PRIOR AUTHORIZATION CRITERIA

This list is current as of December 10, 2025, and pertains to the following formularies:

2026 Pharmacy Benefit Dimensions PDP offered by Niagara County Formulary – D0122

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. ET, April 1st – September 30th: Monday through Friday from 8 a.m. to 8 p.m. ET.

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.

ACTIMMUNE (interferon gamma-1b)

Products Affected

- ACTIMMUNE

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

ADEMPAS (riociguat)

Products Affected

- ADEMPAS ORAL TABLET 0.5 MG, 1 MG, 1.5 MG, 2 MG, 2.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, severe hepatic impairment (Child-Pugh class C), 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 confirmed by right heart catheterization, submission of patient's WHO Group classification, mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance), and pregnancy status for female patients of childbearing potential. For pulmonary arterial hypertension (PAH, WHO Group 1), documentation of pulmonary vascular resistance (PVR) greater than 2 Woods units, submission of current or previous therapies used to treat the condition (see Other Criteria). For chronic thromboembolic pulmonary hypertension (CTEPH, WHO Group 4), confirmation of PVR greater than 3 Woods units, evidence of chronic pulmonary embolism on computed tomography or ventilation/perfusion (V/Q) scan, and attestation patient has inoperable disease or has persistent or recurrent disease after CTEPH surgery (pulmonary thromboendarterectomy).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	For initial authorization for PAH (WHO Group 1), the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to both (1) sildenafil or tadalafil and (2) ambrisentan or bosentan.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ALECENSA (alectinib)

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ALUNBRIG (brigatinib)

Products Affected

- ALUNBRIG

PA Criteria	Criteria Details
Exclusion Criteria	Uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, baseline blood pressure reading, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AQNEURSA (levacetylleucine)

Products Affected

- AQNEURSA

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, patients without neurologic manifestations of Neimann-Pick disease type C (NPC)
Required Medical Information	Diagnosis of covered use, submission of neurological symptoms caused by NPC, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUGTYRO (repotrectinib)

Products Affected

- AUGTYRO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inhibitors or inducers or P-glycoprotein inhibitors
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For non-small cell lung cancer, submission of test confirming tumor is ROS1-positive. For other solid tumors, submission of test confirming tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, attestation patient has progressed following treatment or patient has no satisfactory alternative therapy.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUSTEDO (deutetrabenazine)

Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HOUR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG, 48 MG, 6 MG
- AUSTEDO XR PATIENT TITRATION ORAL TABLET EXTENDED RELEASE THERAPY PACK 12 & 18 & 24 & 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome or a history of cardiac arrhythmia associated with a prolonged QT interval, coadministration with monoamine oxidase inhibitors, actively suicidal or untreated/undertreated depression, hepatic impairment
Required Medical Information	Diagnosis of covered use, submission of Child-Pugh score. For treatment of chorea associated with Huntington's disease, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and psychiatry
Coverage Duration	1 year
Other Criteria	For initial authorization for treatment of chorea associated with Huntington's disease, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to tetrabenazine. For each annual reauthorization for tardive dyskinesia, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AUVELITY (dextromethorphan/bupropion)

Products Affected

- AUVELITY

PA Criteria	Criteria Details
Exclusion Criteria	Seizure disorder, current or prior diagnosis of bulimia or anorexia nervosa, severe hepatic impairment, severe renal impairment, administration of monoamine oxidase inhibitors within 14 days of initiation
Required Medical Information	Diagnosis of covered use, attestation patient has been screened for and does not have bipolar disorder, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to psychiatry
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to two generic on-formulary antidepressants (e.g., bupropion, SSRI, SNRI).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AVMAPKI/FAKZYNJA (avutometinib/defactinib)

Products Affected

- AVMAPKI FAKZYNJA CO-PACK

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inhibitors or inducers, proton pump inhibitors, or H2 receptor antagonists
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of KRAS mutation, pregnancy status for female patients of childbearing potential, attestation patient has received at least one prior systemic therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AYVAKIT (avapritinib)

Products Affected

- AYVAKIT ORAL TABLET 100 MG, 200 MG, 25 MG, 300 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers or strong CYP3A inhibitors. For advanced or indolent systemic mastocytosis, platelet count below 50 x 10^9/L.
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For gastrointestinal stromal tumor (GIST), submission of test result confirming presence of PDGFRA exon 18 mutation. For advanced or indolent systemic mastocytosis, submission of platelet count.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to allergy, hematology, immunology, and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BALVERSA (erdafitinib)

Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	PD-1/PD-L1 inhibitor-eligible patients who have not received this therapy, coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of susceptible FGFR3 genetic alterations, submission of current or previous therapies used to treat the condition (see Other Criteria), pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This drug is not recommended for the treatment of patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BEMPEDOIC ACID

Products Affected

- NEXLETOL
- NEXLIZET

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant pravastatin utilization with doses above 40 mg/day, concomitant simvastatin utilization with doses above 20 mg/day, history of tendon disorders or rupture
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must (1) currently be using a statin (unless contraindicated) plus ezetimibe, or (2) have tried and failed to have an adequate response to or had an intolerance to (a) at least two statins or (b) one statin and ezetimibe. At least one statin previously tried and failed must be a hydrophilic statin. For each annual reauthorization, documentation that the patient remains on previously-used lipid-lowering therapies since the previous approval, unless there is documentation of a new contraindication or intolerance requiring discontinuation of a therapy (or therapies) since the previous approval, is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BENLYSTA (belimumab)

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Severe active central nervous system lupus, patients using other biologic medications or intravenous cyclophosphamide
Required Medical Information	Diagnosis of covered use, submission of current therapies used to treat the condition (see Other Criteria). For systemic lupus erythematosus, submission of autoantibody-positive test result for anti-nuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA).
Age Restrictions	
Prescriber Restrictions	Restricted to immunology, nephrology, and rheumatology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must be using standard therapy, defined as at least one of the following: systemic corticosteroids (e.g., prednisone), antimalarials (e.g., hydroxychloroquine), or immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate mofetil). For each annual reauthorization, confirmation patient is still using some form of standard therapy (as defined above), unless contraindicated, is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BESREMI (ropeginterferon alfa-2b-njft)

Products Affected

- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	History or presence of severe psychiatric disorders (including severe depression or suicidal ideation), history of presence of active serious or untreated autoimmune disease, moderate or severe hepatic impairment (Child-Pugh class B or C), immunosuppressed transplant recipients, severe or unstable cardiovascular disease (e.g., uncontrolled hypertension, NYHA class 2-4 congestive heart failure, serious cardiac arrhythmia, significant coronary artery stenosis, unstable angina), stroke or myocardial infarction within previous 6 months, severe renal impairment (eGFR less than 30 mL/min)
Required Medical Information	Diagnosis of covered use, submission of eGFR, documentation patient has tried and failed to have an adequate response to or had an intolerance/contraindication to hydroxyurea (HU), 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	If patient is taking HU, initially 12 weeks, then 1 year. If patient is not taking HU, 1 year.
Other Criteria	For the first reauthorization in patients using HU at the start of therapy, attestation patient has tapered completely off HU by the end of week 12 is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BEXAROTENE GEL

Products Affected

- *bexarotene external*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to dermatology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BIOLOGIC RESPONSE MODIFIERS

Products Affected

- KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- OTEZLA ORAL TABLET 30 MG
- OTEZLA ORAL TABLET THERAPY PACK 10 & 20 & 30 MG
- SOTYKTU
- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- TYENNE SUBCUTANEOUS
- *ustekinumab subcutaneous*
- VELSIPITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria). For all drugs managed by this policy except Otezla and Velsipity, submission of baseline latent tuberculosis screening test (Mantoux tuberculin skin test [a.k.a. PPD test] or interferon-gamma release assay [IGRA]).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization of a drug managed by this policy, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two preferred agents (an adalimumab biosimilar, Cosentyx, Enbrel, Rinvoq, Skyrizi, an ustekinumab biosimilar, and Xeljanz/Xeljanz XR) for the indication submitted, where possible. For all drugs managed by this policy except Otezla and Velsipity, if TB screening test returns a positive result, coverage will be delayed until latent TB is treated. For each annual reauthorization, yearly TB screening test or chest X-ray required for patients who live in, work in, or travel to areas where TB exposure is likely while on treatment or for those who have previously had a positive TB screening test.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BOSULIF (bosutinib)

Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inhibitors or strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For accelerated or blast phase Ph+ CML, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	For initial authorization for accelerated or blast phase Ph+ CML, the patient must have either (1) tried and had an intolerance to dasatinib, imatinib, or nilotinib or (2) resistance to imatinib, defined as (a) failure to achieve or maintain any hematologic improvement within 4 weeks while on imatinib, or (b) failure to achieve a complete hematologic response by 3 months, cytogenetic response by 6 months or major cytogenetic response by 12 months, or (c) progression of disease after a previous cytogenetic or hematologic response, or (d) presence of a genetic mutation in the BCR-ABL gene associated with imatinib resistance.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BRAFTOVI/MEKTOVI (encorafenib/binimetinib)

Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG
- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of BRAF V600E (or V600K mutation for a melanoma diagnosis, pregnancy status for female patients of childbearing potential. For metastatic melanoma or metastatic non-small cell lung cancer, confirmation that encorafenib and binimetinib will be co-administered. For metastatic colorectal cancer, confirmation that encorafenib and cetuximab will be co-administered.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BRUKINSA (zanubrutinib)

Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For follicular lymphoma, submission of at least two prior systemic regimens tried and failed and attestation medication will be coadministered with obinutuzumab. For mantle cell lymphoma, submission of prior systemic regimen(s) used. For marginal zone lymphoma, documentation patient has tried and failed at least one anti-CD20-based regimen.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BUTALBITAL-CONTAINING PRODUCTS IN OLDER PATIENTS

Products Affected

- ASCOMP-CODEINE
- *butalbital-acetaminophen oral tablet 50-300 mg, 50-325 mg*
- *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*

- TENCON ORAL TABLET 50-325 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient has tried and failed a preferred alternative such as ibuprofen or rizatriptan, or has contraindications to all alternatives.
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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BYLVAY (odevixibat)

Products Affected

- BYLVAY

PA Criteria	Criteria Details
Exclusion Criteria	Clinical evidence of decompensated cirrhosis
Required Medical Information	Diagnosis of covered use confirmed by molecular genetic testing, documentation of cholestasis, defined as one of the following: (1) total serum bile acid greater than the age-adjusted upper limit of normal (ULN), or (2) increased conjugated bilirubin levels, or (3) gamma-glutamyl transferase greater than the age-adjusted ULN, or (4) fat-soluble vitamin deficiency or intractable pruritus explainable only by liver disease, attestation drug-induced pruritus has been ruled out, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to gastroenterology and hepatology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two of the following: cholestyramine, naltrexone, rifampin, ursodiol. For the first reauthorization, attestation of improvement in pruritus symptoms and submission of liver function testing, including serum bilirubin, since the initial authorization is required. For each annual reauthorization, documented maintenance of a clinical benefit and submission of liver function testing, including serum bilirubin, is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CABLIVI (caplacizumab-yhdp)

Products Affected

- CABLIVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, confirmation drug will be given with plasma exchange and immunosuppressive therapy. If the coverage determination request is not for the patient's first use of caplacizumab, submission of previous aTTP recurrences while on caplacizumab.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology, hematology, and immunology
Coverage Duration	3 months
Other Criteria	If the coverage determination request is not for the patient's first use of caplacizumab, coverage will not be authorized if the patient has had more than 2 recurrences of aTTP while on therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CABOMETYX (cabozantinib)

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, submission of baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For hepatocellular carcinoma, confirmation patient was previously treated with sorafenib. For differentiated thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible and submission of previous therapy or therapies tried and failed, which must include a VEGFR-targeted therapy at minimum.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CALQUENCE (acalabrutinib)

Products Affected

- CALQUENCE ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, coadministration with strong CYP3A inhibitors
Required Medical Information	Diagnosis of covered use, submission of 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CAMZYOS (mavacamten)

Products Affected

- CAMZYOS

PA Criteria	Criteria Details
Exclusion Criteria	Left ventricular ejection fraction (LVEF) less than 55%, coadministration with strong CYP2C19 inhibitors, moderate or strong CYP2C19 inducers, moderate or strong CYP3A4 inducers, a non-dihydropyridine (DHP) calcium channel blocker (CCB) plus a beta-blocker, disopyramide, or ranolazine
Required Medical Information	Diagnosis of covered use including all three of the following: (1) attestation patient has exertional symptoms consistent with the definition of NYHA class II or III disease, (2) confirmation of left ventricular (LV) outflow tract obstruction gradient of at least 50 mm Hg either at rest, during Valsalva maneuver testing, or after exercise, and (3) confirmation of LV wall thickness of at least 15 mm or at least 13 mm if condition is familial, submission of current LVEF, current or previous therapies used to treat the condition (see Other Criteria), pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to both a beta-blocker and a non-DHP CCB. For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CAPRELSA (vandetanib)

