PRIOR AUTHORIZATION CRITERIA

This list is current as of December 13, 2024, and pertains to the following formularies:

2024 Pharmacy Benefit Dimensions PDP Part D Formulary Provided by City of Stamford	Version 23

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.

ABILIFY MYCITE (aripiprazole with sensor)

Products Affected

- ABILIFY MYCITE MAINTENANCE KIT ORAL TABLET THERAPY PACK 10 MG, 15 MG, 2 MG, 20 MG, 30 MG, 5 MG
- ABILIFY MYCITE STARTER KIT ORAL TABLET THERAPY PACK 10 MG, 15 MG, 2 MG, 20 MG, 30 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use, documentation of previous aripiprazole use (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval, the patient must have documentation of at least a one-month trial of generic aripiprazole solution, tablets, or orally-disintegrating tablets.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ABRYSVO (respiratory syncytial virus vaccine)

Products Affected

- ABRYSVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient is pregnant.
Age Restrictions	PA applies to patients 59 years of age or younger. PA does not apply to patients 60 years of age or older.
Prescriber Restrictions	
Coverage Duration	9 months
Other Criteria	PA applies to all.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ADEMPAS (riociguat)

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, severe (Child-Pugh class C) hepatic impairment, creatinine clearance below 15 mL/min or on dialysis, concurrent use with nitrates or nitric oxide donors in any form, concurrent use with phosphodiesterase inhibitors
Required Medical Information	Diagnosis of covered use including WHO Group, submission of 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 (WHO Group 1), documentation diagnosis was confirmed by right heart catheterization.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AKEEGA (niraparib/abiraterone)

Products Affected

- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C), uncontrolled hypertension, uncontrolled hypokalemia
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of deleterious BRCA mutation, baseline blood pressure reading, and serum potassium level, attestation patient will be using daily prednisone to match the indication and 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ALPHA-1-PROTEINASE INHIBITORS

Products Affected

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

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	PA applies to all. Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved. 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

ALUNBRIG (brigatinib)

Products Affected

- ALUNBRIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AMANTADINE EXTENDED-RELEASE PRODUCTS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	End stage renal disease (creatinine clearance below 15 mL/min)
Required Medical Information	Diagnosis of covered use, documentation patient tried and failed immediate-release amantadine.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AMVUTTRA (vutrisiran)

Products Affected

- AMVUTTRA

PA Criteria	Criteria Details
Exclusion Criteria	Prior or scheduled liver transplant, New York Heart Association (NYHA) heart failure classification greater than 2
Required Medical Information	Diagnosis of covered use confirmed by (1) genetic testing including a mutation in the TTR gene and (2) signs and/or symptoms of polyneuropathy, including submission of baseline polyneuropathy disability (PND) score (required to be less than or equal to IIIb), submission of NYHA heart failure classification (required to be less than or equal to 2), previous medication(s) patient has tried and failed (at least one of either inotersen or patisiran).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and specialists in genetic diseases
Coverage Duration	1 year
Other Criteria	PA applies to all. For approval, the patient must have tried and failed to have an adequate response to or had an intolerance to either inotersen or patisiran. Documentation of a positive response to therapy will be required for initial reauthorization after the first year. 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 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

ARCALYST (rilonacept)

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	Active or chronic infection, coadministration with TNF-blocking agents
Required Medical Information	Diagnosis of covered use, TB skin test result obtained within the past 12 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ARIKAYCE (amikacin inhalation)

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	Non-refractory Mycobacterium avium complex (MAC) lung disease
Required Medical Information	Diagnosis of covered use, submission of other therapies that have been tried and failed or cannot be used because of a contraindication. For refractory MAC lung disease, submission of sputum culture result.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to infectious diseases and pulmonology
Coverage Duration	1 year
Other Criteria	This medication is covered as a Part B benefit except for enrollees residing in a long-term care facility. PA applies to all when covered as a Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AUGTYRO (repotrectinib)

Products Affected

- AUGTYRO ORAL CAPSULE 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inhibitors or inducers, coadministration with P-glycoprotein inhibitors
Required Medical Information	Diagnosis of covered use, submission of test confirming tumor is ROS1-positive, 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	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

AURYXIA (ferric citrate)

Products Affected

- AURYXIA

PA Criteria	Criteria Details
Exclusion Criteria	Iron overload syndrome
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

AUVELITY (dextromethorphan/bupropion)

