefits of therapy outweigh the risks. |
| Age Restrictions | 2 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 6 months |
| Other Criteria | PA applies to all. |

KEVEYIS (dichlorphenamide)

Products Affected

- KEVEYIS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concomitant use of high dose aspirin, severe pulmonary disease limiting compensation to metabolic acidosis, hepatic insufficiency |
| Required Medical Information | Diagnosis of covered use, submission of baseline serum potassium and bicarbonate. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | Initially 2 months, then 1 year |
| Other Criteria | PA applies to all. Documentation of patient's response at 2 months is required for continuation of approval. |

KISQALI (ribociclib)

Products Affected

- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)
- KISQALI 200 DOSE
- KISQALI 400 DOSE
- KISQALI 600 DOSE
- KISQALI FEMARA (400 MG DOSE)
- KISQALI FEMARA (600 MG DOSE)
- KISQALI FEMARA(200 MG DOSE)

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Congenital long QT syndrome, moderate or severe hepatic impairment, QTcF interval greater than 450 msec, uncorrected hypokalemia or hypomagnesemia, patients on rifampin, phenytoin, or carbamazepine |
| Required Medical Information | Diagnosis of covered use, submission of genetic tumor testing showing that the primary tumor type is HR-positive, HER2-negative, attestation that patient has advanced or metastatic disease and will be taking concurrently with an aromatase inhibitor, submission of baseline liver function tests, ECG, serum electrolytes, and CBC. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

KORLYM (mifepristone)

Products Affected

- KORLYM

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy, female patient with a history of unexplained vaginal bleeding, endometrial hyperplasia with atypia, or endometrial carcinoma, patients on concurrent long-term corticosteroid therapy, simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges |
| Required Medical Information | Diagnosis of covered use, submission of baseline serum potassium, serum creatinine, patient weight, AST, ALT, and alkaline phosphatase, submission of negative pregnancy test result in female patients of reproductive potential. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to endocrinology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

KUVAN (sapropterin)

Products Affected

- KUVAN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of blood phenylalanine level. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initially 6 months, then 1 year |
| Other Criteria | PA applies to all. Submission of blood phenylalanine level required for reauthorization. |

KYNAMRO (mipomersen)

Products Affected

- KYNAMRO SUBCUTANEOUS SOLUTION
 PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Patients with moderate or severe hepatic impairment or active liver disease, including unexplained persistent elevations of serum transaminases |
| Required Medical Information | Diagnosis of covered use, submission of baseline lab values including ALT, AST, alkaline phosphatase, total bilirubin, baseline LDL-C, total cholesterol (TC), apoB, and non-HDL-C, submission of renal indices, documentation of contraindication to or treatment failure with evolocumab. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to cardiology, lipidology, and endocrinology with experience in and a focus on lipid management |
| Coverage Duration | Initially 6 months, then 1 year |
| Other Criteria | PA applies to all. Submission of LDL level documenting clinically significant response to therapy will be required for reauthorization. |

LENVIMA (lenvatinib)

Products Affected

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of creatinine clearance or current body weight with serum creatinine for calculation of estimated creatinine clearance, submission of baseline blood pressure showing blood pressure is controlled, submission of baseline ALT, AST, TSH, and proteinuria evaluation via dipstick. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

LEUKINE (sargramostim, GM-CSF)

Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED
- LEUKINE INTRAVENOUS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of WBC count and ANC. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 3 months |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

LIDOCAINE TRANSDERMAL PATCHES

Products Affected

- *lidocaine external patch 5 %*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

LONG-ACTING SOMATOSTATIN ANALOGS

Products Affected

- SOMATULINE DEPOT

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation of baseline serum GH, IGF-1, TSH, and blood glucose levels. For acromegaly, degree of control of clinical acromegaly symptoms. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to endocrinology and oncology |
| Coverage Duration | Initially 3 months, then up to 1 year |
| Other Criteria | PA applies to new starts only. Continuation of therapy requires documentation of a positive clinical response. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

LONSURF (trifluridine/tipiracil)

Products Affected

- LONSURF

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Moderate or severe hepatic impairment |
| Required Medical Information | Diagnosis of covered use, submission of baseline CBC, absolute neutrophil count, ALT, AST, and bilirubin, documentation of KRAS status. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

LORBRENA (lorlatinib)

Products Affected

- LORBRENA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concomitant use with strong CYP3A inducers |
| Required Medical Information | Diagnosis of covered use, submission of prior therapies used. Additionally, if being given to a female of reproductive potential, documentation of a negative pregnancy prior to initiation and that the patient has been counseled to use non-hormonal contraception during treatment and for at least 6 months after the last dose. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

LUCEMYRA (lofexidine)

Products Affected

- LUCEMYRA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Congenital long QT syndrome, severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 14 days |
| Other Criteria | PA applies to all. |

LYNPARZA (olaparib)

Products Affected

- LYNPARZA ORAL TABLET

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of FDA-approved test confirming presence of applicable mutations depending on cancer type as necessary, submission of baseline CBC. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

MAVENCLAD (cladribine)

Products Affected

- MAVENCLAD (10 TABS)
- MAVENCLAD (4 TABS)
- MAVENCLAD (5 TABS)
- MAVENCLAD (6 TABS)
- MAVENCLAD (7 TABS)
- MAVENCLAD (8 TABS)
- MAVENCLAD (9 TABS)

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Current malignancy, pregnancy, HIV or other active chronic infection (e.g., hepatitis or tuberculosis), lymphocyte count below normal limit before first course or less than 800 cells/microliter before second course, creatinine clearance below 60 mL/min, Child-Pugh score greater than 6 |
| Required Medical Information | Diagnosis of covered use, pregnancy status for female patients of childbearing potential, submission of lymphocyte count, submission of patient weight and serum creatinine (to calculate estimated creatinine clearance). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. After the completion of 2 treatment courses (2 years' treatment), additional treatment courses are not recommended over the following 2 years because of malignancy risk. Reinitiating treatment after those 2 years have passed has not been studied. Requests for therapy for a combined total of greater than 2 years will not be approved. Requests for therapy for more than 20 tablets per treatment course (year) will not be approved. |

MAVYRET (glecaprevir/pibrentasvir)