Products Affected

- CAPRELSA

PA Criteria	Criteria Details
Exclusion Criteria	History of congenital long QT syndrome, torsades de pointes, uncompensated heart failure, or bradyarrhythmias, QTcF interval greater than 450 msec, hypocalcemia, hypokalemia, hypomagnesemia, coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of baseline serum potassium, calcium, magnesium, creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance), ECG (or QT/QTcF interval), and pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CARGLUMIC ACID

Products Affected

- *carglumic acid oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of elevated plasma ammonia level.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, updated plasma ammonia level since the previous authorization is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CERDELGA (eliglustat)

Products Affected

- CERDELGA

PA Criteria	Criteria Details
Exclusion Criteria	Ultrarapid CYP2D6 metabolizers, pre-existing cardiac disease, moderate or severe hepatic impairment, long QT syndrome, coadministration with Class Ia or Class III antiarrhythmics. In patients who are poor or intermediate CYP2D6 metabolizers only, mild hepatic impairment.
Required Medical Information	Diagnosis of covered use, submission of CYP2D6 metabolizer status as detected by a test for determining CYP2D6 genotype, liver function testing or Child-Pugh score.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, updated liver function testing or Child-Pugh score since the previous authorization is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CFTR MODULATOR THERAPIES

Products Affected

- KALYDECO
- ORKAMBI
- SYMDEKO
- TRIKAFTA ORAL TABLET THERAPY PACK 100-50-75 & 150 MG, 50-25-37.5 & 75 MG
- TRIKAFTA ORAL THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers. For Trikafta, severe hepatic impairment.
Required Medical Information	Diagnosis of covered use, submission of cystic fibrosis (CF) mutation test confirming presence of CFTR gene mutations as indicated (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	Initial authorization requires CF mutation test confirming presence of CFTR gene mutations as follows, by drug being requested: (a) for Kalydeco, a mutation predicted to be responsive to ivacaftor based on section 12.1 of the prescribing information, (b) for Orkambi, two copies of the F508del mutation, (c) for Symdeko, two copies of the F508del mutation or at least one mutation predicted to be responsive based on section 12.1 of the prescribing information, (d) for Trikafta, at least one mutation predicted to be responsive based on section 12.1 of the prescribing information or a responsive mutation based on in vitro data.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CHENODAL (chenodiol)

Products Affected

- CHENODAL

PA Criteria	Criteria Details
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	Restricted to gastroenterology and hepatology
Coverage Duration	24 months
Other Criteria	Safety beyond 24 months is not established and will not be authorized.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CHOLBAM (cholic acid)

Products Affected

- CHOLBAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of liver function testing.
Age Restrictions	
Prescriber Restrictions	Restricted to gastroenterology, hepatology, and pediatric gastroenterology
Coverage Duration	Initially 3 months, then 1 year
Other Criteria	For the first reauthorization, documentation of liver function improvement without complete biliary obstruction or persistent clinical or laboratory indications of worsening liver function or cholestasis is required. For each annual reauthorization, updated liver function testing since the previous authorization is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COMETRIQ (cabozantinib)

Products Affected

- COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C), uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, submission of baseline blood pressure reading, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COPIKTRA (duvelisib)

Products Affected

- COPIKTRA ORAL CAPSULE 15 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	Request as first- or second-line therapy, coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of at least two prior systemic therapies tried and failed, submission of pregnancy status for female patients of childbearing potential, attestation patient will receive prophylaxis for Pneumocystis jirovecii pneumonia (PJP) and, if necessary, cytomegalovirus.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CORTICOTROPIN

Products Affected

- CORTROPHIN
- CORTROPHIN GEL

PA Criteria	Criteria Details
Exclusion Criteria	Request for IV administration, 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	3 weeks
Other Criteria	For each reauthorization, updated blood pressure, sodium, and potassium levels since the previous authorization are required. 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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COTELLIC/ZELBORAF (cobimetinib/vemurafenib)

Products Affected

- COTELLIC
- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	For cobimetinib, coadministration with moderate or strong CYP3A inhibitors or inducers. For vemurafenib, electrolyte abnormalities that are not correctable, long QT syndrome, coadministration with drugs that prolong the QT interval.
Required Medical Information	Diagnosis of covered use including verification of BRAF V600 mutation as needed for diagnosis, submission of pregnancy status for female patients of childbearing potential. For patients using cobimetinib, submission of left ventricular ejection fraction (LVEF) with a requirement the baseline LVEF is greater than or equal to 50%. For patients using vemurafenib, submission of QTc interval with a requirement the QT interval is less than or equal to 500 msec.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CRESEMBA (isavuconazonium)

Products Affected

- CRESEMBA ORAL CAPSULE 186 MG

PA Criteria	Criteria Details
Exclusion Criteria	Familial short QT syndrome, coadministration with strong CYP3A inhibitors or inducers
Required Medical Information	Diagnosis of covered use.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Restricted to hematology, infectious diseases, and oncology
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CYSTEAMINE EYE DROPS

Products Affected

- CYSTADROPS
- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, confirmation of corneal cysteine crystal deposits as seen on slit-lamp examination.
Age Restrictions	
Prescriber Restrictions	Restricted to metabolic diseases specialty, ophthalmology, and optometry
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DALFAMPRIDINE

Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
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 creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance), confirmation that patient is able to walk.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, updated creatinine clearance since the previous authorization and confirmation patient is able to walk is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DASATINIB

Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Uncorrected hypokalemia or hypomagnesemia, coadministration with proton pump inhibitors or H2 receptor antagonists
Required Medical Information	Diagnosis of covered use, submission of serum potassium and magnesium, pregnancy status for female patients of childbearing potential. 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DAURISMO (glasdegib)

Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
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, 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DEFERASIROX

Products Affected

- *deferasirox oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, estimated glomerular filtration rate (eGFR) less than 40 mL/min, platelet count below 50 x 10^9/L, high-risk myelodysplastic syndromes, advanced malignancies
Required Medical Information	Diagnosis of covered use, submission of complete blood count (CBC), liver function testing (LFT), ferritin, and eGFR from the previous 3 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	For each reauthorization, updated ferritin level and platelet count drawn within last 3 months and updated CBC, LFT, and eGFR drawn within the previous 6 months is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DEFERIPRONE

Products Affected

- *deferiprone*

PA Criteria	Criteria Details
Exclusion Criteria	Absolute neutrophil count (ANC) below 1.5 x 10^9/L, transfusional iron overload in myelodysplastic syndrome or Diamond Blackfan anemia
Required Medical Information	Diagnosis of covered use, submission of serum ferritin levels, ANC, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, updated ferritin level and ANC within last 3 months is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIACOMIT (stiripentol)

Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	Requests for monotherapy, 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	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DICHLORPHENAMIDE

Products Affected

- *dichlorphenamide*
- ORMALVI

PA Criteria	Criteria Details
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.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initially 2 months, then 1 year
Other Criteria	For each reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DICLOFENAC PATCH

Products Affected

- *diclofenac epolamine external*

PA Criteria	Criteria Details
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 acute pain, defined as short-term pain not lasting longer than a 3-month period.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIGOXIN IN OLDER PATIENTS

Products Affected

- *digoxin oral tablet 250 mcg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. 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	PA not required for cardiology
Coverage Duration	1 year
Other Criteria	PA not required for doses less than or equal to 0.125 mg per day. For each annual reauthorization, provider must attest patient is undergoing required laboratory testing to monitor kidney function and electrolytes and patient is not experiencing signs or symptoms of digoxin toxicity related to drug administration.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DOPTELET (avatrombopag)

Products Affected

- DOPTELET ORAL TABLET 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	Normalization of platelet counts before a procedure in patients with chronic liver disease
Required Medical Information	Diagnosis of covered use. For thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure, submission of platelet count with a requirement it is less than 50 x 10^9/L. For immune thrombocytopenia (ITP), submission of platelet count with a requirement it is less than 30 x 10^9/L or less than 50 x 10^9/L with symptomatic bleeding, documentation patient has undergone splenectomy. If the patient has not undergone splenectomy, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to gastroenterology, hematology, hepatology, and surgery
Coverage Duration	For patients undergoing a procedure, 5 days. For ITP, initially 2 months, then 1 year.
Other Criteria	For initial authorization for ITP, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two ITP therapies from different classes including systemic corticosteroids, immunoglobulins, danazol, fostamatinib, or cytotoxics/immunosuppressants such as rituximab. For first reauthorization for ITP, documentation of an improvement in platelet count greater than or equal to 50 x 10^9/L after at least 4 weeks on the maximum tolerated dose is required. For each annual reauthorization, documented maintenance of this clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DRONABINOL

Products Affected

- *dronabinol*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. If authorization is requested for treatment of nausea and vomiting associated with cancer therapy, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization for treatment of nausea and vomiting associated with cancer therapy, the patient must have tried and failed to have an adequate response to or had an intolerance to at least one 5-HT3 receptor antagonist (e.g., granisetron, ondansetron). 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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ELTROMBOPAG

Products Affected

- *eltrombopag olamine oral packet*
- *eltrombopag olamine oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of platelet count (see Other Criteria). For immune thrombocytopenia (ITP), submission of previous therapies tried and failed (see Other Criteria). For thrombocytopenia in patients with chronic hepatitis C, attestation patient will be receiving interferon therapy to treat HCV. For aplastic anemia (AA), submission of immunosuppressive therapy that will be used concomitantly or, in the case of refractory disease, submission of therapies tried and failed.
Age Restrictions	
Prescriber Restrictions	Restricted to gastroenterology, hematology, hepatology, and infectious diseases
Coverage Duration	For ITP, initially 12 weeks, then 1 year. For AA, 6 months. For all other indications, 1 year.
Other Criteria	For initial authorization for ITP, submission of (1) platelet count less than 30 x 10^9/L or less than 50 x 10^9/L with documented increased risk of bleeding and (2) documentation patient has undergone splenectomy or tried and failed two different ITP therapies including systemic corticosteroids, immunoglobulins, danazol, fostamatinib, or cytotoxics/immunosuppressants such as rituximab is required. For initial authorization in patients with chronic hepatitis C, submission of platelet count less than 75 x 10^9/L is required. For initial authorization for AA, submission of platelet count less than 30 x 10^9/L is required. For first reauthorization, submission of an updated platelet count showing improvement from baseline is required. For each reauthorization, documented maintenance of a clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ENSACOVE (ensartinib)

Products Affected

- ENSACOVE

PA Criteria	Criteria Details
Exclusion Criteria	Prior ALK-inhibitor use, severe hepatic impairment, coadministration with moderate or strong CYP3A4 inhibitors or inducers or P-glycoprotein inhibitors
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, attestation patient has not previously received an ALK-inhibitor, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EOHILIA (budesonide oral suspension)

Products Affected

- EOHILIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation of upper endoscopy with biopsy showing at least 15 eosinophils per high-power field or 60 eosinophils/mm2, documentation of signs/symptoms, including but not limited to trouble swallowing, food sticking in esophagus, acid reflux, abdominal or chest pain, or nausea and vomiting, documentation patient has tried and failed at least an 8-week course of proton pump inhibitor therapy (i.e., patient has eosinophilic esophagitis unrelated to gastroesophageal reflux).
Age Restrictions	11 years of age or older
Prescriber Restrictions	Restricted to allergy, gastroenterology, immunology, and otolaryngology/otorhinolaryngology
Coverage Duration	12 weeks
Other Criteria	A maximum of one 12-week course will be allowed every 365 days.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EPIDIOLEX (cannabidiol)

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ERIVEDGE (vismodegib)

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EVEROLIMUS

Products Affected

- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *everolimus oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with dual strong CYP3A4/P-glycoprotein inhibitors
Required Medical Information	Diagnosis of covered use and submission of pregnancy status for female patients of childbearing potential. For postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer, documentation of treatment failure with letrozole or anastrozole and confirmation drug is being used in combination with exemestane.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FINTEPLA (fenfluramine)

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	Administration of monoamine oxidase inhibitors within 14 days of initiation
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FIRDAPSE (amifampridine)

Products Affected

- FIRDAPSE

PA Criteria	Criteria Details
Exclusion Criteria	History of seizure
Required Medical Information	Diagnosis of covered use confirmed by either electromyography or calcium channel antibody testing.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

FOTIVDA (tivozanib)

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	Uncontrolled hypertension, severe hepatic impairment, coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of baseline blood pressure reading, submission of current or previous therapies used to treat the condition (see Other Criteria), liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential, confirmation patient has not had episodes of symptomatic heart failure or unstable angina, a myocardial infarction, an arterial thrombotic event, or a significant bleeding event in the 6 months preceding the prior authorization request.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to a minimum of two previous systemic therapies, including the failure of at least one prior VEGFR inhibitor.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FRUZAQLA (fruquintinib)

Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, uncontrolled hypertension, coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of baseline blood pressure reading, submission of current or previous therapies used to treat the condition (see Other Criteria), liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential, documentation of any clinically significant cardiovascular disease or thromboembolic events, and, if there is a positive history, prescriber attestation benefit to patient outweighs potential risk of thromboembolic event.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GATTEX (teduglutide)

Products Affected

- GATTEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including confirmation of dependency on parenteral nutrition.
Age Restrictions	
Prescriber Restrictions	Restricted to gastroenterology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For the first reauthorization for adults 18 years of age or older, submission of reduction in weekly parenteral nutrition/intravenous support volume from baseline and documentation that a colonoscopy or alternate imaging of the entire colon and upper GI endoscopy with polyp removal and showing no active gastrointestinal malignancy is required. For each annual reauthorization, documented maintenance of a clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GAVRETO (pralsetinib)

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inhibitors, uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of RET gene fusion or mutation, baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GEFITINIB

Products Affected

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GILOTRIF (afatinib)

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For non-small cell lung cancer, submission of test confirming presence of non-resistant epidermal growth factor receptor mutations. For metastatic squamous non-small cell lung cancer, documentation of progression after platinum-based chemotherapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GLP-1 AGONISTS

Products Affected

- MOUNJARO SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.5ML, 12.5 MG/0.5ML, 15 MG/0.5ML, 2.5 MG/0.5ML, 5 MG/0.5ML, 7.5 MG/0.5ML
- OZEMPIC (0.25 OR 0.5 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/3ML
- OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 4 MG/3ML
- OZEMPIC (2 MG/DOSE)
- RYBELSUS (FORMULATION R2) ORAL TABLET 1.5 MG, 4 MG, 9 MG
- RYBELSUS ORAL TABLET 14 MG, 3 MG, 7 MG
- TRULICITY SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Off-label use for weight management (see Other Criteria)
Required Medical Information	Diagnosis of type 2 diabetes confirmed through one of the following: (1) medical record, or (2) ICD-10 on medical claims, or (3) laboratory results (verifying a hemoglobin A1c greater than or equal to 6.5%, a fasting plasma glucose greater than or equal to 126 mg/dL, a 2-hour postprandial blood glucose greater than or equal to 200 mg/dL after an oral glucose tolerance test, or a random plasma blood glucose greater than or equal to 200 mg/dL combined with classic signs/symptoms of hyperglycemia or hyperglycemic crisis), attestation patient is not receiving another GLP-1 agonist for the treatment of any condition.
Age Restrictions	Age must be consistent with the prescribing information of the drug and condition being treated
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	These products will not be approved for weight management as this off-label use is currently excluded from coverage under Medicare Part D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GOMEKLI (mirdametinib)

Products Affected

- GOMEKLI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GROWTH HORMONE

Products Affected

- NORDITROPIN FLEXPRO SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
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	For each annual reauthorization, submission of updated IGF-1 level, bone age (if applicable based on patient age and diagnosis), height, weight, creatinine clearance (or serum creatinine), fasting glucose, and confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HEREDITARY ANGIOEDEMA THERAPIES, ACUTE EGWP

Products Affected

- *icatibant acetate subcutaneous solution prefilled syringe* SYRINGE
- RUCONEST
- SAJAZIR SUBCUTANEOUS SOLUTION PREFILLED

PA Criteria	Criteria Details
Exclusion Criteria	Requests for prophylactic hereditary angioedema therapy
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	Restricted to allergy, dermatology, hematology, and immunology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HEREDITARY ANGIOEDEMA THERAPIES, MAINTENANCE

Products Affected

- HAEGARDA
- TAKHZYRO SUBCUTANEOUS SOLUTION
- TAKHZYRO SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 300 MG/2ML

PA Criteria	Criteria Details
Exclusion Criteria	Requests for acute hereditary angioedema (HAE) therapy (attacks)
Required Medical Information	Diagnosis of covered use, submission of objective or subjective documentation that prophylactic therapy is medically necessary, including, but not limited to activity of disease and disease burden, the frequency of HAE attacks, and quality of life.
Age Restrictions	Age must be consistent with the prescribing information of the drug
Prescriber Restrictions	Restricted to allergy, dermatology, hematology, and immunology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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
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
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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IBRANCE (palbociclib)

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming primary tumor type is HR-positive, HER2-negative, attestation the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant, pregnancy status for female patients of childbearing potential. For endocrine-resistant breast cancer, submission of genetic tumor testing confirming primary tumor type is PIK3CA-mutated, attestation patient will be taking palbociclib concurrently with inavolisib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IBTROZI (taletrectinib)

Products Affected

- IBTROZI

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inhibitors or inducers, proton pump inhibitors, or H2 receptor antagonists
Required Medical Information	Diagnosis of covered use, submission of test confirming tumor is ROS1-positive, pregnancy status for female patients of childbearing potential, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to either crizotinib or entrectinib or have contraindications to both crizotinib and entrectinib.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ICLUSIG (ponatinib)

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	Newly diagnosed chronic phase chronic myeloid leukemia (CP-CML), uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, documentation of T315I mutation status (present or absent), submission of baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For newly-diagnosed Ph+ acute lymphoblastic leukemia (ALL), attestation drug will be used with chemotherapy. For CP-CML that is not T315I-positive, documentation of resistance or intolerance to at least two prior kinase inhibitors. For Philadelphia chromosome-positive, T315I-negative ALL (monotherapy requests only), accelerated phase CML, or blast phase CML, attestation no other kinase inhibitors are indicated.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IDHIFA (enasidenib)

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of IDH2 mutation, 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IMBRUVICA (ibrutinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C), coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential. For chronic graft-versus-host disease, documentation of treatment failure with any other systemic immunosuppressive agent.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology, oncology, and transplant specialty
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMKELDI (imatinib)

Products Affected

- *imkeldi*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of clinical rationale or documentation detailing why the patient cannot use imatinib oral tablets.
Age Restrictions	
Prescriber Restrictions	Restricted to allergy, dermatology, hematology, and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

IMMUNE GLOBULIN

Products Affected

- GAMASTAN S/D
- GAMMAGARD
- GAMMAGARD S/D LESS IGA
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 10 GM/100ML, 10 GM/200ML, 2 GM/20ML, 2.5 GM/50ML, 20 GM/200ML, 5 GM/100ML, 5 GM/50ML
- PRIVIGEN

PA Criteria	Criteria Details
Exclusion Criteria	IgA-deficient patients with antibodies against IgA and a history of hypersensitivity.
Required Medical Information	Diagnosis of covered use. For ITP, submission of platelet count. For CLL, documentation of 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, intolerant, or has a contraindication to systemic corticosteroids at 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	For each reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. For IV formulations, covered as a Part B benefit if administered in the home for the treatment of primary immune deficiency. For any other combination of treatment site and indication, additional information may need to be submitted to determine if the immune globulin will be covered as a Part B or Part D benefit.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

INLYTA (axitinib)

Products Affected

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	Uncontrolled hypertension, evidence of untreated brain metastasis, recent active gastrointestinal bleeding, coadministration with strong CYP3A4/5 inducers
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential, attestation patient does not have uncontrolled hypertension and that axitinib will be used with either avelumab or pembrolizumab or, if being used as a single agent, documentation of at least one previous systemic therapy that was tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

INQOVI (decitabine/cedazuridine)

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

INREBIC (fedratinib)

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, thiamine deficiency, coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of thiamine level (see Other Criteria) and baseline platelet count, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to ruxolitinib. If baseline thiamine level is low, coverage will be delayed until thiamine is repleted.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

INVEGA INJECTABLE (paliperidone injectable suspension)

Products Affected

- INVEGA HAFYERA
- INVEGA TRINZA INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE 273 MG/0.88ML, 410 MG/1.32ML, 546 MG/1.75ML, 819 MG/2.63ML

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use. For the 3-month injection, documentation of at least 4 months' treatment with 1-month paliperidone palmitate extended-release injectable suspension. For the 6-month injection, documentation of at least 4 months' treatment with 1-month paliperidone palmitate extended-release injectable suspension or at least one 3-month injection of 3-month paliperidone palmitate extended-release injectable suspension.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ITOVEBI (inavolisib)

Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming primary tumor type is HR-positive, HER2-negative, and PIK3CA-mutated, submission of current or previous therapies used to treat the condition (see Other Criteria), attestation that patient has locally advanced or metastatic disease, has not experienced disease progression on or following other PI3K inhibitors, and will be taking inavolisib concurrently with fulvestrant and palbociclib, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to endocrine therapy (e.g., tamoxifen or an aromatase inhibitor) and must not have received prior chemotherapy for metastatic breast cancer. In addition, documentation of clinical rationale why abemaciclib, palbociclib, or ribociclib combined with endocrine therapy is not suitable for the patient must be submitted.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IWILFIN (eflornithine)

Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient demonstrated at least a partial response to prior multiagent, multimodal therapy including an anti-GD2 immunotherapy, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	2 years (see Other Criteria)
Other Criteria	Per the prescribing information, the maximum length of therapy with eflornithine is 2 years and reauthorizations for use longer than 2 years will not be approved.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JAKAFI (ruxolitinib)

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	For myelofibrosis, platelet count less than 50 x 10^9/L
Required Medical Information	Diagnosis of covered use. For myelofibrosis, submission of baseline platelet count. For polycythemia vera, documented intolerance or inadequate response to hydroxyurea. For acute graft-versus-host disease, documented inadequate response to systemic corticosteroids. For chronic graft-versus-host-disease, documented failure of at least one previous line of systemic therapy.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology, oncology, and transplant specialty
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JAYPIRCA (pirtobrutinib)

Products Affected

- JAYPIRCA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria), 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	For initial authorization for mantle cell lymphoma, the patient must have tried and failed to have an adequate response to two previous lines of therapy, including a Bruton's tyrosine kinase (BTK) inhibitor. For initial authorization for chronic lymphocytic leukemia or small lymphocytic lymphoma, the patient must have tried and failed to have an adequate response to two previous lines of therapy, including a BTK inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JOENJA (leniolisib)

Products Affected

- JOENJA

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, moderate or severe hepatic impairment (Child-Pugh class B or C)
Required Medical Information	Diagnosis of covered use including submission of test confirming presence of a pathogenic variant of either PIK3CD or PIK3R1, submission of liver function testing or Child-Pugh score, confirmation of negative pregnancy status for female patients of childbearing potential or attestation from physician patient is not pregnant and will be using a highly effective method of contraception, attestation patient is not currently using an immunosuppressive medication.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to specialists in genetic diseases or inborn errors of metabolism
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For each reauthorization, submission of objective documentation of a clinical benefit (e.g., normalization of lymphocyte subsets, normalization of lymphadenopathy, reduction in spleen size, etc.) or maintenance of a benefit previously achieved is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KETOCONAZOLE ORAL

Products Affected

- *ketoconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	Acute or chronic liver disease, treatment of fungal meningitis or fungal infections of the skin or nails
Required Medical Information	Diagnosis of culture-proven systemic blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis, submission of baseline ALT, AST, total bilirubin, alkaline phosphatase, prothrombin time and INR, prescriber attestation that the potential benefits of therapy outweigh the risks.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KISQALI (ribociclib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome, QTcF interval greater than or equal to 450 msec at treatment initiation, uncorrected hypokalemia or hypomagnesemia, coadministration with strong CYP3A4 inducers or drugs that can prolong the QT interval
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HR-positive, HER2-negative, submission of QTcF interval, serum potassium and magnesium drawn within the previous 6 months, pregnancy status for female patients of childbearing potential, attestation that the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KOSELUGO (selumetinib)

Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	Initiation: 2-17 years of age. Continuation: 2 years of age or older.
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	Selumetinib is indicated in pediatric patients and will not be approved for adults unless the patient started on the medication prior to 18 years of age.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KRAZATI (adagrasib)

Products Affected

- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome, coadministration with strong CYP3A4 inducers or drugs that prolong the QT interval
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of KRAS G12C mutation. For non-small cell lung cancer, documentation of at least one previous therapy that was tried and failed. For colorectal cancer, documentation of previous therapy with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LAPATINIB

Products Affected

- *lapatinib ditosylate*

PA Criteria	Criteria Details
Exclusion Criteria	Uncorrected hypokalemia or hypomagnesemia
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HER2-positive, submission of baseline potassium and magnesium levels, pregnancy status for female patients of childbearing potential, and attestation that the treatment regimen will include concomitant use of either capecitabine or letrozole. For patients who will be using lapatinib with capecitabine, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	For initial authorization for lapatinib in combination with capecitabine, the patient must have had prior therapy with at least an anthracycline, a taxane, and trastuzumab.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LAZCLUZE (lazertinib)

Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, attestation that the medication will be used in combination with amivantamab and will be given with anticoagulant prophylaxis for the first four months of therapy, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LENALIDOMIDE

Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, chronic lymphocytic leukemia (outside of a controlled clinical trial)
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplant (auto-HSCT), submission of absolute neutrophil count (with the requirement it is at least 1,000/mcL) and platelet count (with the requirement it is at least 75,000/mcL). For mantle cell lymphoma, documentation of at least two prior therapies tried, one of which included bortezomib (or a documented contraindication to bortezomib). For follicular lymphoma and marginal zone lymphoma, submission of prior treatments tried and attestation medication will be coadministered with a rituximab product. For transfusion-dependent anemia due to myelodysplastic syndromes, documentation of a 5q cytogenetic abnormality.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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
Exclusion Criteria	Uncorrected electrolyte abnormalities, uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, submission of baseline blood pressure, pregnancy status for female patients of childbearing potential. For thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible. For renal cell carcinoma, attestation drug will be coadministered with pembrolizumab or everolimus. If being coadministered with everolimus, submission of anti-angiogenic therapy tried and failed. For endometrial carcinoma, submission of test confirming the tumor is mismatch repair proficient or not microsatellite instability-high, submission of other systemic therapies tried and failed, attestation the candidate is not a candidate for surgery or radiation and drug will be coadministered with pembrolizumab.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LEUKINE (sargramostim, GM-CSF)

Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

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

L-GLUTAMINE

Products Affected

- *l-glutamine oral packet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of sickle cell disease, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to hematology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must be using, tried and failed to have an adequate response to, or had an intolerance/contraindication to hydroxyurea.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LIDOCAINE TRANSDERMAL PATCHES

Products Affected

- *lidocaine external patch 5 %*
- LIDOCAN
- TRIDACAINE II

PA Criteria	Criteria Details
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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LIVTENCITY (maribavir)

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including a documented history of hematopoietic stem cell or solid organ transplant, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to hematology, infectious diseases, oncology, and transplant specialty
Coverage Duration	8 weeks
Other Criteria	For authorization, the patient must have tried and failed to have an adequate response to at least one of cidofovir, foscarnet, ganciclovir, or valganciclovir.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LODOCO (colchicine)

Products Affected

- LODOCO

PA Criteria	Criteria Details
Exclusion Criteria	Requests for the treatment of gout, renal failure, severe hepatic impairment, pre-existing blood dyscrasias, coadministration with strong CYP3A4 or P-glycoprotein inhibitors
Required Medical Information	Diagnosis, documented by either (1) prior acute coronary syndrome, or (2) prior ischemic stroke, transient ischemic attack, or carotid artery stenosis greater than 50%, or (3) prior coronary revascularization, or (4) proven coronary artery disease on invasive coronary angiography or computer tomography angiography, or (5) coronary-artery calcium score greater than or equal to 300 Agatston units, or (6) aortic atherosclerotic disease, or (7) symptomatic peripheral vascular disease, submission of estimated glomerular filtration rate (eGFR) or creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance) with a requirement the eGFR or creatinine clearance is greater than or equal to 15 mL/min, and attestations patient (1) does not have severe hepatic impairment, and (2) has had a recent complete blood count and does not have evidence of any cytopenia, and (3) does not have NYHA functional Class 3 or 4 heart failure.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, submission of updated eGFR or creatinine clearance and complete blood count since the previous authorization is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LONSURF (trifluridine/tipiracil)

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For colorectal cancer, documentation of KRAS status and attestation patient was previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and, depending on KRAS status, an anti-EGFR therapy. For gastric cancer, attestation patient was previously treated with at least two lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LORBRENA (lorlatinib)

Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers, uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, baseline blood pressure, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LUMAKRAS (sotorasib)

Products Affected

- LUMAKRAS

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers, coadministration with proton pump inhibitors or H2 receptor antagonists
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of KRAS G12C mutation. For non-small cell lung cancer, attestation patient has received at least one prior systemic therapy. For colorectal cancer, attestation patient was treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LYBALVI (olanzapine/samidorphan)

Products Affected

- LYBALVI

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis, coadministration with opioids, levodopa, dopamine agonists, or strong CYP3A inducers, acute opioid withdrawal, end-stage renal disease
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and psychiatry
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to both (1) generic olanzapine, including documentation showing a positive therapeutic benefit but unacceptable weight gain as a result of the drug, and (2) one other generic second-generation antipsychotic with low incidence of metabolic side effects (e.g., aripiprazole, lurasidone, ziprasidone).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LYTGOBI (futibatinib)

Products Affected

- LYTGOBI (12 MG DAILY DOSE)
- LYTGOBI (16 MG DAILY DOSE)
- LYTGOBI (20 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with dual strong CYP3A4/P-glycoprotein inhibitors or inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of FGFR2 fusion or rearrangement, attestation previous systemic treatment has been tried, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MAVYRET (glecaprevir/pibrentasvir)

Products Affected

- MAVYRET

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment (Child-Pugh class B or C), coadministration with rifampin or atazanavir
Required Medical Information	Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) infection and HCV genotype.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Criteria for coverage duration will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MECASERMIN

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	Patients with closed epiphyses, as a substitute for growth hormone (GH) for approved GH indications
Required Medical Information	Diagnosis of covered use, documentation of primary insulin-like growth factor (IGF-1) deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH, submission of IGF-1 level and GH level.
Age Restrictions	
Prescriber Restrictions	Restricted to endocrinology and nephrology
Coverage Duration	1 year
Other Criteria	For each reauthorization, updated IGF-1 and GH levels since the previous authorization is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEGESTROL IN OLDER PATIENTS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use.
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 hematology or oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEKINIST/TAFINLAR (trametinib/dabrafenib)

Products Affected

- MEKINIST
- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of BRAF V600E or V600K mutation, pregnancy status for female patients of childbearing potential. For anaplastic thyroid cancer, BRAF V600E-mutated solid tumors, low-grade glioma, and adjuvant BRAF V600E- and/or V600K-mutated melanoma indications, confirmation that trametinib and dabrafenib will be co-administered.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEMANTINE/DONEPEZIL

Products Affected

- *memantine hcl-donepezil hcl*
- NAMZARIC ORAL CAPSULE EXTENDED RELEASE 24 HOUR 7-10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of documentation that the patient has tolerated donepezil 10 mg daily for a minimum of 1 month.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

MIFEPRISTONE (CUSHING'S SYNDROME)

Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, severe hepatic impairment, uncorrected hypokalemia, female patients with a history of unexplained vaginal bleeding or endometrial hyperplasia with atypia or endometrial carcinoma, patients using systemic corticosteroids for life-saving purposes, coadministration with strong CYP3A4 inducers, simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges
Required Medical Information	Diagnosis of covered use, attestation surgery is not an option for the patient or has not been curative, documentation patient has type 2 diabetes mellitus or glucose intolerance, submission of Child-Pugh score, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MIGLUSTAT

Products Affected

- *miglustat*
- YARGESA

PA Criteria	Criteria Details
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 (e.g., allergy, poor central venous access, hypersensitivity), submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MYTESI (crofelemer)

Products Affected

- MYTESI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, attestation infectious causes of diarrhea have been ruled out.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NERLYNX (neratinib)

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with proton pump inhibitors, strong CYP3A4 inhibitors, moderate CYP3A4 and P-glycoprotein dual inhibitors, or moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HER2-positive, confirmation member has completed adjuvant trastuzumab-based therapy or will be using in combination with capecitabine, pregnancy status for female patients of childbearing potential. For advanced or metastatic breast cancer, submission of previous anti-HER2 regimens used.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NILOTINIB

Products Affected

- DANZITEN
- *nilotinib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	Uncorrected hypokalemia or hypomagnesemia, long QT syndrome, coadministration with drugs that prolong the QT interval, proton pump inhibitors, or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, confirmation of positive Philadelphia chromosome (Ph) status, baseline serum potassium and magnesium levels.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NINLARO (ixazomib)

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inducers
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, 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NITISINONE

Products Affected

- *nitisinone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of succinylacetone in urine or plasma.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For each reauthorization, submission of objective documentation of a clinical benefit, such as reductions in urine succinylacetone level, alpha-fetoprotein level, serum tyrosine level, or serum phenylalanine level, or maintenance of a benefit previously achieved is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUCALA (mepolizumab)

Products Affected

- NUCALA SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML
- NUCALA SUBCUTANEOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	Regular (non-eosinophilic) granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)
Required Medical Information	Diagnosis of covered use. For asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), and hypereosinophilic syndrome (HES), submission of current and previous therapies used to treat the condition (see Other Criteria). For asthma, (1) documentation of a pre-bronchodilator FEV1 less than 80% predicted in adults, or less than 90% in children, and (2) submission of blood eosinophil (eos) count of at least 150 cells/mcL obtained within 6 weeks of therapy initiation or at least 300 cells/mcL within 12 months of therapy initiation. For CRSwNP, (1) documentation of evidence of nasal polyps, and (2) attestation that patient has symptomatic nasal congestion. For eosinophilic granulomatosis with polyangiitis, documentation of (1) an eos percentage greater than or equal to 10% or an absolute eos count greater than 1000 cells/cubic millimeter from the previous 6 weeks, and (2) disease lasting at least 6 months that is relapsed or refractory to oral corticosteroids and/or immunosuppressive therapies. For HES, documentation of (1) uncontrolled disease defined as a history of at least 2 flares requiring systemic therapy within the past 12 months and a blood eos count of at least 1000 cells/mcL from the previous 6 weeks, and (2) attestation disease does not have an identifiable non-hematologic secondary cause.
Age Restrictions	
Prescriber Restrictions	Restricted to allergy, hematology, immunology, otorhinolaryngology, pulmonology, and rheumatology
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For initial authorization for asthma, patient must be on a drug regimen as recommended by GINA guidelines prior to the use of biologic medications, consisting of, at a minimum, a maximally-tolerated dose of inhaled corticosteroid (ICS), a long-acting beta-agonist (LABA), and a long-acting antimuscarinic antagonist (LAMA), and the provider must attest this therapy will be continued after starting mepolizumab. For initial authorization for CRSwNP, patient must have tried an intranasal corticosteroid for at least two months (and provider must attest this will be continued after starting mepolizumab), have a contraindication to intranasal corticosteroids, or documentation must be submitted as to why this therapy is not otherwise advisable. For initial authorization for HES, patient must have been using a course of oral corticosteroids, cytotoxic therapy, or immunosuppressive therapy for at least the previous 4 weeks. For each reauthorization for asthma, confirmation patient is still using triple ICS-LABA-LAMA inhaler therapy is required. For each reauthorization for asthma, EGPA, or HES, documentation of a clinical benefit (e.g., reduction from baseline in rate of annual exacerbations or severe exacerbations, systemic corticosteroid dose, or disease symptom score, improvement in FEV1) or maintenance of a benefit previously achieved, is required. For each reauthorization for CRSwNP, confirmation patient is still using an intranasal corticosteroid, unless contraindicated, and documentation of a clinical benefit (e.g., reduction from baseline in nasal congestion, nasal polyp score or systemic corticosteroid dose) or maintenance of a benefit previously achieved is required. 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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NUPLAZID (pimavanserin)

Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	Psychosis unrelated to Parkinson's disease psychosis, cardiac arrhythmias, symptomatic bradycardia, congenital QT prolongation, coadministration with moderate or strong CYP3A4 inducers or drugs that prolong the QT interval, uncorrected hypokalemia or hypomagnesemia
Required Medical Information	Diagnosis of covered use, submission of baseline serum potassium and magnesium levels.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ODOMZO (sonidegib)

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, coadministration with strong CYP3A4 inhibitors or moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, attestation patient is not a candidate for surgery or radiation therapy or carcinoma has recurred following surgery or radiation therapy, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OFEV (nintedanib)

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment (Child-Pugh class B or C), coadministration of a dual P-glycoprotein/CYP3A4 inducer
Required Medical Information	Diagnosis of covered use, submission of liver function tests or Child-Pugh score, pregnancy status for female patients of childbearing potential. For chronic fibrosing interstitial lung diseases with a progressive phenotype and systemic sclerosis-associated interstitial lung disease, submission of HRCT scan showing fibrosis of the lungs within the previous 12 months.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to pulmonology and rheumatology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, submission of updated liver function testing or Child-Pugh score since the previous authorization and confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OGSIVEO (nirogacestat)

Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inhibitors or inducers, proton pump inhibitors, or H2 receptor antagonists
Required Medical Information	Diagnosis of covered use with documentation of tumor progression, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and sarcoma specialty
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJEMDA (tovorafenib)

Products Affected

- OJEMDA ORAL SUSPENSION RECONSTITUTED
- OJEMDA ORAL TABLET 100 MG, 100 MG (16 PACK), 100 MG (24 PACK)

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP2C8 inhibitors or inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of BRAF V600 mutation or BRAF gene fusion or rearrangement, documentation of previous systemic therapy/therapies for pediatric low-grade glioma tried and failed with a minimum of one previous therapy necessary for approval, pregnancy status for female patients of childbearing potential. If genetic testing does not reveal a BRAF gene fusion or rearrangement, documentation of previous intolerance to, contraindication to, or other reason why the patient cannot use the combination of trametinib and dabrafenib.
Age Restrictions	Initiation: 21 years of age or younger (see Other Criteria)
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	Tovorafenib is indicated as therapy in children and young adults and will not be approved for adults unless the patient started on the medication prior to 22 years of age.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OJJAARA (momelotinib)