Products Affected

- AUVELITY

PA Criteria	Criteria Details
Exclusion Criteria	Seizure disorder, current or prior diagnosis of bulimia or anorexia nervosa, administration of monoamine oxidase inhibitors within 14 days of initiation
Required Medical Information	Diagnosis of covered use, prescription claims or documentation from physician showing patient has tried and failed or had an intolerance to at least two different medications that are indicated for the diagnosis.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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, immunology, and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BALVERSA (erdafitinib)

Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of susceptible FGFR3 genetic alterations, prior chemotherapy regimen(s) used (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	PA applies to new starts only. 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. Balversa will not be approved in PD-1/PD-L1 inhibitor-eligible patients who have not received this therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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
Required Medical Information	Diagnosis of covered use, submission of current or previous lipid-lowering therapies (see Other Criteria). For heterozygous familial hypercholesterolemia, documentation of genetic test result documenting HeFH or diagnosis by clinical criteria using Simon Broom or WHO/Dutch Lipid Network criteria. For atherosclerotic cardiovascular disease, "established" disease is defined as either (1) a documented history of coronary heart disease (CHD), to include at least one of the following: (a) prior myocardial infarction (MI, "heart attack"), (b) prior silent MI, (c) unstable angina, (d) prior coronary revascularization procedure, or (e) clinically significant CHD diagnosed by invasive or non-invasive testing, or (2) at least one CHD risk equivalent, to include (a) peripheral arterial disease, or (b) previous ischemic stroke with a focal ischemic neurological deficit that persisted more than 24 hours, considered as being of atherothrombotic origin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval, the patient must currently be using a statin plus ezetimibe or the patient must have tried and failed to have an adequate response to or had an intolerance to at least two statins or one statin and ezetimibe. At least one statin previously tried and failed must be a hydrophilic statin.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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, confirmation that the patient is taking 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 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	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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/1.73 m2)
Required Medical Information	Diagnosis of covered use, submission of eGFR, documentation patient has tried and failed, has a contraindication to, or could not tolerate hydroxyurea, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BEXAROTENE GEL

Products Affected
- *bexarotene external*

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

BIOLOGIC RESPONSE MODIFIERS

Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS
- CIMZIA (2 SYRINGE)
- CIMZIA SUBCUTANEOUS KIT 2 X 200 MG
- CIMZIA SUBCUTANEOUS PREFILLED SYRINGE KIT
- KEVZARA
- OTEZLA ORAL TABLET 30 MG
- OTEZLA ORAL TABLET THERAPY PACK 10 & 20 & 30 MG
- SIMPONI SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- SIMPONI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- SOTYKTU
- TREMFYA SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML
- TREMFYA SUBCUTANEOUS SOLUTION PEN-INJECTOR
- TREMFYA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML
- TYENNE SUBCUTANEOUS
- VELSIPITY
- ZEPOSIA
- ZEPOSIA 7-DAY STARTER PACK
- ZEPOSIA STARTER KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Zeposia for the treatment of multiple sclerosis, only diagnosis of covered use is required. For all other drugs managed by this policy and for Zeposia for indications other than multiple sclerosis, diagnosis of covered use, submission of previous therapies. For all drugs managed by this policy except Otezla, Velsipity, and Zeposia, 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	PA applies to all. With the exception of Zeposia for the treatment of multiple sclerosis only, for approval 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 (Cosentyx, Enbrel, Humira, Rinvoq, Skyrizi, Stelara, and Xeljanz/Xeljanz XR) for the indication submitted, where possible. For all drugs managed by this policy except Otezla, Velsipity, and Zeposia, if TB screening test returns a positive result, coverage will be delayed until latent TB is treated. For re-authorization, 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 Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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 renal function testing, submission of pregnancy status for female patients of childbearing potential. For accelerated or blast phase Ph+ CML, documentation of resistance or intolerance to at least one of the following prior therapies: imatinib, dasatinib, or nilotinib.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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 based on requirements for diagnosis. 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BRONCHITOL (mannitol powder for inhalation)

Products Affected

- BRONCHITOL

PA Criteria	Criteria Details
Exclusion Criteria	Documented Bronchitol Tolerance Test failure
Required Medical Information	Diagnosis of covered use, documentation patient has passed the Bronchitol Tolerance Test.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 mantle cell lymphoma or marginal zone lymphoma, submission of prior regimen(s) used.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BUTALBITAL-CONTAINING PRODUCTS IN OLDER PATIENTS

Products Affected

- ASCOMP-CODEINE
- BUPAP ORAL TABLET 50-300 MG
- *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
- ZEBUTAL ORAL CAPSULE 50-325-40 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	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

BYLVAY (odevixibat)

Products Affected

- BYLVAY
- BYLVAY (PELLETS)