Products Affected

- MAVYRET

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment (Child-Pugh class C), patients on rifampin or atazanavir |
| Required Medical Information | Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV), documentation of whether cirrhosis is present or not and whether or not it is compensated or decompensated, confirmation a test for HBV infection (HBsAg and anti-HBc) was completed. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | Criteria for coverage duration will be applied consistent with current AASLD-IDSA guidance. |
| Other Criteria | PA applies to all. |

MECASERMIN

Products Affected

- INCRELEX

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation of primary insulin-like growth factor (IGF-1) deficiency or growth hormone gene deletion in patients who have developed neutralizing antibodies to growth hormone, submission of IGF-1 level and growth hormone level. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to endocrinology and nephrology |
| Coverage Duration | 6 months |
| Other Criteria | PA applies to all. Requests for continuation of therapy require annual submission of updated IGF-1 and growth hormone levels. |

MEGESTROL IN OLDER PATIENTS

Products Affected

- *megestrol acetate oral suspension 40 mg/ml, 400 mg/10ml, 625 mg/5ml*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | All 4 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation the provider is aware of the associated risks of megestrol including an increased risk of thrombotic events and death, (3) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, (4) documentation that the benefits of the drug outweigh the potential risks to the patient. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

MEKINIST (trametinib)

Products Affected

- MEKINIST

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Progression of disease on prior BRAF-inhibitor therapy |
| Required Medical Information | Diagnosis of covered use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation, submission of baseline LVEF, submission of blood pressure reading. For non-small cell lung cancer, attestation that therapy will be used in combination with dabrafenib. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

METHAMPHETAMINE

Products Affected

- DESOXYN
- *methamphetamine hcl*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Use for exogenous obesity, patients with glaucoma, advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, or a history of drug abuse, use during or within 14 days following the administration of monoamine oxidase inhibitors |
| Required Medical Information | Diagnosis of covered use. For patients 65 years of age and older, attestation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services (CMS) and that the benefits of methamphetamine therapy outweigh the potential risks to the patient. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. PA will not be authorized if using for exogenous obesity (excluded category per CMS). |

METHOTREXATE INJECTABLE (SUBCUTANEOUS)

Products Affected

- OTREXUP SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.4ML, 12.5 MG/0.4ML, 15 MG/0.4ML, 17.5 MG/0.4ML, 20 MG/0.4ML, 22.5 MG/0.4ML, 25 MG/0.4ML
- RASUVO SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.2ML, 12.5 MG/0.25ML, 15 MG/0.3ML, 17.5 MG/0.35ML, 20 MG/0.4ML, 22.5 MG/0.45ML, 25 MG/0.5ML, 30 MG/0.6ML, 7.5 MG/0.15ML

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of covered use, documentation of intolerance or inadequate response to oral or non-subcutaneous injectable forms of methotrexate. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to rheumatology and dermatology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

METHYLTESTOSTERONE

Products Affected

- METHITEST
- *methyltestosterone oral*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Male patients with breast or prostate cancer, women who are or may become pregnant |
| Required Medical Information | Diagnosis of covered use. For patients 65 years of age and older, submission of documentation stating provider is aware this is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services and that the benefit of therapy outweighs the potential risk to the patient. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

MIGLUSTAT

Products Affected

- *miglustat*
- ZAVESCA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe renal impairment (CrCl less than 30 mL/min) |
| Required Medical Information | Diagnosis of covered use, documentation that enzyme replacement is not a therapeutic option. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

MODANIFIL AND DERIVATIVES

Products Affected

- *armodafinil*
- *modafinil*
- NUVIGIL
- PROVIGIL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 17 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

MYALEPT (metreleptin)

Products Affected

- MYALEPT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | General obesity not associated with congenital leptin deficiency |
| Required Medical Information | Diagnosis of covered use, submission of leptin level laboratory test result confirming leptin deficiency, baseline HbA1c, fasting glucose, fasting triglyceride levels, and weight. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation of approval requires submission of patient weight, updated HbA1c, fasting glucose, and fasting triglyceride levels. |

MYTESI (crofelemer)

Products Affected

- MYTESI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

NAMZARIC (memantine and donepezil)

Products Affected

- NAMZARIC

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of documentation that the patient has been stabilized on donepezil 10 mg daily. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

NATPARA (parathyroid hormone)

Products Affected

- NATPARA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation that (albumin-corrected) serum calcium is greater than 7.5 mg/dL and confirmation that 25-hydroxyvitamin D stores are sufficient. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

NAYZILAM (midazolam nasal spray)

Products Affected

- NAYZILAM

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Acute narrow-angle glaucoma |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 12 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

NERLYNX (neratinib)

Products Affected

- NERLYNX

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of genetic tumor testing showing that the primary tumor type is HER2-positive, confirmation member has completed adjuvant trastuzumab-based therapy, submission of baseline liver function tests. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

NEULASTA (pegfilgrastim)

Products Affected

- NEULASTA ONPRO
- NEULASTA SUBCUTANEOUS SOLUTION
PREFILLED SYRINGE
- UDENYCA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of FDA-approved indication. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 6 months |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

NEXAVAR (sorafenib)

Products Affected

- NEXAVAR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

NINLARO (ixazomib)

Products Affected

- NINLARO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation that medication will be administered concomitantly with lenalidomide and dexamethasone, documentation of prior therapy regimen for multiple myeloma, submission of baseline platelet count and absolute neutrophil count. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | Initially 3 months, then 1 year |
| Other Criteria | PA applies to new starts only. For continuation, documentation of platelet count greater than 30,000/mm ³ , ANC greater than 500/mm ³ , and Grade 1 or lower non-hematological toxicities (including rash, peripheral neuropathies) required. |

NORTHERA (droxidopa)

Products Affected

- NORTHERA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | Initially 2 weeks, then 1 year |
| Other Criteria | PA applies to all. |

NUEDEXTA (dextromethorphan and quinidine)

Products Affected

- NUEDEXTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Prolonged QT interval, congenital long QT syndrome, heart failure, history suggestive of torsades de pointes, AV block without implanted pacemaker |
| Required Medical Information | Diagnosis of covered use, submission of ECG (specifically QT interval). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. The medication will not be approved for agitation or Alzheimer's disease as this is considered an off-label use. |

NUPLAZID (pimavanserin)

Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG, 17 MG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Dementia-related psychosis unrelated to Parkinson's disease psychosis |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | Initially 3 months, then 1 year |
| Other Criteria | PA applies to new starts only. Re-authorization requires documentation of a patient's positive response to therapy including a decrease in the frequency and/or severity of hallucinations and delusions or a maintenance of the initial response to therapy. |

OCALIVA (obeticholic acid)

Products Affected

- OCALIVA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Complete biliary obstruction |
| Required Medical Information | Diagnosis of covered use, documentation either (1) drug will be used in combination with ursodeoxycholic acid (UDCA) and UDCA has been used for 1 year or (2) patient had intolerance to UDCA, submission of baseline LFTs including ALP and total bilirubin. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | Initially 3 months, then 1 year |
| Other Criteria | PA applies to all. Submission of ALP obtained within the previous 3 months required for continuation of therapy. |

ODOMZO (sonidegib)

Products Affected

- ODOMZO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ORBACTIV (oritavancin)

Products Affected

- ORBACTIV

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Known medical need for intravenous unfractionated heparin sodium within 120 hours (5 days) after Orbactiv administration |
| Required Medical Information | Diagnosis of covered use, documentation of a culture and sensitivity showing that the suspected causative agent is susceptible to this medication. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to infectious diseases |
| Coverage Duration | 1 dose |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

ORENITRAM (treprostinil)

Products Affected

- ORENITRAM

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Moderate or severe (Child-Pugh class B or C) hepatic impairment |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to cardiology and pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ORFADIN (nitisinone)

Products Affected

- *nitisinone*
- NITYR
- ORFADIN

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initially 6 months, then 1 year |
| Other Criteria | PA applies to all. Submission of liver function tests, urine succinylacetone levels, alpha-fetoprotein level, serum tyrosine level, serum phenylalanine level required for reauthorization. |

ORILISSA (elagolix)

Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy, severe (Child-Pugh class C) hepatic impairment, known osteoporosis |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to endocrinology and gynecology |
| Coverage Duration | Up to 24 months based on liver function and coexisting dyspareunia. See "Other Criteria" section. |
| Other Criteria | PA applies to all. For endometriosis with dyspareunia or in women with moderate hepatic impairment, up to 6 months. For endometriosis without dyspareunia, 150 mg daily up to 24 months. |

ORKAMBI (lumacaftor/ivacaftor)

Products Affected

- ORKAMBI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation that the patient is homozygous for the F508del mutation in the CFTR gene provided from an FDA-cleared CF mutation test, submission of baseline AST, ALT, bilirubin, and percent predicted FEV1 (ppFEV1), submission of documentation that baseline and follow-up ophthalmologic exams will be performed in pediatric patients starting on therapy. |
| Age Restrictions | 2 years of age or older |
| Prescriber Restrictions | Restricted to pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

OXERVATE (cenegermin-bkbj)

Products Affected

- OXERVATE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to optometry and ophthalmology |
| Coverage Duration | 8 weeks |
| Other Criteria | PA applies to all. |

PALYNZIQ (pegvaliase-pqpz)

Products Affected

- PALYNZIQ

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of blood phenylalanine concentration. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation of therapy after 1 year requires documentation of blood phenylalanine concentration below 600 micromol/L or at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline. |

PCSK9 INHIBITORS

Products Affected

- PRALUENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- PRALUENT SUBCUTANEOUS SOLUTION PEN-INJECTOR
- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | For all indications, submission of LDL level obtained within the previous 6 months and LDL-C goal. For HeFH and ASCVD indications, documentation that medication is being used as an adjunct to maximally-tolerated statin therapy or documentation of inability to tolerate statin therapy (with at least one hydrophilic statin having been tried and failed). For HeFH, documentation of genetic test result documenting HeFH or diagnosis by clinical criteria using Simon Broom or WHO/Dutch Lipid Network criteria. For ASCVD, documented history of MI, ACS, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or PAD. |
| Age Restrictions | For Repatha, 13 years of age or older. For Praluent, 18 years of age or older. |
| Prescriber Restrictions | Restricted to prescribing by/under the documented recommendation of a cardiologist, lipidologist, and endocrinologist with experience in and a focus on lipid management |
| Coverage Duration | Initially 6 months, then 1 year |
| Other Criteria | PA applies to all. Submission of LDL level documenting clinically significant response to therapy will be required for reauthorization. |

PIQRAY (alpelisib)

Products Affected

- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Concomitant use with strong CYP3A inducers or BCRP inhibitors |
| Required Medical Information | Diagnosis of covered use, submission of genetic tumor testing showing that the primary tumor type is HR-positive, HER2-negative, PIK3CA-mutated, attestation that patient has advanced or metastatic disease and will be taking concurrently with fulvestrant, submission of prior therapies tried, pregnancy status for female patients of childbearing potential. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

POMALYST (pomalidomide)

Products Affected

- POMALYST

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of covered use, submission of baseline serum bilirubin, AST, ALT, and CBC including ANC and platelet count. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

PREVYMIS (letermovir)

Products Affected

- PREVYMIS ORAL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of day number post-HSCT, documentation of any previous doses of letermovir. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology, oncology, and infectious diseases |
| Coverage Duration | Up to 100 days per HSCT |
| Other Criteria | PA applies to all. |

PRIOR AUTHORIZATION TO OVERRIDE SPECIALTY RESTRICTIONS

Products Affected

- *acitretin*
- APOKYN SUBCUTANEOUS SOLUTION CARTRIDGE
- CRINONE
- FABIOR
- PEGASYS PROCLICK SUBCUTANEOUS SOLUTION 180 MCG/0.5ML
- PEGASYS SUBCUTANEOUS SOLUTION
- PEGINTRON SUBCUTANEOUS KIT 50 MCG/0.5ML
- *tazarotene external*
- TAZORAC
- VABOMERE
- XYREM

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | The following physician specialties are exempt from prior authorization (by drug): (a) for acitretin, Fabior, tazarotene, and Tazorac: dermatology exempt, (b) for Pegasys: gastroenterology, hepatology, or infectious diseases exempt, (c) for Crinone: gynecology, obstetrics, reproductive endocrinology, or women's health exempt, (d) for Vabomere: infectious diseases or nephrology exempt, (e) for Apokyn: neurology exempt, (f) for Xyrem: neurology or pulmonology exempt |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