Products Affected

- OJJAARA ORAL TABLET 100 MG, 150 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	Active infection, uncontrolled acute or chronic liver disease
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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ONUREG (azacitidine)

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	Diagnosis of myelodysplastic syndrome
Required Medical Information	Diagnosis of covered use, documentation patient achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and attestation patient cannot complete intensive curative therapy, submission of absolute neutrophil count (with the requirement it is at least 500/mcL), submission of 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORIAHNN (elagolix/estradiol/norethindrone)

Products Affected

- ORIAHNN

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, known liver impairment or disease, known osteoporosis, undiagnosed abnormal uterine bleeding, women who are at increased risk of, have a history of, or currently have thrombotic or thromboembolic disorders (including women over 35 years of age who smoke and women with uncontrolled hypertension), current/history of breast cancer or other hormone-sensitive cancer
Required Medical Information	Diagnosis of covered use, attestation patient is premenopausal, submission of baseline blood pressure, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	Restricted to endocrinology and gynecology
Coverage Duration	2 years (see Other Criteria)
Other Criteria	Use of this drug for more than 2 years increases risk of bone loss and requests for therapy for more than 2 years will not be approved.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORILISSA (elagolix)

Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, severe hepatic impairment (Child-Pugh class C), known osteoporosis, coadministration with OATP1B1 inhibitors
Required Medical Information	Diagnosis of covered use, attestation patient is premenopausal and will be using non-hormonal contraception during therapy, submission of liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential. If the patient has previously used elagolix, submission of dose used and number of total months of prior use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology and gynecology
Coverage Duration	Up to 24 months based on dose and coexisting conditions (see Other Criteria)
Other Criteria	Due to increased risk of bone loss, maximum duration of use is limited based on dose and coexisting conditions. For (1) endometriosis with dyspareunia where dose will be 200 mg twice daily, or (2) women with moderate hepatic impairment, the maximum duration of use is 6 months. Requests for use greater than 6 months will not be approved in these situations. For (3) endometriosis without dyspareunia, 150 mg daily for 24 months. Requests for use greater than 24 months will not be approved in this situation.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORSERDU (elacestrant)

Products Affected

- ORSERDU

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C), coadministration with moderate or strong CYP3A inhibitors or inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming the primary tumor type is ER-positive, HER2-negative, and ESR1-mutated, submission of liver function testing or Child-Pugh score, attestation patient had disease progression after at least one prior endocrine therapy. For female patients, attestation patient is postmenopausal.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

OXERVATE (cenegermin-bkbj)

Products Affected

- OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use confirming Stage 2 or 3 neurotrophic keratitis in at least one eye.
Age Restrictions	
Prescriber Restrictions	Restricted to optometry and ophthalmology
Coverage Duration	8 weeks
Other Criteria	PA applies to all. Safety and efficacy beyond on 8-week course of therapy is not established and will not be authorized.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OXYBATE SALT MEDICATIONS

Products Affected

- *sodium oxybate*

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with sedative hypnotics, diagnosis of insomnia
Required Medical Information	Diagnosis of covered use confirmed with documentation from a sleep study. For adults with excessive daytime sleepiness associated with narcolepsy, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	7 years of age or older
Prescriber Restrictions	Restricted to neurology, psychiatry, and sleep medicine
Coverage Duration	1 year
Other Criteria	For initial authorization for adults with excessive daytime sleepiness associated with narcolepsy, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to both (1) armodafinil or modafinil, and (2) solriamfetol. For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PANRETIN (alitretinoin)

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, instances where systemic Kaposi sarcoma therapy is required (more than 10 new Kaposi's sarcoma lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary Kaposi sarcoma, or symptomatic visceral involvement)
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to dermatology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PARKINSON'S DISEASE "OFF" EPISODE (AS NEEDED) THERAPIES

Products Affected

- *apomorphine hcl subcutaneous*
- INBRIJA

PA Criteria	Criteria Details
Exclusion Criteria	For Inbrija, administration of non-selective monoamine oxidase inhibitors within 14 days of initiation, asthma, COPD, or other chronic underlying lung disease.
Required Medical Information	Diagnosis of covered use, attestation patient is experiencing "off" episodes despite carbidopa/levodopa therapy, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to medications from at least two different classes that can help to reduce off episodes (COMT inhibitors, dopamine agonists, monoamine oxidase B inhibitors), unless contraindicated. For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PAZOPANIB

Products Affected

- *pazopanib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, uncontrolled hypertension, uncorrected hypokalemia, hypocalcemia, or hypomagnesemia, coadministration with strong CYP3A4 inducers, proton pump inhibitors, H2-receptor antagonists, or drugs that can prolong the QT interval
Required Medical Information	Diagnosis of covered use, submission of baseline blood pressure, serum potassium, calcium, and magnesium levels, pregnancy status for female patients of childbearing potential. For soft tissue sarcoma, submission of previous chemotherapy regimen(s).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PEGFILGRASTIM

Products Affected

- UDENYCA
- UDENYCA ONBODY

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

PEMAZYRE (pemigatinib)

Products Affected

- PEMAZYRE ORAL TABLET 13.5 MG, 4.5 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of either FGFR1 rearrangement or FGFR2 fusion or rearrangement depending on the indication, attestation patient has used previous systemic treatment for the indication, submission of 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PIQRAY (alpelisib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HR-positive, HER2-negative, and PIK3CA-mutated, attestation that patient has advanced or metastatic disease and will be taking concurrently with fulvestrant, submission of at least one endocrine-based (e.g., anastrozole, exemestane, letrozole, tamoxifen, etc.) regimen tried and failed, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PIRFENIDONE

Products Affected

- *pirfenidone oral tablet 267 mg, 801 mg*

PA Criteria	Criteria Details
Exclusion Criteria	End-stage renal disease on dialysis, severe hepatic impairment (Child-Pugh class C)
Required Medical Information	Diagnosis of covered use, submission of liver function tests or Child-Pugh score.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, submission of updated liver function testing or Child-Pugh score since the previous authorization and confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

POMALYST (pomalidomide)

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For multiple myeloma, documentation patient has previously used lenalidomide and a proteasome inhibitor and patient has demonstrated disease progression on or within 60 days of the completion of the previous therapy. For Kaposi sarcoma, attestation patient is HIV-negative or patient has failed highly-active antiretroviral therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PRETOMANID

Products Affected

- *pretomanid*

PA Criteria	Criteria Details
Exclusion Criteria	Inability to use bedaquiline or linezolid, drug-sensitive tuberculosis, coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, attestation pretomanid will be used in combination with bedaquiline and linezolid.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to infectious diseases and pulmonology
Coverage Duration	26 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PREVYMIS (letermovir)

Products Affected

- PREVYMIS ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C), coadministration with ergot alkaloids, pimozide, or pitavastatin or simvastatin when coadministered with cyclosporine
Required Medical Information	Diagnosis of covered use, submission of day number post-transplant. For use after kidney transplant, documentation patient is high risk, defined as donor CMV seropositive/recipient CMV seronegative (D+/R-), submission of explanation why valganciclovir is contraindicated or cannot be used for prophylaxis.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology, infectious diseases, oncology, and transplant speciality
Coverage Duration	100 days post-HSCT or 200 days post-kidney transplant or post-HSCT at risk for late CMV infection
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PRIOR AUTHORIZATION TO OVERRIDE SPECIALTY RESTRICTIONS

Products Affected

- CORLANOR ORAL SOLUTION
- *diclofenac sodium external gel 3 %*
- *ivabradine hcl oral tablet 5 mg, 7.5 mg*
- NAYZILAM
- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE NASAL LIQUID THERAPY PACK 2 X 7.5 MG/0.1ML
- VALTOCO 20 MG DOSE NASAL LIQUID THERAPY PACK 2 X 10 MG/0.1ML
- VALTOCO 5 MG DOSE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. Drugs in this policy require prior authorization but are exempted from this requirement if prescribed by certain specialists (see Prescriber Restriction).
Age Restrictions	
Prescriber Restrictions	(1) for Corlanor and ivabradine: cardiology exempt, (2) for diclofenac 3% gel: dermatology and oncology exempt, (3) for Nayzilam and Valtoco: neurology exempt, (4) for Pegasys: gastroenterology, hepatology, and infectious diseases exempt
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PROLASTIN-C (alpha-1-proteinase inhibitor)

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Individuals with immunoglobulin A (IgA) deficiency who have known antibodies against IgA
Required Medical Information	Diagnosis of covered use, submission of pre-treatment alpha-1-antitrypsin (AAT) showing levels below 11 mmol/L (80 mg/dL), 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	For each reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. 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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PROMETHAZINE IN OLDER PATIENTS

Products Affected

- *promethazine hcl oral solution 6.25 mg/5ml*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal suppository 12.5 mg, 25 mg*
- *promethazine-phenylephrine*
- PROMETHEGAN RECTAL SUPPOSITORY 25 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. 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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PROSTATE CANCER ORAL MEDICATIONS

Products Affected

- AKEEGA
- ERLEADA
- NUBEQA
- XTANDI

PA Criteria	Criteria Details
Exclusion Criteria	For Akeega, severe hepatic impairment (Child-Pugh class C), uncontrolled hypertension, uncontrolled hypokalemia
Required Medical Information	Diagnosis of covered use. For Nubeqa, submission of current or previous therapies used to treat the condition (see Other Criteria). For Akeega, submission of test confirming presence of deleterious BRCA mutation, Child-Pugh score or liver function testing, baseline blood pressure reading, and serum potassium level.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and urology
Coverage Duration	1 year
Other Criteria	For initial authorization of Nubeqa, the patient must have tried and failed to have an adequate response or had an intolerance to both Erleada and Xtandi.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

PULMONARY HYPERTENSION MEDICATIONS

Products Affected

- ALYQ
- *ambrisentan oral tablet 10 mg, 5 mg*
- *bosentan oral tablet 125 mg, 62.5 mg*
- OPSUMIT
- ORENITRAM
- ORENITRAM MONTH 1
- ORENITRAM MONTH 2
- ORENITRAM MONTH 3
- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate oral tablet 20 mg*
- *tadalafil (pah)*

PA Criteria	Criteria Details
Exclusion Criteria	For ambrisentan, bosentan, or Opsumit, pregnancy. For ambrisentan or Orenitram, moderate or severe hepatic impairment. For tadalafil, severe hepatic impairment or creatinine clearance below 30 mL/min or on hemodialysis. For ambrisentan, idiopathic pulmonary fibrosis.
Required Medical Information	Diagnosis of covered use confirmed by right heart catheterization, submission of mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, pulmonary vascular resistance greater than 2 Woods units, and attestation patient is WHO Group 1. For ambrisentan, bosentan, or Opsumit, submission of pregnancy status for female patients of childbearing potential. For Opsumit only, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	For all drugs in this policy except bosentan, 18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	For initial authorization of Opsumit, the patient must have tried and failed to have an adequate response to or had an intolerance to ambrisentan or bosentan.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

QINLOCK (ripretinib)

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	Uncontrolled hypertension, coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of previous kinase inhibitor therapies, baseline blood pressure reading, baseline left ventricular ejection fraction with a requirement it is greater than or equal to 50%, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RADICAVA ORS (edaravone)

Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of ALS Functional Rating Scale - Revised (ALSFRS-R) scoring with the requirement the patient has scores of 2 points or better on each of the 12 individual ALSFRS-R items.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RECORLEV (levoketoconazole)

Products Affected

- RECORLEV

PA Criteria	Criteria Details
Exclusion Criteria	Treatment of fungal infection, cirrhosis, acute, poorly-controlled chronic, or extensive metastatic liver disease, baseline AST or ALT greater than 3 times the upper limit of normal, recurrent symptomatic cholelithiasis, a prior history of drug-induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, prolonged QTcF interval greater than 470 msec at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, prolonged QT syndrome, coadministration with drugs that cause QT prolongation associated with ventricular arrhythmias
Required Medical Information	Diagnosis of covered use, submission of 24-hour urine free cortisol (UFC) level demonstrating a baseline value more than 1.5 times the upper limit of normal (50 micrograms or 145 nmol), attestation pituitary gland surgery is not an option for the patient or has not been curative, electrocardiogram (including QTcF), and liver function tests all performed within 3 months of prior authorization request, documentation patient tried and failed at least one other therapy for Cushing's syndrome (e.g., mifepristone, pasireotide).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	1 year
Other Criteria	For each reauthorization, documentation of clinically relevant response to therapy, including but not limited to reduction of 24-hour UFC level, or maintenance of a benefit previously achieved, is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RETACRIT (epoetin alfa-epbx)