PA Criteria	Criteria Details
Exclusion Criteria	History of liver transplant, clinical evidence of decompensated cirrhosis
Required Medical Information	Diagnosis of covered use confirmed by molecular genetic testing, attestation drug-induced pruritus has been ruled out.
Age Restrictions	
Prescriber Restrictions	Restricted to gastroenterology and hepatology
Coverage Duration	1 year
Other Criteria	PA applies to all. Attestation of improvement in pruritus symptoms and submission of liver function testing, including serum bilirubin, since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to all. 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 Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 pregnancy status for female patients of childbearing potential. For hepatocellular carcinoma, confirmation patient was previously treated with sorafenib. For differentiated thyroid cancer, submission of previous therapy or therapies tried and failed.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CALQUENCE (acalabrutinib)

Products Affected

- CALQUENCE

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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CAMZYOS (mavacamten)

Products Affected

- CAMZYOS

PA Criteria	Criteria Details
Exclusion Criteria	Left ventricular ejection fraction (LVEF) less than 55%, coadministration with a non-dihydropyridine (DHP) calcium channel blocker (CCB) plus disopyramide
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 mmHg 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, any previous or current therapies tried for the condition, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. For approval, 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. Documentation of a positive response to therapy will be required for initial reauthorization after the first 6 months. Maintenance of a clinical benefit and attestation that prescriber believes benefits of continuing therapy outweigh the potential risks to the patient will be required for subsequent annual reauthorizations.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

CAPLYTA (lumateperone)

Products Affected

- CAPLYTA ORAL CAPSULE 10.5 MG, 21 MG, 42 MG

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis, coadministration with CYP3A4 inducers
Required Medical Information	Diagnosis of covered use. For schizophrenia, submission of previous therapies used (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to psychiatry
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval for schizophrenia, 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.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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
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, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to all. Updated plasma ammonia level since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CERDELGA (eliglustat)

Products Affected

- CERDELGA

PA Criteria	Criteria Details
Exclusion Criteria	Pre-existing cardiac disease, long QT syndrome, coadministration with Class Ia or Class III antiarrhythmics
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	PA applies to all. Updated liver function testing or Child-Pugh score since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CGRP INHIBITORS

Products Affected

- AIMOVIG SUBCUTANEOUS SOLUTION AUTO-INJECTOR 140 MG/ML, 70 MG/ML
- AJOVY
- EMGALITY
- EMGALITY (300 MG DOSE)
- NURTEC
- QULIPTA
- UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For migraine headache prevention, submission of baseline headache days per month from medical chart, documentation patient (a) has tried and failed at least two non-CGRP inhibitor FDA-approved (propranolol, timolol, topiramate, valproic acid) or compendial alternatives (e.g., amitriptyline, atenolol) for migraine prophylaxis, or (b) has tried and failed at least one alternative from (a) if they have contraindications to all other alternatives, or (c) has contraindications to all alternatives from (a). For acute migraine treatment, documentation of prior use of at least one triptan.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	For migraine headache prevention, initially 3 months, then 1 year. For acute migraine, 1 year.
Other Criteria	PA applies to all. For episodic migraine prevention, the patient must have documentation of fewer than 15 headache days per month. For approval of Emgality for migraine headache prevention, the patient must have tried and failed to have an adequate response to or had an intolerance to Aimovig and Ajovy. For migraine headache prevention reauthorization after the first 3 months, submission of on-treatment headache days per month demonstrating improvement from baseline will be required. Documentation of maintenance of a clinical benefit will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	
Coverage Duration	24 months
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 hepatology, gastroenterology, and pediatric gastroenterology
Coverage Duration	Initially 3 months, then 1 year
Other Criteria	PA applies to all. Documentation of liver function improvement without complete biliary obstruction or persistent clinical or laboratory indications of worsening liver function or cholestasis will be required for initial reauthorization after the first 3 months. Updated liver function testing since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

COBENFY ((xanomeline and trospium)

Products Affected

- COBENFY
- COBENFY STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	Moderate to severe hepatic impairment, pre-existing urinary retention, gastric retention, untreated narrow-angle glaucoma.
Required Medical Information	Diagnosis of covered use. Baseline liver enzymes, bilirubin, and heart rate.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to psychiatry
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval for schizophrenia, 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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	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)
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 oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

COPIKTRA (duvelisib)

Products Affected

- COPIKTRA ORAL CAPSULE 15 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of at least two prior 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 or oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

CORTROPHIN (corticotropin)