PRIOR AUTHORIZATION TO OVERRIDE SPECIALTY RESTRICTIONS (PROTECTED CLASS DRUGS)

Products Affected

- SYLATRON SUBCUTANEOUS KIT 200 MCG, 300 MCG, 600 MCG
- *temsirolimus*
- TORISEL
- VALCHLOR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. Physicians who specialize in the treatment of medical conditions most commonly treated with this medication are exempt from prior authorization. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

PROCYSBI (cysteamine)

Products Affected

- PROCYSBI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation that patient has tried and failed or had an intolerance to immediate-release cysteamine. |
| Age Restrictions | 1 year of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

PROMACTA (eltrombopag)

Products Affected

- PROMACTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation of previous therapies tried (corticosteroids, immunoglobulins), submission of lab values including ALT, AST, bilirubin, CBC with differentials and platelet count. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 6 months |
| Other Criteria | PA applies to all. |

PROMETHAZINE IN OLDER PATIENTS

Products Affected

- *phenadoz rectal suppository 12.5 mg* *mg*
- *promethazine hcl oral*
- *promethazine hcl rectal*
- *promethegan rectal suppository 25 mg, 50*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | For all diagnoses of covered use, justification why the benefits of the drug will outweigh the risks for the specific patient must be submitted. For allergic conditions, documentation must be submitted showing patient has tried and failed or had an inadequate response to a second-generation antihistamine. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | Promethazine is a potent anticholinergic considered high-risk in older patients due to risks of confusion, dry mouth, constipation, and decreased clearance with advanced age. |

PROMETHAZINE VC

Products Affected

- *promethazine-phenylephrine*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use including treatment of medical condition causing a cough, not due to symptomatic relief of cough and/or cold. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

RAVICTI (glycerol phenylbutyrate)

Products Affected

- RAVICTI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of baseline fasting plasma ammonia level. |
| Age Restrictions | 2 months of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

REVLIMID (lenalidomide)

Products Affected

- REVLIMID

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy, chronic lymphocytic leukemia (outside of a controlled clinical trial) |
| Required Medical Information | Diagnosis of covered use, submission of CBC including ANC and platelet count. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ROZLYTREK (entrectinib)

Products Affected

- ROZLYTREK

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. For non-small cell lung cancer, submission of results showing tumor is ROS1-positive as detected by an FDA-approved test. For solid tumors, submission of evidence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation. |
| Age Restrictions | 12 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

RUBRACA (rucaparib)

Products Affected

- RUBRACA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of baseline CBC. For BRCA mutation-associated ovarian, fallopian tube, or primary peritoneal cancer, confirmation of deleterious BRCA mutation as detected by FDA-approved companion diagnostic test, documentation that the patient has been treated with two or more chemotherapies. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. For initial approval, patient must have recovered from hematological toxicity caused by previous chemotherapy (Grade 1 or less). |

RYDAPT (midostaurin)

Products Affected

- RYDAPT

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

SAMSCA (tolvaptan)

Products Affected

- SAMSCA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Anuria |
| Required Medical Information | Diagnosis of covered use, submission of serum sodium. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 30 days |
| Other Criteria | PA applies to all. Treatment is limited to 30 days to prevent liver injury. |

SEDATING ANTIHISTAMINES IN OLDER PATIENTS

Products Affected

- *carbinoxamine maleate oral solution*
- *carbinoxamine maleate oral tablet 4 mg*
- *clemastine fumarate oral tablet 2.68 mg*
- *cyproheptadine hcl oral*
- *diphenhydramine hcl oral elixir*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | All 4 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation patient tried and failed or had an inadequate response to a second-generation antihistamine, (3) documentation provider is aware the medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, and (4) justification is submitted which explains the benefits of the drug and how that benefit outweighs the potential risks to the patient. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

SEROSTIM (somatropin)

Products Affected

- SEROSTIM SUBCUTANEOUS SOLUTION
RECONSTITUTED 4 MG, 5 MG, 6 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

SIGNIFOR (pasireotide)

Products Affected

- SIGNIFOR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of fasting plasma glucose, hemoglobin A1c, ALT, aspartate aminotransferase, alkaline phosphatase, total bilirubin, TSH, free T4, GH/IGF-1, 24-hour urinary free cortisol, ECG results, and gallbladder ultrasound results. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

SILDENAFIL (PAH)

Products Affected

- REVATIO ORAL TABLET
- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate oral tablet 20 mg*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to cardiology and pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

SIMVASTATIN 80 mg per day

Products Affected

- *ezetimibe-simvastatin oral tablet 10-80 mg*
- *simvastatin oral tablet 80 mg*
- ZOCOR ORAL TABLET 80 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Any new start to therapy. Not recommended as initial therapy nor for patients already taking lower doses of simvastatin whose response is inadequate. |
| Required Medical Information | Diagnosis of covered use, documentation that patient has been taking simvastatin 80 mg daily for 12 months or longer without ill effect, submission of lipid panel and liver function tests both obtained within the past 12 months, submission of serum creatinine level obtained within the past 3 months. |
| Age Restrictions | 10 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

SIRTURO (bedaquiline)

Products Affected

- SIRTURO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of baseline ECG, serum potassium, calcium, magnesium, ALT, AST, alkaline phosphatase, and bilirubin, confirmation that Sirturo will be co-administered with at least 3 other drugs proven to be or at least 4 other drugs suspected to be effective against the patient's M. tuberculosis isolate and submission of susceptibility testing, if available. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to infectious diseases |
| Coverage Duration | 24 weeks |
| Other Criteria | PA applies to all. |

SIVEXTRO (tedizolid)

Products Affected

- SIVEXTRO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation of a culture and sensitivity showing that the suspected causative agent is susceptible to this medication. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to infectious diseases |
| Coverage Duration | 6 days |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

SKELETAL MUSCLE RELAXANTS IN OLDER PATIENTS

Products Affected

- *carisoprodol oral*
- *chlorzoxazone oral tablet 500 mg*
- *cyclobenzaprine hcl oral*
- FEXMID
- *metaxall*
- *metaxalone*
- *methocarbamol oral*
- *orphenadrine citrate er*
- ROBAXIN ORAL
- ROBAXIN-750
- SOMA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | For diagnosis of fibromyalgia, coverage will be provided for cyclobenzaprine for patients who have tried and failed to tolerate or had an inadequate response to at least 2 of the following: gabapentin, fluoxetine, pregabalin, or milnacipran. For treatment of acute, painful musculoskeletal conditions, coverage will be provided when the prescriber attests to understanding the risks of skeletal muscle relaxants in the elderly, which include increased risk of fall and fracture due to sedation and anticholinergic effects. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