Products Affected

- RETACRIT INJECTION SOLUTION 10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 40000 UNIT/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of hemoglobin level less than 10 g/dL (at initial submission for non-surgery indications only), attestation serum iron, total iron-binding capacity (TIBC), and transferrin saturation level have been assessed within 30 days of request date, documentation that the patient does not have uncontrolled hypertension.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	ESRD-related conditions or anemia due to zidovudine therapy: 1 year. All other indications: 90 days.
Other Criteria	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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RETEVMO (selpercatinib)

Products Affected

- RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	Uncontrolled hypertension, coadministration with moderate or strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of RET gene fusion or mutation, baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For RET fusion-positive thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible. For solid tumors with a RET gene fusion, documentation of previous systemic therapy tried or reason why patient has no satisfactory alternative treatment options.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REVCOVI (elapegademase-lvlr)

Products Affected

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	Severe thrombocytopenia
Required Medical Information	Diagnosis of covered use confirmed by either biochemical testing showing less than 1% of adenosine deaminase (ADA) catalytic activity in red blood cells or genetic testing showing biallelic ADA pathogenic variants, submission of baseline plasma ADA level (if genetic testing was submitted as confirmation of diagnosis) and platelet count.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology, immunology, and specialists in genetic diseases
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, submission of updated plasma ADA level demonstrating an improvement from baseline and platelet count is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REVUFORJ (revumenib)

Products Affected

- REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	QTcF interval greater than 450 msec at treatment initiation, white blood cell (WBC) count greater than 25 x 10^9/L, uncorrected hypokalemia or hypomagnesemia, coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of a lysine methyltransferase 2A gene (KMT2A) translocation that is not a 11q23 partial tandem duplication, submission of baseline QTcF interval, serum potassium, serum magnesium, baseline WBC count, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZDIFFRA (resmetirom)

Products Affected

- REZDIFFRA

PA Criteria	Criteria Details
Exclusion Criteria	Decompensated cirrhosis, moderate or severe hepatic impairment
Required Medical Information	Diagnosis of covered use, confirmation patient has F2 or F3 fibrosis by either liver biopsy, magnetic resonance elastography, or vibration-controlled elastography, submission of liver function testing or Child-Pugh score.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to gastroenterology and hepatology
Coverage Duration	1 year
Other Criteria	For the first reauthorization, documentation confirming resolution of metabolic dysfunction-associated steatohepatitis or improvement or stabilization of fibrosis stage from baseline, as assessed by biopsy or noninvasive testing, is required. For each annual reauthorization, documented maintenance of a clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZLIDHIA (olutasidenib)

Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of IDH1 mutation, 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZUROCK (belumosudil)

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment (Child-Pugh class B or C) without liver graft-versus-host disease
Required Medical Information	Diagnosis of covered use, submission of at least 2 previous therapies tried and failed for chronic graft-versus-host disease, pregnancy status for female patients of childbearing potential.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to hematology, oncology, and transplant specialty
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RIVFLOZA (nedosiran)

Products Affected

- RIVFLOZA

PA Criteria	Criteria Details
Exclusion Criteria	Estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73 m2
Required Medical Information	Diagnosis of covered use, documentation of AGXT mutation confirmed by liver enzyme analysis or genetic testing, submission of 24-hour urinary oxalate (Uox) excretion with a requirement it is greater than or equal to 0.7 mmol (normalized to body surface area if patient is under 18 years of age) and eGFR, attestation patient has not received a prior kidney or liver transplant, attestation patient will not be using in combination with lumasiran (Oxlumo).
Age Restrictions	
Prescriber Restrictions	Restricted to nephrology and urology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For the first reauthorization, documentation of clinically relevant response to therapy as evidenced by reduced Uox or plasma oxalate levels is required. For each annual reauthorization, documented maintenance of a clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ROMVIMZA (vimseltinib)

Products Affected

- ROMVIMZA

PA Criteria	Criteria Details
Exclusion Criteria	Active liver or biliary tract disease (including increased ALP), pre-existing increased serum transaminases, total or direct bilirubin greater than the upper limit of normal
Required Medical Information	Diagnosis of covered use (and documentation surgical intervention is not possible or practical), submission of serum transaminases, total and direct bilirubin, and ALP, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ROZLYTREK (entrectinib)

Products Affected

- ROZLYTREK

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers or drugs that prolong the QTc interval
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For non-small cell lung cancer, submission of test confirming presence of ROS1-positive tumor. For solid tumors, submission of evidence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation and attestation tumor is metastatic or surgical resection/other systemic therapies are unsatisfactory treatment options.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RUBRACA (rucaparib)

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of deleterious BRCA mutation. For ovarian, fallopian tube, or primary peritoneal cancer, documentation of response to platinum-based chemotherapy and submission of pregnancy status for female patients of childbearing potential. For BRCA mutation-associated metastatic castration-resistant prostate cancer, confirmation patient (1) has been treated with or is not a candidate for taxane-based chemotherapy, and (2) is using a gonadotropin-releasing hormone analog or has had a bilateral orchiectomy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and urology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RYDAPT (midostaurin)

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For acute myeloid leukemia, submission of test confirming presence of FLT3 mutation, attestation patient will be receiving cytarabine and daunorubicin induction and cytarabine consolidation with midostaurin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to allergy, hematology, and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SAPROPTERIN

Products Affected

- JAVYGTOR
- *sapropterin dihydrochloride oral packet*
- *sapropterin dihydrochloride oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of blood phenylalanine concentration.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For the first reauthorization, documentation of reduction in blood phenylalanine concentration from pre-treatment baseline is required. For each annual reauthorization, documented maintenance of a clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SCEMBLIX (asciminib)

Products Affected

- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For use in patients with a T315I mutation, documentation patient has first tried and failed or become intolerant to ponatinib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SECOND-GENERATION ANTIPSYCHOTICS

Products Affected

- CAPLYTA ORAL CAPSULE 10.5 MG, 21 MG, 42 MG
- COBENFY
- COBENFY STARTER PACK
- FANAPT ORAL TABLET 1 MG, 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG
- FANAPT TITRATION PACK
- FANAPT TITRATION PACK A
- FANAPT TITRATION PACK B ORAL TABLET
- FANAPT TITRATION PACK C ORAL TABLET
- REXULTI ORAL TABLET 0.25 MG, 0.5 MG, 1 MG, 2 MG, 3 MG, 4 MG
- SECUADO TRANSDERMAL PATCH 24 HOUR 3.8 MG/24HR, 5.7 MG/24HR, 7.6 MG/24HR

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis. For Cobenfy only, moderate to severe renal impairment, urinary retention, gastric retention, hepatic impairment, untreated narrow-angle glaucoma.
Required Medical Information	Diagnosis of covered use. For schizophrenia, an indication related to bipolar disorder type I, or for Rexulti for major depressive disorder, submission of current or previous therapies used to treat the condition (see Other Criteria). For Cobenfy only, submission of estimated glomerular filtration rate with the requirement it is at least 60 mL/min, attestation patient does not have hepatic impairment.
Age Restrictions	
Prescriber Restrictions	Restricted to psychiatry
Coverage Duration	1 year
Other Criteria	For initial authorization for schizophrenia or acute treatment of manic/mixed episodes of bipolar I disorder, the patient must have tried and failed to have an adequate response to or had an intolerance to aripiprazole and at least one other generic second-generation atypical antipsychotic. For initial authorization of Caplyta for depressive episodes associated with bipolar I disorder, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two of the following drugs: cariprazine, lurasidone, olanzapine, or quetiapine. For Rexulti as an adjunctive therapy to antidepressants for major depressive disorder, the patient must have tried and failed to have an adequate response to or had an intolerance to aripiprazole and cariprazine or quetiapine.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SEDATIVE HYPNOTICS IN OLDER PATIENTS

Products Affected

- AMBIEN
- AMBIEN CR
- *eszopiclone*
- *zaleplon*
- *zolpidem tartrate er*
- *zolpidem tartrate oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation at least two of the following medications were tried and deemed ineffective or intolerable: Belsomra, doxepin tablets, ramelteon, and trazodone.
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	Sedative hypnotic medications are high-risk medications in older patients due to increased risks of cognitive impairment, delirium, unsteady gait, syncope, falls, fractures, and motor vehicle accidents.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SIGNIFOR (pasireotide)

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C), uncorrected hypokalemia or hypomagnesemia
Required Medical Information	Diagnosis of covered use, submission of 24-hour urine free cortisol (UFC) level demonstrating a baseline value more than 1.5 times the upper limit of normal (50 micrograms or 145 nmol), attestation pituitary gland surgery is not an option for the patient or has not been curative, submission of ALT, aspartate aminotransferase, alkaline phosphatase, total bilirubin, and serum potassium and magnesium levels.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	1 year
Other Criteria	For the first reauthorization, documentation of clinically relevant response to therapy including but not limited to reduction of 24-hour UFC level is required. For each annual reauthorization, documented maintenance of a clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SIMVASTATIN 80 mg per day

Products Affected

- *ezetimibe-simvastatin oral tablet 10-80 mg*
- *simvastatin oral tablet 80 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation that patient has been taking simvastatin 80 mg daily for 30 days or longer without adverse effects.
Age Restrictions	10 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Not recommended as initial therapy nor for patients already taking lower doses of simvastatin whose response is inadequate.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SIVEXTRO (tedizolid)

Products Affected

- SIVEXTRO

PA Criteria	Criteria Details
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	
Prescriber Restrictions	Restricted to infectious diseases
Coverage Duration	6 days
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SKYCLARYS (omaveloxolone)

Products Affected

- SKYCLARYS

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C), coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use confirmed by genetic testing, submission of liver function testing or Child-Pugh score.
Age Restrictions	16 years of age or older
Prescriber Restrictions	Restricted to neurology and specialists in genetic diseases
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SOFOSBUVIR/VELPATASVIR

Products Affected

- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) infection and HCV genotype, attestation that patients with decompensated cirrhosis will receive concomitant ribavirin therapy unless ribavirin therapy is contraindicated.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SOHONOS (palovarotene)

Products Affected

- SOHONOS

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of R206H ACVR1 mutation, pregnancy status for female patients of childbearing potential.
Age Restrictions	For female patients, 8 years of age or older. For male patients, 10 years of age or older.
Prescriber Restrictions	Restricted to orthopedics, rheumatology, and specialists in rare connective tissue diseases
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) and attestation the patient continues to undergo regular pregnancy testing (as necessary for patients of childbearing potential) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SOMAVERT (pegvisomant)

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including attestation that surgery or radiation was not curative or is not an option, submission of baseline IGF-1, submission of baseline liver function testing (LFT) including bilirubin with the requirement liver transaminases are less than or equal to 3 times the upper limit of normal (ULN). If liver transaminases are greater than 3 times ULN, submission of the cause of liver dysfunction determined through a comprehensive workup.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	1 year
Other Criteria	For the first reauthorization, submission of updated IGF-1 level demonstrating an improvement from baseline, LFT showing liver transaminases below 5 times the ULN, and attestation patient does not have signs or symptoms of liver injury (e.g., jaundice, elevated bilirubin level or bilirubinuria, fatigue, nausea, vomiting, right upper quadrant pain, ascites, unexplained edema, easy bruisability) is required. For each annual reauthorization, documented improvement/maintenance of IGF-1 level is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SORAFENIB

Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome, coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For differentiated thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

STIVARGA (regorafenib)

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	Severe or uncontrolled hypertension, coadministration with strong CYP3A4 inhibitors or inducers
Required Medical Information	Diagnosis of covered use, submission of baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For metastatic colorectal cancer, documentation of previous treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy. For gastrointestinal stromal tumor, documentation of previous treatment with imatinib and sunitinib. For hepatocellular carcinoma, documentation of previous treatment with sorafenib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SUCRAID (sacrosidase)

Products Affected

- SUCRAID

PA Criteria	Criteria Details
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	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SUNITINIB

Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For gastrointestinal stromal tumor, documentation of prior use of imatinib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TABRECTA (capmatinib)

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of MET exon 14 skipping mutation, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAFAMIDIS

Products Affected

- VYNDAMAX
- VYNDAQEL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of transthyretin amyloid cardiomyopathy (ATTRwt or ATTRm) confirmed by one of the following: (1) presence of amyloid deposits on cardiac biopsy, (2) presence of transthyretin precursor protein confirmed on immunohistochemical analysis, (3) technetium 99-labeled nuclear scintigraphy or single-photon emission computer tomography (SPECT), or (4) a TTR genetic mutation plus cardiac involvement defined as thickening of the interseptal ventricular wall. In addition, patients should also have documentation of history of heart failure, with at least one prior hospitalization for heart failure or clinical evidence of heart failure with signs or symptoms of volume overload requiring treatment with a diuretic for improvement.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAGRISSO (osimertinib)