Products Affected

- CORTROPHIN

PA Criteria	Criteria Details
Exclusion Criteria	Request for IV administration, treatment of patients under 2 years of age in whom congenital infections are suspected, patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, a history of or presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin
Required Medical Information	Diagnosis of covered use, submission of blood pressure reading and baseline serum sodium and potassium levels.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated blood pressure, sodium, and potassium levels since the previous authorization will be required for subsequent reauthorizations. 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

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.
Required Medical Information	Diagnosis of covered use including verification of BRAF V600 mutation as needed for diagnosis. For patients using cobimetinib, submission of left ventricular ejection fraction (LVEF) with a requirement the baseline LVEF is greater than or equal to 40%. 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	PA applies to new starts only. Vemurafenib is not indicated in wild-type BRAF melanoma and will not be approved for this use.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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, optometry, and ophthalmology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to all. Updated creatinine clearance since the previous authorization and confirmation patient is able to walk will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DEFERASIROX

Products Affected

- *deferasirox oral tablet*
- *deferasirox oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, estimated glomerular filtration rate less than 40 mL per min, platelet count below 50 x 10^9/L, high-risk myelodysplastic syndromes, advanced malignancies
Required Medical Information	Diagnosis of covered use, submission of CBC, LFTs, ferritin, and urine protein values, estimated glomerular filtration rate, documentation that member has had yearly ophthalmic and auditory testing.
Age Restrictions	2 years of age or older
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	PA applies to all. Updated ferritin level within last 3 months and updated CBC, LFT, urine protein value, estimated glomerular filtration rate, and ophthalmic and auditory testing since the previous authorization (within previous year) will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DEFERIPRONE

Products Affected

- *deferiprone*
- FERRIPROX ORAL SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Absolute neutrophil count (ANC) below 1.5 x 10^9/L
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	PA applies to all. Updated ferritin level and ANC within last 3 months will be required for subsequent reauthorizations. Safety and effectiveness have not been established for transfusional iron overload in patients with myelodysplastic syndrome or Diamond Blackfan anemia and will not be approved for these indications.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DIACOMIT (stiripentol)

Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe renal impairment, moderate or severe hepatic impairment
Required Medical Information	Diagnosis of covered use, confirmation patient is also receiving clobazam.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. Monotherapy requests for Dravet syndrome will not be approved as there are no clinical data to support using stiripentol in this manner.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to all. Documentation of a positive response to therapy will be required for initial reauthorization after the first 2 months. Maintenance of a clinical benefit will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	PA applies to all. Product is approved for acute pain, defined as short-term pain not lasting longer than a 3-month period.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	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, submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance) with result greater than or equal to 30 mL/min. Patient must have tried and failed to respond adequately to 0.125 mg of digoxin.
Age Restrictions	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
Prescriber Restrictions	PA not required for cardiology
Coverage Duration	1 year
Other Criteria	PA applies to all except cardiology. PA not required for doses less than or equal to 0.125 mg per day. Updated creatinine clearance since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DOPTELET (avatrombopag)

Products Affected

- DOPTELET ORAL TABLET 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. 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 documented increased risk of bleeding, documentation patient has undergone splenectomy and/or tried and failed two different ITP therapies including systemic corticosteroids, immunoglobulins, danazol, fostamatinib, or cytotoxics/immunosuppressants such as rituximab.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to gastroenterology, hematology, hepatology, and surgery
Coverage Duration	For patients undergoing a procedure, 5 days. For ITP, initially 6 months, then 1 year.
Other Criteria	PA applies to all. For ITP, documentation of an improvement in platelet count will be required for initial reauthorization after the first 6 months. Maintenance of a clinical benefit will be required for subsequent annual reauthorizations. This medication should not be administered to patients with chronic liver disease not scheduled to undergo a procedure in an attempt to normalize platelet counts and will not be approved for this indication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DRONABINOL

Products Affected

- *dronabinol*
- SYNDROS

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, documentation of previous conventional antiemetic therapies utilized is required.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. If authorization is requested for treatment of nausea and vomiting associated with cancer therapy, the patient must have tried and failed to have an adequate response 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. If the medication is being requested for the use of anorexia associated with weight loss in patients with AIDS, approval may be covered under Part D.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DUOBRII (halobetasol/tazarotene)

Products Affected

- DUOBRII

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential, documentation patient tried and failed augmented betamethasone dipropionate, clobetasol, fluocinonide 0.1%, halobetasol, or another Class I ultra-high potency topical steroid.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to dermatology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

DUPIXENT (dupilumab)