SOMAVERT (pegvisomant)

Products Affected

- SOMAVERT

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of baseline IGF-1, ALT, AST, alkaline phosphatase, and serum total bilirubin. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to endocrinology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation of therapy requests require submission of updated IGF-1, ALT, AST, alkaline phosphatase, and serum total bilirubin levels. |

SOVALDI (sofosbuvir)

Products Affected

- SOVALDI ORAL TABLET 200 MG, 400 MG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) genotype 1a, 1b, 2, 3, or 4 infection, documentation of whether cirrhosis is present or not and whether or not it is compensated or decompensated, confirmation a test for HBV infection (HBsAg and anti-HBc) was completed. |
| Age Restrictions | 12 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | Criteria for coverage duration will be applied consistent with current AASLD-IDSA guidance. |
| Other Criteria | PA applies to all. For adult patients with genotype 1 ineligible for interferon treatment, 24 weeks of therapy may be considered by the provider. |

SPRYCEL (dasatinib)

Products Affected

- SPRYCEL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Uncorrected hypokalemia, uncorrected hypomagnesemia |
| Required Medical Information | Diagnosis of covered use, submission of serum potassium, magnesium, and CBC including platelet count and ANC. For adults with resistance or intolerance to prior therapy, documentation of prior therapy. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

STIVARGA (regorafenib)

Products Affected

- STIVARGA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe or uncontrolled hypertension |
| Required Medical Information | Diagnosis of covered use, submission of baseline ALT, AST, serum bilirubin, and blood pressure reading. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

SUBLINGUAL ALLERGY IMMUNOTHERAPY

Products Affected

- ORALAIR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe, unstable, or uncontrolled asthma, history of any severe systemic allergic reaction |
| Required Medical Information | Diagnosis of covered use, submission of either skin test or in vitro testing demonstrating a positive result for pollen-specific IgE antibodies for species covered in package insert, confirmation therapy is being initiated prior to the start of respective pollen season at a time consistent with product's labeling. |
| Age Restrictions | 10 years of age through 65 years of age |
| Prescriber Restrictions | Restricted to allergy and immunology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Confirmation auto-injectable epinephrine therapy has been prescribed and patient has been instructed on the proper use of emergency self-injection epinephrine. |

SUCRAID (sacrosidase)

Products Affected

- SUCRAID

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of laboratory-confirmed congenital sucrase-isomaltase deficiency via differential urinary disaccharide test or measurement of intestinal disaccharides following small bowel biopsy. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

SUNOSI (solriamfetol)

Products Affected

- SUNOSI

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | End stage renal disease, concurrent treatment with monoamine oxidase inhibitor (MAOI) or use of an MAOI within the past 14 days |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Solriamfetol is not indicated to treat the underlying airway obstruction in obstructive sleep apnea and will not be approved for this use. |

SUTENT (sunitinib)

Products Affected

- SUTENT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of baseline ALT, AST, and bilirubin. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

SYMDEKO (tezacaftor/ivacaftor)

Products Affected

- SYMDEKO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. Documentation that the patient is homozygous for the F508del mutation or has at least one mutation in the CTFR gene responsive to the drug (see section 12.1, table 4 of package insert for full list) provided from an FDA-cleared CF mutation test. Submission of baseline AST, ALT, and bilirubin. Submission of documentation that baseline and follow-up ophthalmologic exams will be performed in pediatric patients starting on therapy. |
| Age Restrictions | 6 years of age or older |
| Prescriber Restrictions | Restricted to pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

SYMLIN (pramlintide)

Products Affected

- SYMLINPEN 120 SUBCUTANEOUS SOLUTION
PEN-INJECTOR
- SYMLINPEN 60 SUBCUTANEOUS SOLUTION
PEN-INJECTOR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Gastroparesis |
| Required Medical Information | Diagnosis of covered use, confirmation of current use of a mealtime insulin. |
| Age Restrictions | |
| Prescriber Restrictions | PA not required for endocrinology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all except when prescribed by endocrinology. |

SYMPROIC (naldemedine)

Products Affected

- SYMPROIC

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Known or suspected gastrointestinal obstruction or increased risk of recurrent obstruction, severe hepatic impairment (Child-Pugh class C) |
| Required Medical Information | Diagnosis of covered use, documentation patient has been using opioids at a morphine equivalent dose of at least 30 mg daily for at least 4 weeks prior to initiation, provider must attest that if opioid medication is stopped for any reason, naldemedine will be discontinued. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

SYNAREL (nafarelin)

Products Affected

- SYNAREL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy/breast-feeding, undiagnosed abnormal vaginal bleeding |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | For endometriosis, 6 months. For all other diagnoses, 1 year. |
| Other Criteria | PA applies to all. Re-treatment for endometriosis is not recommended because safety data are not available. |

SYNRIBO (omacetaxine)

Products Affected

- SYNRIBO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

TAFAMIDIS

Products Affected

- VYNDAMAX
- VYNDAQEL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to cardiology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

TAFINLAR (dabrafenib)

Products Affected

- TAFINLAR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation. For non-small cell lung cancer or unresectable/metastatic melanoma with a BRAF V600K mutation, attestation that therapy will be used in combination with trametinib. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

TAGRISSO (osimertinib)

Products Affected

- TAGRISSO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, confirmation of the presence of required genetic mutations/deletions as detected by an FDA-approved test, submission of baseline LVEF. For EGFR T790M mutation-positive NSCLC, documentation that the patient has progressed on or after EGFR TKI therapy. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | Initially 3 months, then 1 year |
| Other Criteria | PA applies to new starts only. Continuation of approval requires affirmation of absence of unacceptable toxicities. |

TAKHZYRO (lanadelumab-flyo)

Products Affected

- *takhzyro*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 12 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

TALZENNA (talazoparib)