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of EGFR exon 19 deletions, exon 21 L858R mutations, or T790M mutations, pregnancy status for female patients of childbearing potential. For EGFR T790M mutation-positive NSCLC, submission of previous EGFR tyrosine kinase inhibitor therapy used for indication.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TALZENNA (talazoparib)

Products Affected

- TALZENNA ORAL CAPSULE 0.1 MG, 0.25 MG, 0.35 MG, 0.5 MG, 0.75 MG, 1 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For breast cancer, submission of test results confirming germline BRCA mutation-positive, human epidermal growth factor receptor 2 (HER2) negative disease. For prostate cancer, submission of test results confirming HRR gene-mutated disease, confirmation talazoparib will be used in combination with enzalutamide.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TASIMELTEON

Products Affected

- *tasimelteon*

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, coadministration with strong CYP1A2 inhibitors or CYP3A4 inducers
Required Medical Information	Diagnosis of covered use. For non-24-hour sleep-wake disorder, attestation patient is totally blind. For Smith-Magenis Syndrome, documentation of genetic testing results confirming chromosome 17p11.2 deletion.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology and sleep medicine
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAVNEOS (avacopan)

Products Affected

- TAVNEOS

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inducers, active serious infection, chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis, cirrhosis
Required Medical Information	Diagnosis of covered use (granulomatosis with polyangiitis or microscopic polyangiitis variants of anti-neutrophil cytoplasmic antibody [ANCA]-associated vasculitis), submission of HBV serology testing, attestation patient is using rituximab, cyclophosphamide/azathioprine, or another compendium-supported therapy for the treatment of ANCA-associated vasculitis, along with glucocorticoids.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to immunology, nephrology, pulmonology, and rheumatology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For the first reauthorization, documentation of clinically relevant response to therapy, including but not limited to disease remission defined using changes in Birmingham Vasculitis Activity Score, a documented reduction in maintenance glucocorticoid dose, or improved or sustained renal function, is required. For each annual reauthorization, documented maintenance of a clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAZVERIK (tazemetostat)

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For relapsed/refractory follicular lymphoma, documentation (1) of test confirming presence of EZH2 mutation and treatment with at least two prior systemic therapies, or (2) patient has no satisfactory alternative treatment option.
Age Restrictions	16 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TEPMETKO (tepotinib)

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of MET exon 14 skipping mutation, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TERIPARATIDE

Products Affected

- *teriparatide subcutaneous solution pen-injector 560 mcg/2.24ml, 620 mcg/2.48ml*

PA Criteria	Criteria Details
Exclusion Criteria	Pre-existing hypercalcemia, underlying hypercalcemic disorder (such as primary hyperparathyroidism), patients with an increased risk of osteosarcoma (such as those with Paget's disease)
Required Medical Information	Diagnosis of covered use where "high risk for fracture" is defined as documentation of (1) a history of fracture of the hip or vertebra regardless of bone mineral density (BMD), or (2) a history of fracture of the proximal humerus, pelvis, or distal forearm and T-score between -1.0 and -2.5, or (3) T-score less than or equal to -2.5 at the total hip, femoral neck, spine, or distal third of the radius, or (4) T-score between -1.0 and -2.5 at the total hip, femoral neck, spine, or distal third of the radius, and (a) a 10-year probability of hip fracture as assessed by FRAX score of at least 3%, or (b) a 10-year probability of a major osteoporosis-related fracture as assessed by FRAX score of at least 20%, submission of baseline serum calcium, postmenopausal status, current or previous therapies used to treat the condition (see Other Criteria), 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 unless patient is at high risk for fracture after 2 years of therapy (see Other Criteria)
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to at least one bisphosphonate. Therapeutic failure is defined as either a fracture or a decrease in BMD while using a bisphosphonate for at least 3 months. Use of parathyroid hormone analogs and/or parathyroid hormone related peptides for more than 2 years during a patient's lifetime is generally not recommended. For annual reauthorization beyond 2 years, submission of updated serum calcium since initial authorization and evidence the patient remains at high risk for fracture as defined in the Required Medical Information section is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

TESTOSTERONE REPLACEMENT PRODUCTS

Products Affected

- *testosterone transdermal gel 10 mg/act (2%), 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
Exclusion Criteria	History of breast cancer
Required Medical Information	Diagnosis of covered use, submission of serum testosterone level, attestation that patient has been evaluated for the presence of prostate cancer prior to initiation of therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, submission of increased serum testosterone level (or maintenance of a previous increase in serum testosterone level) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TIBSOVO (ivosidenib)

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of IDH1 mutation. For cholangiocarcinoma, documentation of at least one previous therapy that was tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TOLVAPTAN (ADPKD)

Products Affected

- *tolvaptan oral tablet 15 mg, 30 mg*
- *tolvaptan oral tablet therapy pack 15 mg, 30 & 15 mg, 45 & 15 mg, 60 & 30 mg, 90 & 30 mg*

PA Criteria	Criteria Details
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, coadministration with strong CYP3A inhibitors or inducers or desmopressin
Required Medical Information	Diagnosis of covered use where rapidly progressing autosomal dominant polycystic kidney disease is defined as positive identification of kidney cysts on imaging plus (1) Mayo Imaging Classification 1C, 1D, or 1E, or (2) historical eGFR decline of at least 3 mL/min/1.73 m2 year over a 4-year period, or (3) PROPKD score greater than 6, submission of serum sodium concentration.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to nephrology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOLVAPTAN (HYPONATREMIA)

Products Affected

- *tolvaptan (hyponatremia)*

PA Criteria	Criteria Details
Exclusion Criteria	Underlying liver disease, need to raise serum sodium acutely, inability to sense or respond to thirst, hypovolemia, anuria, coadministration with strong CYP3A inhibitors or inducers or desmopressin
Required Medical Information	Diagnosis of covered use, submission of evidence of clinically significant hyponatremia, defined as (1) serum sodium less than 125 mEq/L, or (2) serum sodium less than 135 mEq/L that is symptomatic and has resisted correction with fluid restriction.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	30 days (see Other Criteria)
Other Criteria	Treatment should be initiated in a setting where serum sodium can be monitored closely. Treatment is limited to 30 days to prevent liver injury. This formulation of tolvaptan will not be approved for autosomal dominant polycystic kidney disease (ADPKD) as it is not indicated for ADPKD and the tolvaptan formulation approved for ADPKD has a mandatory REMS program, making it only available through a restricted distribution program.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TOPICAL RETINOIDS

Products Affected

- *adapalene external cream*
- *adapalene external gel 0.3 %*
- *tazarotene external cream*
- *tazarotene external gel*
- *tretinoin external cream*
- *tretinoin external gel 0.01 %, 0.025 %*

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic use (e.g., hyperpigmentation, keloids, photoaging, wrinkles)
Required Medical Information	For adapalene or tretinoin, diagnosis of acne vulgaris. For tazarotene, diagnosis of acne vulgaris or plaque psoriasis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of improvement previously achieved) is required. Drugs in this policy will not be approved for cosmetic uses as these uses are currently excluded from coverage under Medicare Part D.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRUQAP (capivasertib)

Products Affected

- TRUQAP ORAL TABLET
- TRUQAP ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming that the primary tumor type is HR-positive, HER2-negative and has at least one PIK3CA, AKT1, and/or PTEN mutation, submission of pregnancy status for female patients of childbearing potential, attestation patient has (1) progressed on at least one endocrine-based regimen in the metastatic setting, or (2) has recurrent disease on or within 12 months of completing adjuvant therapy, attestation drug will be given with fulvestrant.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TUKYSA (tucatinib)

Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, coadministration with strong CYP3A inducers or moderate CYP2C8 inducers
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming that the primary tumor type is HER2-positive, pregnancy status for female patients of childbearing potential. For breast cancer, submission of previous anti-HER2-directed therapy. For metastatic colon cancer, documentation tumor is RAS wild-type, attestation patient experienced progression following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TURALIO (pexidartinib)

Products Affected

- TURALIO ORAL CAPSULE 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	Active liver or biliary tract disease (including increased ALP), pre-existing increased serum transaminases, total or direct bilirubin greater than the upper limit of normal, coadministration with other hepatotoxic medications, strong CYP3A inducers, or proton pump inhibitors
Required Medical Information	Diagnosis of covered use (and documentation surgical intervention is not possible or practical), documentation of patient's severe morbidity or functional limitations, submission of serum transaminases, total and direct bilirubin, and ALP, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VALCHLOR (mechlorethamine)

Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	Use as initial therapy
Required Medical Information	Diagnosis of covered use, submission of previous skin-directed therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to dermatology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VANFLYTA (quizartinib)

Products Affected

- VANFLYTA

PA Criteria	Criteria Details
Exclusion Criteria	Requests for maintenance monotherapy after allogeneic hematopoietic stem cell transplant, uncorrected hypokalemia or hypomagnesemia, long QT syndrome, QTcF interval greater than 450 msec at treatment initiation, coadministration with moderate or strong CYP3A inducers
Required Medical Information	Diagnosis of covered use including submission of test confirming presence of FLT3 internal tandem duplication-positive mutation, submission of QTcF interval, baseline serum potassium and magnesium levels, and pregnancy status for female patients of childbearing potential, attestation patient does not have history of ventricular arrhythmias or torsades de pointes.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VENCLEXTA (venetoclax)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers. For CLL/SLL, coadministration with strong CYP3A inhibitors at treatment initiation and initial dosage titration.
Required Medical Information	Diagnosis of covered use, 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VEOZAH (fezolinetant)

Products Affected

- VEOZAH

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with CYP1A2 inhibitors, severe renal impairment or end-stage renal disease, known cirrhosis, any aminotransferase or total bilirubin at or above 2 times the upper limit of normal
Required Medical Information	Diagnosis of covered use, submission of estimated glomerular filtration rate, liver function testing, current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two prior systemic hormone therapies or FDA-approved or compendia-supported non-hormonal therapies (e.g., SSRI, SNRI, clonidine, gabapentin, etc.) for the treatment of vasomotor symptoms due to menopause. The drugs tried must come from different medication classes. For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VERQUVO (vericiguat)

Products Affected

- VERQUVO ORAL TABLET 10 MG, 2.5 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, concomitant use of another soluble guanylate cyclase (sGC) stimulator or a phosphodiesterase-5 (PDE-5) inhibitor
Required Medical Information	Diagnosis, including either hospitalization for heart failure with reduced ejection fraction (HFrEF) within the previous 6 months or outpatient IV diuretic use within the previous 3 months, submission of left ventricular ejection fraction with the requirement it is less than 45%, pregnancy status for female patients of childbearing potential, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient's regimen for HFrEF must be submitted and must include (1) an angiotensin-converting enzyme (ACE) inhibitor, angiotensin II receptor blocker (ARB), or sacubitril/valsartan, and (2) a beta-blocker (BB), and (3) a mineralocorticoid receptor antagonist, each at maximally-tolerated doses. Using the recommended dose of each therapeutic component to treat HFrEF is required. If the doses of any of these three components have not been optimized to the recommended dose to treat HFrEF or any of these three therapies are not currently being used, prescriber is required to submit documentation as to why (e.g., intolerances, physiologic parameters, contraindications, etc.). If the patient is using a BB not indicated for HFrEF, the patient will be required to switch to one of the three FDA-approved BBs for HFrEF (bisoprolol, carvedilol, or metoprolol succinate). For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VERZENIO (abemaciclib)

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inducers or ketoconazole
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming that the primary tumor type is HR-positive, HER2-negative, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VIBERZI (eluxadoline)

Products Affected

- VIBERZI

PA Criteria	Criteria Details
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	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VIJOICE (alpelisib)

Products Affected

- VIJOICE ORAL PACKET
- VIJOICE ORAL TABLET THERAPY PACK 125 MG, 200 & 50 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use including at least one target lesion on imaging with requesting provider attestation patient has severe or life-threatening disease, submission of test confirming presence of mutation in PIK3CA gene, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	Restricted to specialists in genetic diseases or inborn errors of metabolism
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For each reauthorization, submission of objective documentation of a symptomatic or clinical benefit (e.g., reductions in target lesion size, pain, vascular malformations, limb enlargements, etc.), or maintenance of improvement previously achieved, is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VITRAKVI (larotrectinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of evidence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, attestation tumor is metastatic or surgical resection and other systemic therapies are unsatisfactory treatment options, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VIVJOA (oteseconazole)

Products Affected

- VIVJOA

PA Criteria	Criteria Details
Exclusion Criteria	Women of reproductive potential
Required Medical Information	Diagnosis of covered use, including attestation patient has had at least three episodes of vulvovaginal candidiasis in the previous 12 months, attestation patient is either (1) postmenopausal, or (2) infertile.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VIZIMPRO (dacomitinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with a proton pump inhibitor
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of EGFR exon 19 deletions or exon 21 L858R substitution mutations, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VONJO (pacritinib)