Products Affected

- DUPIXENT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For atopic dermatitis, (1) documentation of at least 10% body surface area involvement, and (2) documentation of treatment with at least a moderate strength topical corticosteroid for at least four weeks, a contraindication to the use of topical corticosteroids, or documentation why this therapy is not otherwise advisable. For moderate-to-severe asthma, (1) for adult patients, documentation patient has a pre-bronchodilator FEV1 less than 80 percent predicted, (2) submission of either blood eosinophil count of at least 150 cells/mcL obtained within 6 weeks of therapy initiation or documentation asthma requires daily oral corticosteroid for control, and (3) attestation dupilumab will be used in addition to other chronic therapies. For chronic rhinosinusitis with nasal polyposis, (1) documentation of treatment with an intranasal corticosteroid for at least three months, a contraindication to the use of intranasal corticosteroids, or why therapy is not otherwise advisable, and (2) if the patient does not have an intolerance or contraindication to intranasal corticosteroids, attestation dupilumab will be used in addition to this therapy. As add-on maintenance treatment for adults with inadequately controlled COPD, (1) documentation of COPD diagnosis and an eosinophilic phenotype, (2) documentation patient is symptomatic (modified Medical Research Council (mMRC) dyspnea scale grade of 2 or higher or COPD Assessment Test (CAT) score of at least 10), (3) patient must be on a stable dose of standard-of-care COPD medications (including ICS, LABA, LAMA or combination products) for at least one month prior to starting dupilumab, and (4) attestation that patient will remain on standard-of-care therapy after starting dupilumab.
Age Restrictions	
Prescriber Restrictions	Restricted to allergy, dermatology, gastroenterology, immunology, otolaryngology/otorhinolaryngology, and pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to all. Continuation requires documentation of a positive response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EGRIFTA SV (tesamorelin)

Products Affected

- EGRIFTA SV

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, active malignancy, disruption of HPA axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation, or head trauma
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	
Coverage Duration	1 year
Other Criteria	PA applies to all. Continuation of therapy requests require confirmation that the patient has demonstrated a clinical improvement (or maintenance of improvement once achieved) from baseline. Tesamorelin is not indicated for weight loss management and will not be approved for this indication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ENDARI (L-glutamine)

Products Affected

- *l-glutamine oral packet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of sickle cell disease
Age Restrictions	
Prescriber Restrictions	Restricted to hematology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ENDOTHELIN RECEPTOR ANTAGONISTS

Products Affected

- *ambrisentan oral tablet 10 mg, 5 mg*
- *bosentan oral tablet 125 mg, 62.5 mg*
- OPSUMIT
- OPSYNVI
- TRACLEER ORAL TABLET SOLUBLE

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy. For ambrisentan, idiopathic pulmonary fibrosis and moderate or severe hepatic impairment.
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For Opsumit or Opsynvi, documentation of previous endothelin receptor antagonists tried and reason patient can no longer use them.
Age Restrictions	For ambrisentan, Opsumit, and Opsynvi, 18 years of age or older. For bosentan, 3 years of age or older.
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval of Opsumit or Opsynvi, the patient must have tried and failed to have an adequate response to or had an intolerance or contraindication to both ambrisentan and bosentan.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ENSPRYNG (satralizumab-mwge)

Products Affected

- ENSPRYNG

PA Criteria	Criteria Details
Exclusion Criteria	Active hepatitis B infection, active or untreated latent tuberculosis (TB)
Required Medical Information	Diagnosis of covered use, submission of confirmation patient has anti-aquaporin-4 (AQP4) antibody-positive NMOSD, submission of baseline latent TB screening test (Mantoux tuberculin skin test [a.k.a. PPD test] or interferon-gamma release assay [IGRA]), attestation patient does not have any active infection.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and ophthalmology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 positive symptomatology, 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 EoE 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	PA applies to all. 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

EPIDIOLEX (cannabidiol)

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	1 year of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ERLOTINIB

Products Affected

- *erlotinib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For non-small cell lung cancer, submission of test confirming presence of EGFR exon 19 deletion or exon 21 L858R substitution mutation and prior treatments used.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ERYTHROPOIETINS

Products Affected

- ARANESP (ALBUMIN FREE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 40 MCG/ML, 60 MCG/ML
- ARANESP (ALBUMIN FREE) INJECTION SOLUTION PREFILLED SYRINGE
- 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	For non-ESRD-related conditions: 90 days. For ESRD-related conditions: 1 year.
Other Criteria	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EVEROLIMUS

Products Affected

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

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 renal cell carcinoma, documented prior use of sunitinib or sorafenib. 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	1 year of age or older
Prescriber Restrictions	Restricted to neurology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