Products Affected

- TALZENNA ORAL CAPSULE 0.25 MG, 1 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of FDA-approved companion test showing patient is a candidate for therapy. Additionally, if being given to a female of reproductive potential, documentation of a negative pregnancy prior to initiation and that the patient has been counseled to use effective contraception during treatment and for at least 7 months after the last dose. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

TAVALISSE (fostamatinib)

Products Affected

- TAVALISSE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of platelet count, documentation patient had an insufficient response to prior treatment (including at least one of the following: corticosteroids, immunoglobulins, splenectomy, and/or a thrombopoietin receptor agonist). |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology |
| Coverage Duration | Initially 12 weeks, then 1 year |
| Other Criteria | PA applies to all. Continuation of therapy requires submission of platelet count. |

TEGSEDI (inotersen)

Products Affected

- TEGSEDI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Platelet count less than 100×10^9 L |
| Required Medical Information | Diagnosis of covered use, submission of platelet count. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

TESTOSTERONE REPLACEMENT PRODUCTS

Products Affected

- ANDRODERM TRANSDERMAL PATCH 24 HOUR
- ANDROGEL TRANSDERMAL GEL 25 MG/2.5GM (1%)
- FORTESTA
- NATESTO
- STRIANT
- TESTOSTERONE TRANSDERMAL GEL 10 MG/ACT (2%)
- *testosterone transdermal gel 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)*
- *testosterone transdermal solution*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of serum testosterone level, documentation that patient has been evaluated for the presence of breast and prostate cancer prior to initiation of therapy. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

THROMBOPOIETIN RECEPTOR AGONISTS

Products Affected

- DOPTELET
- MULPLETA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology, gastroenterology, and surgery |
| Coverage Duration | Doptelet: 5 days for undergoing a procedure or 1 year for immune thrombocytopenia. Mulpleta: 7 days. |
| Other Criteria | PA applies to all. These medications should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts and will not be approved for this indication. |

TIBSOVO (ivosidenib)

Products Affected

- TIBSOVO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of FDA-approved test confirming presence of IDH1 mutation. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

TOBI PODHALER (tobramycin)

Products Affected

- TOBI PODHALER

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 6 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 month |
| Other Criteria | PA applies to new starts only. |

TOPICAL ONYCHOMYCOSIS TREATMENTS

Products Affected

- JUBLIA
- KERYDIN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of culture-proven Trichophyton rubrum or Trichophyton mentagrophytes infection, documentation patient has tried and failed to respond to or tolerate oral terbinafine therapy or a documented contraindication to its use exists. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 48 weeks |
| Other Criteria | PA applies to all. |

TRICYCLIC ANTIDEPRESSANTS IN OLDER PATIENTS

Products Affected

- *amitriptyline hcl oral*
- *chlordiazepoxide-amitriptyline*
- *clomipramine hcl oral*
- *doxepin hcl oral*
- *imipramine hcl oral*
- *imipramine pamoate*
- *perphenazine-amitriptyline*
- *trimipramine maleate oral*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. Patient must have tried and failed to tolerate or had an inadequate response to two preferred alternative therapies for labeled indications or off-labeled uses including the following: (1) for depression (applies to amitriptyline, imipramine, doxepin, and trimipramine): paroxetine, sertraline, venlafaxine, duloxetine, citalopram, escitalopram, fluoxetine, or trazodone, (2) for headache treatment and prophylaxis (applies to amitriptyline): propranolol, timolol, topiramate, valproic acid, or divalproex, (3) for anxiety (applies to doxepin): paroxetine, venlafaxine, duloxetine, or buspirone, (4) for postherpetic neuralgia (applies to amitriptyline) or other neuropathic pain: gabapentin or pregabalin, (5) for obsessive-compulsive disorder (applies to clomipramine): paroxetine, sertraline, fluoxetine, or fluvoxamine, (6) for irritable bowel syndrome (applies to amitriptyline, trimipramine, and doxepin): laxatives or loperamide. Documentation must be submitted confirming that the prescriber is aware the medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services and justification is submitted by the prescriber which explains how the benefits outweigh the potential risks for the specific patient. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

TRIENTINE

Products Affected

- *trientine hcl*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation of intolerance to penicillamine. |
| Age Restrictions | 6 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

TRIMETHOBENZAMIDE IN OLDER PATIENTS

Products Affected

- TIGAN ORAL
- *trimethobenzamide hcl oral*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | All 3 of the following criteria must be met: (1) diagnosis of nausea and vomiting, (2) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, (3) documentation that the benefits of the drug outweigh the potential risks to the patient. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

TURALIO (pexidartinib)

Products Affected

- TURALIO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Active liver or biliary tract disease, pre-existing increased serum transaminases, total or direct bilirubin greater than the upper limit of normal, unavoidable concomitant use of other hepatotoxic medications, strong CYP3A inducers, or proton pump inhibitors |
| Required Medical Information | Diagnosis of covered use (and surgical intervention is not possible or practical), submission of serum transaminases, total and direct bilirubin, ALP. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

TYKERB (lapatinib)

Products Affected

- TYKERB

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Uncorrected hypokalemia, uncorrected hypomagnesemia |
| Required Medical Information | Diagnosis of covered use, submission of baseline ECG, LVEF, ALT, AST, potassium, and magnesium levels. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

TYMLOS (abaloparatide)

Products Affected

- TYMLOS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Males |
| Required Medical Information | Diagnosis of covered use where "high risk for fracture" is defined as (1) a history of osteoporotic fracture or (2) multiple risk factors for fracture or (3) patients who have failed or are intolerant of other available osteoporosis therapies, submission of baseline serum calcium, postmenopausal status, documentation that at least one bisphosphonate was tried and failed (or a bisphosphonate is contraindicated), submission of a value, condition, or past medical history that assesses fracture risk (e.g., DEXA scan results or prior fracture), submission of number of total months of all prior use of parathyroid hormone analogs and parathyroid hormone related peptides. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 2 years maximum dependent on patient's prior use of all PTH analogs and PTH-related peptides |
| Other Criteria | PA applies to all. Use of parathyroid hormone analogs and/or parathyroid hormone related peptides for more than 2 years during a patient's lifetime is not recommended and requests for therapy with any of these agents for a combined total of greater than 2 years will not be approved. |

UPTRAVI (selexipag)

Products Affected

- UPTRAVI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe (Child-Pugh class C) hepatic impairment |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to cardiology and pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