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment (Child-Pugh class B or C), estimated glomerular filtration rate (eGFR) less than 30 mL/min, QTc interval greater than 480 msec at baseline, uncorrected hypokalemia, coadministration with strong CYP3A4 inducers or strong CYP3A4 inhibitors
Required Medical Information	Diagnosis of covered use, submission of platelet count, serum potassium level, eGFR, and QTc interval, Child-Pugh score, documentation from a physical exam patient has splenomegaly.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VOQUEZNA (vonoprazan)

Products Affected

- VOQUEZNA ORAL TABLET 10 MG, 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For erosive esophagitis and non-erosive gastroesophageal reflux disease (GERD), submission of current or previous therapies used to treat the condition (see Other Criteria). For Helicobacter pylori infection only, attestation patient will be administering with amoxicillin or a combination of amoxicillin and clarithromycin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Up to 32 weeks based on covered use (see Other Criteria)
Other Criteria	For initial authorization for erosive esophagitis and non-erosive GERD, the patient must have tried and failed to have an adequate response to two different proton pump inhibitors or have contraindications to the proton pump inhibitor class. For non-erosive GERD, the initial coverage duration will be 4 weeks, with the option to reauthorize for an additional 20 weeks (for a total of 24 weeks of therapy per 365 days) if the provider attests to medical need. For H. pylori infection, a maximum of one 14-day course of vonoprazan will be approved. For all other indications, a maximum of one 32-week course of vonoprazan will be allowed per 365 days.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VORANIGO (vorasidenib)

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of IDH1 or IDH2 mutation, pregnancy status for female patients of childbearing potential, attestation patient has had at least one prior surgery (biopsy, sub-total resection, or gross total resection).
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VOWST (fecal microbiota spores, live-brpk) EGWP

Products Affected

- VOWST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use with the requirement patient is being treated after at least 2 recurrent (3 total) Clostridioides difficile infections (confirmation of pathogen with stool test or other confirmatory test), submission of time of last planned dose of antibiotic for latest recurrent C. difficile infection and attestation patient will be using a bowel cleanse the evening prior to starting Vowst.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 course (3 days)
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

WEIGHT LOSS MEDICATIONS

Products Affected

- ADIPEX-P
- CONTRAVE
- *liraglutide -weight management*
- *phentermine hcl oral capsule*
- *phentermine hcl oral tablet 37.5 mg*
- *phentermine-topiramate er*
- WEGOVY SUBCUTANEOUS SOLUTION AUTO-INJECTOR 0.25 MG/0.5ML, 0.5 MG/0.5ML, 1

MG/0.5ML, 1.7 MG/0.75ML, 2.4 MG/0.75ML

PA Criteria	Criteria Details
Exclusion Criteria	Body mass index (BMI) less than 30 kg/m2 or less than 27 kg/m2 if the patient also has diabetes, high blood pressure, or dyslipidemia. For Wegovy, indication of risk reduction for major adverse cardiovascular events in cardiovascular disease or for metabolic dysfunction-associated steatohepatitis (see Other Criteria).
Required Medical Information	Submission of BMI, body weight and patient's exercise/diet plan.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	After initial 1-year approval, documentation the patient has maintained a loss of 5 percent body weight will be required for further 1-year reauthorizations. Medication will not be approved if patient does not have a diet/exercise plan. Criteria for use of Wegovy to reduce risk of major adverse cardiovascular events (MACE) or to treat metabolic dysfunction-associated steatohepatitis (MASH) are located in the Wegovy (semaglutide) NC EGWP policy.
Indications	Some FDA-approved Indications Only.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

WELIREG (belzutifan)

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For von Hippel-Lindau (VHL) disease, confirmation of a germline VHL alteration and attestation patient does not require immediate surgery. For advanced renal cell carcinoma, confirmation patient was previously treated with a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XALKORI (crizotinib)

Products Affected

- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome, coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming tumor is ALK or ROS1-positive, pregnancy status for female patients of childbearing potential.
Age Restrictions	For ALK-positive systemic anaplastic large cell lymphoma only, 1 year of age to 21 years of age
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XDEMVY (lotilaner)

Products Affected

- XDEMVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including documentation of presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination, documentation of at least mild erythema of lid margin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to ophthalmology and optometry
Coverage Duration	6 weeks
Other Criteria	The safety and efficacy of retreating with additional courses has not been fully described. For this reason, only one 6-week treatment course will be allowed every 365 days.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XERMELO (telotristat)

Products Affected

- XERMELO

PA Criteria	Criteria Details
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	1 year
Other Criteria	For each reauthorization, documentation patient remains on somatostatin analog therapy (unless contraindicated) and confirmation that the patient has not experienced episodes of severe constipation is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XIFAXAN (rifaximin)

Products Affected

- XIFAXAN ORAL TABLET 550 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current and previous therapies used to treat the condition (see Other Criteria). For diarrhea-predominant irritable bowel disease (IBS-D), documentation of the number of previous 14-day courses of rifaximin used during the patient's lifetime. For small intestinal bacterial overgrowth (SIBO), documentation of positive results on a carbohydrate breath test and the number of previous 14-day courses of rifaximin used during the previous 365 days, including the date ranges of those courses of therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to gastroenterology and hepatology
Coverage Duration	For HE, 1 year. For IBS-D and SIBO, 14 days.
Other Criteria	For initial authorization for hepatic encephalopathy (HE), the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to lactulose. For authorization for IBS-D, the patient must have tried and failed to have an adequate response to at least two of the following classes of medications: (1) antidiarrheals (e.g., loperamide), or (2) antispasmodics (e.g., dicyclomine), or (3) tricyclic antidepressants (e.g., nortriptyline). For initial authorization for SIBO, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two other medications with evidence of efficacy including amoxicillin-clavulanate, ciprofloxacin, metronidazole, sulfamethoxazole/trimethoprim, and tetracycline. For IBS-D, a maximum of three 14-day courses per patient's lifetime will be approved. For SIBO, a maximum of two 14-day courses per 365 days can be approved.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XOLAIR (omalizumab)

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	Weight greater than 150 kg, other forms of urticaria that are not chronic spontaneous urticaria (CSU)
Required Medical Information	Diagnosis of covered use, submission of pre-treatment weight. For asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), and CSU, submission of current and previous therapies used to treat the condition (see Other Criteria). For asthma, (1) documentation patient has a pre-bronchodilator FEV1 less than 80 percent predicted or less than 90% in children, and, (2) submission of pre-treatment serum IgE level between 30 and 700 IU/mL in patients 12 years of age and older, and (3) positive skin test result or demonstrated in vitro reactivity (RAST test) to a perennial aeroallergen. For CRSwNP, (1) documentation of evidence of nasal polyps, and (2) attestation that patient has symptomatic nasal congestion, and (3) submission of pre-treatment serum IgE level with a requirement it must be at least 30 IU/mL. For food allergy, (1) documentation of at least one IgE-mediated food allergy proven by skin prick test and positive IgE testing, and (2) submission of pre-treatment serum IgE level with a requirement it must be at least 30 IU/mL, and (3) attestation patient will continue to follow a food allergen-avoidance diet, and (4) attestation patient is not using other immunotherapy (e.g., Palforzia) for indication.
Age Restrictions	
Prescriber Restrictions	Restricted to allergy, dermatology, immunology, otolaryngology/otorhinolaryngology, and pulmonology
Coverage Duration	Initially 6 months, then 1 year

PA Criteria	Criteria Details
Other Criteria	For initial authorization for asthma, patient must be on a drug regimen as recommended by GINA guidelines prior to the use of biologic medications, consisting of, at a minimum, a maximally-tolerated dose of inhaled corticosteroid (ICS), a long-acting beta-agonist (LABA), and a long-acting antimuscarinic antagonist (LAMA), and the provider must attest this therapy will be continued after starting omalizumab. For initial authorization for CRSwNP, patient must have tried an intranasal corticosteroid for at least two months (and provider must attest this will be continued after starting omalizumab), have a contraindication to intranasal corticosteroids, or documentation must be submitted as to why this therapy is not otherwise advisable. For initial authorization for CSU, patient must have tried and continued to experience severe itching and hives despite a trial of at least 30 days of an oral antihistamine. For each reauthorization for asthma, confirmation patient is still using triple ICS-LABA-LAMA inhaler therapy and documentation of a clinical benefit (reduction from baseline in rate of annual exacerbations or severe exacerbations, systemic corticosteroid dose, or asthma symptom score, improvement in FEV1) or maintenance of a benefit previously achieved is required. For each reauthorization for CRSwNP, confirmation patient is still using an intranasal corticosteroid and documentation of a clinical benefit (reduction from baseline in nasal congestion, nasal polyp score or systemic corticosteroid dose) or maintenance of a benefit previously achieved is required. For each reauthorization for CSU, documentation of a clinical benefit (reduction from baseline in itch severity or hive count) or maintenance of a benefit previously achieved is required. For each reauthorization for food allergy, attestation patient has medical necessity and is not using other immunotherapies for food allergy is required. 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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XOSPATA (gilteritinib)

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	Uncorrected hypokalemia or hypomagnesemia, coadministration with dual strong CYP3A/P-glycoprotein inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of FLT3 mutation, baseline serum potassium and magnesium levels, 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XPOVIO (selinexor)

Products Affected

- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 10 MG, 40 MG
- XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 60 MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG
- XPOVIO (80 MG TWICE WEEKLY)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For multiple myeloma in combination with bortezomib and dexamethasone, documented failure of at least one previous therapy. For relapsed or refractory multiple myeloma, documented failure of at least four previous lines of systemic therapy including at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. For relapsed or refractory diffuse large B-cell lymphoma, documented failure of at least two previous lines of systemic therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XURIDEN (uridine triacetate)

Products Affected

- XURIDEN

PA Criteria	Criteria Details
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	For each annual reauthorization, documentation of improvements or stabilization of urine orotic acid level, neutrophil count, and mean corpuscular volume is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZEJULA (niraparib)

Products Affected

- ZEJULA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential, documentation of response to platinum-based chemotherapy. For germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, submission of test confirming presence of deleterious BRCA mutation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZEPBOUND (tirzepatide) NC EGWP

Products Affected

- ZEPBOUND

PA Criteria	Criteria Details
Exclusion Criteria	Body mass index (BMI) less than 30 kg/m2 or less than 27 kg/m2 if the patient also has diabetes, high blood pressure, or dyslipidemia. For obstructive sleep apnea (OSA), apnea-hypopnea index (AHI), respiratory disturbance index (RDI) or respiratory event index (REI) score less than 15, diagnosis of central or mixed sleep apnea.
Required Medical Information	Submission of BMI. For weight loss, body weight and patient's exercise/diet plan. For obstructive sleep apnea, confirmation of moderate-to-severe OSA (i.e., sleep study with AHI/RDI/REI greater than or equal to 15).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For weight loss, after initial 1-year approval, documentation the patient has maintained a loss of 5 percent body weight will be required for further 1-year reauthorizations. Medication will not be approved if patient does not have a diet/exercise plan. For obstructive sleep apnea, after initial 1-year approval, further 1-year reauthorizations will require (1) documentation of symptom improvement, and (2) documentation the patient has been stabilized on a weekly dose of 10 mg or greater. Doses below 10 mg once weekly are not approved as maintenance doses for obstructive sleep apnea per the prescribing information and will not be approved for continuation.
Indications	Some FDA-approved Indications Only.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZILBRYSQ (zilucoplan)

Products Affected

- ZILBRYSQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including confirmation via a history of abnormal neuromuscular transmission tests or improvement with acetylcholinesterase inhibitors and a positive serological test for AChR-Ab, submission of MGFA classification with a requirement the patient has class II-IV myasthenia gravis and baseline MG-ADL score with a requirement the score is at least 6, attestation patient will not concurrently use rituximab or eculizumab, submission of current or previous therapies used to treat the condition (see Other Criteria), attestation patient has received meningococcal vaccination against subgroups A, B, C, W, and Y and does not have an unresolved N. meningitidis infection.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For the initial authorization, the patient must have tried and failed to have an adequate response to at least one drug in two of the following three classes: (1) acetylcholinesterase inhibitors (e.g., pyridostigmine), or (2) corticosteroids (e.g., prednisone), or (3) non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate). For the first reauthorization, confirmation of a symptomatic or clinical improvement is required. For each annual reauthorization, confirmation of maintenance of an improvement previously achieved and attestation the patient is up to date on all vaccinations is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZILRETTA (triamcinolone intra-articular injection)

Products Affected

- ZILRETTA

PA Criteria	Criteria Details
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. 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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZTALMY (ganaxolone)

Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use confirmed by genetic testing including either (1) a CDKL5 gene that is pathogenic or likely to be pathogenic, or (2) CDKL5 deficiency.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZYDELIG (idelalisib)

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	History of toxic epidermal necrolysis with any drug, untreated active infection, coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, attestation therapy will be coadministered with rituximab, documentation of at least one previous line of systemic therapy, submission of 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZYKADIA (ceritinib)

Products Affected

- ZYKADIA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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