EVRYSDI (risdiplam)

Products Affected

- EVRYSDI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use confirmed by genetic testing including either (a) homozygous deletion of SMN1 exon 7 or (b) compound heterozygosity for SMN1 exon 7 deletion and small mutation, documentation of two or more copies of the SMN2 gene by genetic testing, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Maintenance of or improvement in any motor score or function compared to baseline will be required for reauthorization.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FABHALTA (iptacopan) EGWP

Products Affected
- FABHALTA

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C), severe renal impairment
Required Medical Information	Diagnosis of covered use. For paroxysmal nocturnal hemoglobinuria, submission of flow cytometry analysis confirming presence of clones of paroxysmal nocturnal hemoglobinuria (PNH) cells, submission of any laboratory result or objective sign attributable to PNH, including but not limited to hemoglobin less than 10 g/dL, lactate dehydrogenase greater than 1.5 times the upper limit of normal, hemosiderinuria, anemia, or unexplained/unusual (e.g., skin, splanchnic vein, cerebral vein) thrombosis, attestation the patient does not have severe hepatic or renal impairment. For the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN), the diagnosis is confirmed by biopsy or submission of 24-hour urine protein-to-creatinine ratio of at least 1.5 g/g.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and nephrology
Coverage Duration	1 year
Other Criteria	PA applies to all. Continuation of therapy requests require confirmation that the patient has demonstrated a clinical improvement (or maintenance of improvement once achieved) from baseline.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

FENTANYL TRANSMUCOSAL

Products Affected

- *fentanyl citrate buccal*

PA Criteria	Criteria Details
Exclusion Criteria	Patients not tolerant to the effects of a chronic opioid, treatment of acute or postoperative pain including headache, migraines, or dental pain
Required Medical Information	Diagnosis of covered use with the requirement transmucosal fentanyl will only be used for the treatment of breakthrough cancer pain, verified claim or documentation of patient's morphine milligram equivalent opioid dose.
Age Restrictions	For the buccal tablet, 18 years of age or older. For the lozenge, 16 years of age or older.
Prescriber Restrictions	PA not required for oncology
Coverage Duration	1 year
Other Criteria	PA applies to all except oncology. Transmucosal fentanyl is only covered as a Part D drug for the treatment of breakthrough cancer pain and will not be authorized for other uses.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

FILSPARI (sparsentan)

Products Affected

- FILSPARI

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, hepatic impairment, coadministration with renin-angiotensin system antagonists or endothelin receptor antagonists
Required Medical Information	Diagnosis of primary IgA nephropathy confirmed by biopsy, submission of 24-hour urine protein of at least 1 g/day or 24-hour urine protein-to-creatinine ratio of at least 0.8 g/g, eGFR, and liver function testing or Child-Pugh class, pregnancy status for female patients of childbearing potential, attestation patient is stable on a maximally-tolerated ACE inhibitor or ARB and will discontinue this drug upon receiving sparsentan, documentation patient has progressed on at least one immunosuppressant (e.g., azathioprine, mycophenolate, etc.).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to immunology and nephrology
Coverage Duration	1 year
Other Criteria	PA applies to all. Reauthorization requires documentation of clinically relevant response to therapy, including, but not limited to stabilization or improvement of urine protein-to-creatinine ratio or eGFR.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

FILSUVEZ (birch triterpenes)

Products Affected

- FILSUVEZ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of genetic testing showing a mutation consistent with the diagnosis of dystrophic epidermolysis bullosa or junctional epidermolysis bullosa, attestation drug will not be applied to an area with a history of or current squamous cell carcinoma.
Age Restrictions	
Prescriber Restrictions	Restricted to dermatology and specialists in genetic diseases
Coverage Duration	1 year
Other Criteria	PA applies to all. Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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, submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance) and liver function testing or Child-Pugh score.
Age Restrictions	2 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

FIRST-GENERATION ANTIHISTAMINES IN OLDER PATIENTS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For carbinoxamine or cyproheptadine for dermatographism, documentation patient tried and had an inadequate response to a second-generation antihistamine. For hydroxyzine for pruritus, documentation patient tried and had an inadequate response to a second-generation antihistamine. For hydroxyzine for anxiety, documentation patient has tried and had an inadequate response to at least 2 other FDA-approved products for the management of anxiety OR documentation medication is being used as a sedative before and after general anesthesia.
Age Restrictions	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. First-generation antihistamines are anticholinergic medications considered high-risk in older patients due to risks of confusion, dry mouth, constipation, and decreased clearance with advanced age.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 previous systemic therapies used to treat renal cell carcinoma including the failure of at least one prior VEGFR inhibitor, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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, liver function testing or Child-Pugh score, and 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	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