VECAMEYL (mecamylamine)

Products Affected

- VECAMEYL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Mild, moderate, labile hypertension, coronary insufficiency or history of recent myocardial infarction, uremia, glaucoma, organic pyloric stenosis |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to cardiology and neurology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

VEMLIDY (tenofovir alafenamide)

Products Affected

- VEMLIDY

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | End stage renal disease, decompensated (Child-Pugh class B or C) hepatic impairment |
| Required Medical Information | Diagnosis of covered use, confirmation of HIV test and that drug will not be used by itself in the case of HIV co-infection, submission of baseline serum creatinine, phosphorus, estimated creatinine clearance, urine glucose, and urine protein. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | PA not required for gastroenterology or infectious diseases |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

VENCLEXTA (venetoclax)

Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

VENTAVIS (iloprost)

Products Affected

- VENTAVIS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to cardiology and pulmonology |
| Coverage Duration | 1 year |
| Other Criteria | This medication is covered as a Part B benefit except for enrollees residing in a long-term care facility. PA applies to new starts only when covered as a Part D benefit. |

VERZENIO (abemaciclib)

Products Affected

- VERZENIO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of genetic tumor testing showing that the primary tumor type is HR-positive, HER2-negative, submission of baseline liver function tests and CBC. Additionally, if being given to a female of reproductive potential, documentation of a negative pregnancy prior to initiation and that the patient has been counseled to use effective contraception during treatment and for at least three weeks after the last dose. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

VIBERZI (eluxadoline)

Products Affected

- VIBERZI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Prior cholecystectomy, known or suspected biliary duct obstruction, known or suspected sphincter of Oddi disease or dysfunction, alcoholism, alcohol abuse, alcohol addiction, or patients who drink more than 3 alcoholic beverages/day, history of pancreatitis, structural diseases of pancreas including known or suspected pancreatic duct obstruction, severe hepatic impairment (Child-Pugh class C), severe constipation or sequelae from constipation, known or suspected mechanical gastrointestinal obstruction |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to gastroenterology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

VITRAKVI (larotrectinib)

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of evidence the solid tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation. Additionally, if being given to a female of reproductive potential, documentation of a negative pregnancy test prior to initiation and that the patient has been counseled to use effective contraception during treatment and for at least 1 week after the last dose. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

VIZIMPRO (dacomitinib)

Products Affected

- VIZIMPRO ORAL TABLET 15 MG, 30 MG, 45 MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Coadministration with a proton pump inhibitor |
| Required Medical Information | Diagnosis of covered use, submission of FDA-approved test confirming presence of EGFR exon 19 deletion or exon 21 L858R substitution mutation. Additionally, if being given to a female of reproductive potential, documentation of a negative pregnancy prior to initiation and that the patient has been counseled to use effective contraception during treatment and for at least 17 days after the last dose. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

VMAT2 INHIBITORS

Products Affected

- AUSTEDO
- INGREZZA
- *tetrabenazine*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | For tetrabenazine and Austedo, actively suicidal or untreated/undertreated depression, hepatic impairment |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology and psychiatry |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

VORICONAZOLE

Products Affected

- *voriconazole intravenous*
- *voriconazole oral*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 3 months |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

VOSEVI (sofosbuvir, velpatasvir, voxilaprevir)

Products Affected

- VOSEVI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Patients on rifampin |
| Required Medical Information | Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) and genotype, documentation of whether cirrhosis is present or not and whether or not it is compensated or decompensated, confirmation a test for HBV infection (HBsAg and anti-HBc) was completed. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 12 weeks |
| Other Criteria | PA applies to all. |

VOTRIENT (pazopanib)

Products Affected

- VOTRIENT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment |
| Required Medical Information | Diagnosis of covered use, submission of baseline ALT, AST, and bilirubin. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

VRAYLAR (cariprazine)

Products Affected

- VRAYLAR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Dementia-related psychosis |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology and psychiatry |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

WAKIX (pitolisant)

Products Affected

- WAKIX ORAL TABLET 4.45 MG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment, end stage renal disease |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to neurology and sleep medicine |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Wakix will be authorized only if the patient previously tried and had an inadequate clinical response or an intolerance to armodafinil or modafinil. |

WEIGHT LOSS MEDICATIONS

Products Affected

- ADIPEX-P
- BELVIQ
- BELVIQ XR
- CONTRAVE
- *phentermine hcl oral*
- QSYMIA
- SAXENDA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Body mass index (BMI) less than 30 kg/m ² or less than 27 kg/m ² if the patient also has diabetes, high blood pressure, or dyslipidemia. |
| Required Medical Information | Submission of BMI and patient's exercise/diet plan. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Medication will not be approved if patient does not have a diet/exercise plan. |

XALKORI (crizotinib)

Products Affected

- XALKORI

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Congenital long QT syndrome |
| Required Medical Information | Diagnosis of covered use, submission of results showing tumor is ALK or ROS1-positive as detected by an FDA-approved test, submission of baseline CBC. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

XATMEP (methotrexate oral solution)

Products Affected

- XATMEP

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Pregnancy (for polyarticular juvenile idiopathic arthritis [pJIA] indication only) |
| Required Medical Information | Diagnosis of covered use. For pJIA, confirmation that member is intolerant to or had an inadequate response to first-line therapy. For acute lymphoblastic leukemia, confirmation that medication is being used as a component of a combination chemotherapy maintenance regimen. |
| Age Restrictions | 2 years of age through 18 years of age |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

XERMELO (telotristat)

Products Affected

- XERMELO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation patient has been on at least 12 weeks of prior somatostatin analog therapy. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 12 weeks |
| Other Criteria | PA applies to all. Continuation of therapy requires that symptoms have stabilized or improved and that the patient has not experienced episodes of severe constipation. |

XOLAIR (omalizumab)

Products Affected

- XOLAIR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Patients whose pre-treatment serum IgE level and body weight place them in the "do not dose" category based on dosing charts in the prescribing information |
| Required Medical Information | Diagnosis of covered use. For asthma, documentation that patient's symptoms are poorly controlled with inhaled corticosteroids, submission of patient's current body weight, pre-treatment serum IgE level, pulmonary function test results including FEV1, positive skin test result or demonstrated in vitro reactivity (RAST test) to a perennial aeroallergen, frequency of inhaled short-acting beta2-agonist therapy, frequency of daily and nighttime symptoms and exacerbations, and effect of exacerbations on activity. For chronic idiopathic urticaria, documentation that the patient continues to experience severe itching and hives despite the use of an H1 antihistamine at an approved dose. |
| Age Restrictions | 6 years of age or older |
| Prescriber Restrictions | Restricted to allergy, pulmonology, dermatology, and immunology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