FUMARATES FOR MULTIPLE SCLEROSIS

Products Affected

- BAFIERTAM
- VUMERITY

PA Criteria	Criteria Details
Exclusion Criteria	Hypersensitivity to dimethyl fumarate, coadministration with another fumarate. For Vumerity, moderate or severe renal impairment.
Required Medical Information	Diagnosis of covered use. For Vumerity, 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	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to all. For approval of Bafiertam or Vumerity, the patient must have tried and failed to have an adequate response to or had an intolerance to dimethyl fumarate. Updated creatinine clearance since the previous authorization will be required for subsequent annual reauthorizations of Vumerity.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

GALAFOLD (migalastat)

Products Affected

- GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	Severe renal impairment (eGFR less than 30 mL/min/1.73 m2) or end-stage renal disease requiring dialysis
Required Medical Information	Diagnosis of covered use, documentation that the patient has an amenable galactosidase alpha gene variant (see section 12.1, table 2 of package insert for full list) based on in vitro assay data as interpreted by a clinical genetics professional.
Age Restrictions	16 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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 at least 3 times per week. For adults 18 years of age or older only, submission of documentation that a colonoscopy (or alternate imaging) of the entire colon with polyp removal was performed within 6 months prior to starting treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. For adults 18 years of age or older, continuation of therapy requires submission of findings from a follow-up colonoscopy or alternate imaging result at the end of 1 year of teduglutide treatment. Subsequent imaging should be performed every 5 years, or sooner if polyps are found at the 1-year mark.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

GAVRETO (pralsetinib)

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inhibitors
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of RET gene fusion or mutation, attestation patient does not have uncontrolled hypertension, pregnancy status for female patients of childbearing potential.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

GILOTRIF (afatinib)

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

GROWTH HORMONE

Products Affected

- NORDITROPIN FLEXPRO SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 10 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 20 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- NUTROPIN AQ NUSPIN 5 SUBCUTANEOUS SOLUTION PEN-INJECTOR

- SOGROYA

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	PA applies to all. Updated IGF-1 level, bone age (if applicable based on patient age and diagnosis) height, weight, creatinine clearance (or serum creatinine), and fasting glucose since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

HEREDITARY ANGIOEDEMA THERAPIES, ACUTE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Requests for prophylactic hereditary angioedema therapy. For Ruconest, acute laryngeal attacks.
Required Medical Information	Diagnosis of covered use. For Ruconest, documentation of the patient's typical attack presentation/symptoms.
Age Restrictions	
Prescriber Restrictions	Restricted to allergy, dermatology, hematology, or immunology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. 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

HEREDITARY ANGIOEDEMA THERAPIES, MAINTENANCE

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Requests for acute hereditary angioedema therapy (attacks). For Orladeyo, end-stage renal disease.
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	
Prescriber Restrictions	Restricted to allergy, dermatology, hematology, or immunology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval of either Haegarda or Orladeyo for patients 12 years of age and older, the patient must have tried and failed to have an adequate response to or had an intolerance or contraindication to Takhzyro. 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

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, confirmation that the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ICLUSIG (ponatinib)

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	Newly diagnosed chronic phase CML
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For chronic phase CML that is not T315I-positive, documentation of resistance or intolerance to at least two prior kinase inhibitors.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

IMBRUVICA (ibrutinib)

Products Affected

- IMBRUVICA

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, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

IMMUNE GLOBULIN

Products Affected

- BIVIGAM INTRAVENOUS SOLUTION 5 GM/50ML
- FLEBOGAMMA DIF
- GAMASTAN S/D
- GAMMAGARD
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML, 10 GM/100ML, 20 GM/200ML, 5 GM/50ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 20 GM/400ML, 5 GM/100ML, 5 GM/50ML
- GAMUNEX-C
- 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	PA applies to all. For continuation of any diagnosis, documentation of the clinical response to therapy must be submitted. 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 Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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, attestation patient does not have uncontrolled hypertension. If axitinib is being used as a single agent, submission of prior therapy or therapies tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

INREBIC (fedratinib)

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, thiamine deficiency, coadministration with moderate or strong CYP3A4 inducers or dual CYP3A4/CYP2C19 inhibitors
Required Medical Information	Diagnosis of covered use, submission of thiamine level and baseline platelet count, submission of all prior therapies used.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval, the patient must have tried and failed to have an adequate response to or had an intolerance to ruxolitinib.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