XOSPATA (gilteritinib)

Products Affected

- XOSPATA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of FDA-approved test confirming presence of FLT3 mutation. Additionally, if being given to a female of reproductive potential, documentation of a negative pregnancy prior to initiation and that the patient has been counseled to use effective contraception during treatment and for at least 6 months after the last dose. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

XPOVIO (selinexor)

Products Affected

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (60 MG ONCE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY)
- XPOVIO (80 MG TWICE WEEKLY)

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All FDA-approved indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation of treatment failure with or intolerance to all prior therapies to match the indication. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

XURIDEN (uridine triacetate)

Products Affected

- XURIDEN

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of baseline CBC including neutrophil count and mean corpuscular volume, baseline urine orotic acid level. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. Continuation of approval requires submission of CBC including neutrophil count and mean corpuscular volume and urine orotic acid level. |

ZEJULA (niraparib)

Products Affected

- ZEJULA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, documentation of response to platinum-based chemotherapy. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ZELBORAF (vemurafenib)

Products Affected

- ZELBORAF

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Long QT syndrome, QTc greater than 500 msec, uncorrected electrolyte abnormalities |
| Required Medical Information | Diagnosis of covered use, submission of results showing BRAF V600 mutation as detected by an FDA-approved test, submission of ECG, serum potassium, magnesium, and calcium levels. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ZERBAXA (ceftolozane/tazobactam)

Products Affected

- ZERBAXA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, confirmation patient will receive concurrent metronidazole therapy when used for the treatment of complicated intra-abdominal infections. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | For UTI including pyelonephritis, 7 days. For intra-abdominal infections, up to 14 days. |
| Other Criteria | PA applies to all. A description of the drug's use and/or how it will be obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the provider's office by the patient for provider administration, it will may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B. |

ZILEUTON ER

Products Affected

- ZILEUTON ER

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Active liver disease or persistent hepatic function elevation enzyme greater than or equal to 3 times the upper limit of normal |
| Required Medical Information | Diagnosis of covered use, submission of hepatic function enzymes and serum bilirubin. |
| Age Restrictions | 12 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

ZILRETTA (triamcinolone intra-articular injection)

Products Affected

- ZILRETTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 treatment only |
| Other Criteria | PA applies to all. Use for hip and shoulder osteoarthritis were not evaluated in trials and PA will not be approved for this use. Re-authorization will not be approved. |

ZOLPIDEM IN OLDER PATIENTS

Products Affected

- AMBIEN
- AMBIEN CR
- *zolpidem tartrate er*
- *zolpidem tartrate oral*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | All 4 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation provider is aware of risks of therapy including cognitive impairment, delirium, unsteady gait, syncope, falls, fractures and motor vehicle accidents and that the medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, (3) documentation that the benefits of the drug outweigh the potential risks to the patient, (4) documentation that at least two of the following medications were tried and deemed ineffective or intolerable: trazodone, ramelteon, and Silenor. |
| Age Restrictions | PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. |

ZONTIVITY (vorapaxar)

Products Affected

- ZONTIVITY

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | History of stroke, transient ischemic attack, or intracranial hemorrhage |
| Required Medical Information | Diagnosis of covered use, confirmation that patient has not had prior stroke, transient ischemic attack, or intracranial hemorrhage, documentation of concurrent use with aspirin and/or clopidogrel. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ZORBTIVE (somatropin)

Products Affected

- ZORBTIVE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 4 weeks |
| Other Criteria | PA applies to all. |

ZURAMPIC (lesinurad)

Products Affected

- ZURAMPIC

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe renal impairment (eCrCl less than 45 mL/min), end stage renal disease, kidney transplant recipient, or on dialysis, tumor lysis syndrome or Lesch-Nyhan syndrome |
| Required Medical Information | Diagnosis of covered use, documentation that patient's hyperuricemia is symptomatic, submission of patient weight and serum creatinine level obtained within the previous month, submission of patient's serum uric acid target goal and serum uric acid level obtained within the previous 3 months documenting patient has not been able to achieve target serum uric acid levels with a xanthine oxidase inhibitor alone, confirmation therapy will be used in conjunction with a xanthine oxidase inhibitor, confirmation patient does not have severe hepatic impairment. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to all. For continuation, submission of uric acid level and eCrCl. |

ZYDELIG (idelalisib)

Products Affected

- ZYDELIG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | History of serious hypersensitivity reactions, including anaphylaxis and toxic epidermal necrolysis |
| Required Medical Information | Diagnosis of covered use. For relapsed small lymphocytic lymphoma and follicular B-cell non-Hodgkin lymphoma, documentation of at least two prior systemic therapies. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ZYKADIA (ceritinib)

Products Affected

- ZYKADIA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use, submission of results showing tumor is ALK-positive as detected by an FDA-approved test. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ZYTIGA (abiraterone)

Products Affected

- *abiraterone acetate*
- ZYTIGA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | Severe hepatic impairment (Child-Pugh class C) |
| Required Medical Information | Diagnosis of covered use, documentation of other treatments tried, confirmation patient will receive concurrent prednisone, submission of baseline ALT, AST, bilirubin, and serum potassium level. |
| Age Restrictions | 18 years of age or older |
| Prescriber Restrictions | Restricted to hematology and oncology |
| Coverage Duration | 1 year |
| Other Criteria | PA applies to new starts only. |

ZYVOX (linezolid)

Products Affected

- *linezolid intravenous solution 600 mg/300ml*
- *linezolid oral*
- ZYVOX ORAL

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Covered Uses | All medically accepted indications not otherwise excluded from Part D. |
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of covered use and culture. |
| Age Restrictions | |
| Prescriber Restrictions | Restricted to infectious diseases |
| Coverage Duration | For vancomycin-resistant E. faecium infections, 28 days. For all other uses, 14 days. |
| Other Criteria | PA applies to all. |

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