INTRANASAL SEIZURE MEDICATIONS

Products Affected

- NAYZILAM
- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE
- VALTOCO 20 MG DOSE
- VALTOCO 5 MG DOSE

PA Criteria	Criteria Details
Exclusion Criteria	Acute narrow-angle glaucoma
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	PA not required for neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to new starts only. 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

IQIRVO (elafibranor)

Products Affected

- IQIRVO

PA Criteria	Criteria Details
Exclusion Criteria	Patient does not have evidence of portal hypertension, complete biliary obstruction, or cirrhosis, and has not had a prior hepatic decompensation event.
Required Medical Information	Diagnosis of primary biliary cholangitis (PBC) as defined by ONE of the following, 1) alkaline phosphatase (ALP) is elevated above the upper limit of normal, OR 2) histological evidence of PBC on liver biopsy. Documentation that 1) elafibranor will be used in combination with ursodeoxycholic acid (UDCA) and UDCA has been usedat a stable dose for at least 3 months OR 2) patient had intolerance to UDCA. Submission of baseline liver function tests, ALP and total bilirubin. Attestation patient does not have evidence of portal hypertension, complete biliary obstruction, or cirrhosis, and has not had a prior decompensation event.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Restricted to hepatology and gastroenterology
Coverage Duration	6 months initially, then 1 year
Other Criteria	PA applies to all. For reauthorization, documentation of a reduction in ALP will be required after the first 6 months. Maintenance of a clinical benefit will be required for subsequent annual reauthorizations.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ISTURISA (osilodrostat)

Products Affected

- ISTURISA

PA Criteria	Criteria Details
Exclusion Criteria	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 baseline serum potassium and magnesium levels.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Continuation requires documentation of clinically relevant response to therapy, including, but not limited to 24-hour UFC level.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	1 year
Other Criteria	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

JAKAFI (ruxolitinib)

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	Platelet count less than 50 x 10^9/L
Required Medical Information	Diagnosis of covered use, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

JAYPIRCA (pirtobrutinib)

Products Affected

- JAYPIRCA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient has tried and failed at least two previous lines of systemic therapy (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	PA applies to new starts only. For mantle cell lymphoma, one of two previous lines of therapy must have included a Bruton's tyrosine kinase (BTK) inhibitor. For chronic lymphocytic leukemia or small lymphocytic lymphoma, previous lines of therapy must have included a Bruton's tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to all. Submission of objective documentation of a clinical benefit (e.g., normalization of lymphocyte subsets, normalization of lymphadenopathy, reduction in spleen size, etc.) in the absence of unacceptable toxicity will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

JUXTAPID (lomitapide)

Products Affected

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, moderate or severe hepatic impairment (Child-Pugh class B or C), active liver disease, coadministration with moderate or strong CYP3A4 inhibitors
Required Medical Information	Diagnosis of covered use, including at least one of the following criteria: (1) documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality, (2) skin fibroblast LDL receptor activity less than 20% of normal, or (3) untreated total cholesterol above 500 mg/dL and triglycerides less than 300 mg/dL and both parents with a documented untreated total cholesterol above 250 mg/dL, submission of baseline lab values including ALT, AST, alkaline phosphatase, total bilirubin, baseline LDL-C, total cholesterol (TC), apoB, and non-HDL-C, pregnancy status for female patients of childbearing potential, documentation of contraindication to or treatment failure with evolocumab.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology, lipidology, and endocrinology with experience in and a focus on lipid management
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Submission of LDL level drawn after the initial LDL level submission documenting clinically significant response to therapy will be required for reauthorization. For approval, the patient must have tried and failed to have an adequate response to, had an intolerance to, or have a contraindication to therapy with evolocumab. There is no evidence for effectiveness in heterozygous familial hypercholesterolemia and will not be approved for this indication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

JYNARQUE (tolvaptan)

Products Affected

- JYNARQUE

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 (1) total kidney volume increases of at least 5% per year confirmed by repeat MRI or ultrasound measurements at least 6 months apart or (2) GFR decline of at least 2.5 mL/min/year over a 5-year period or (3) GFR decline of at least 5 mL/min/year over the previous year, submission of serum sodium concentration.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to nephrology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

KALYDECO (ivacaftor)

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of cystic fibrosis mutation test confirming presence of a CFTR gene mutation predicted to be responsive to ivacaftor (see section 12.1 of package insert for full list).
Age Restrictions	
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

KERENDIA (finerenone)

Products Affected

- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	Adrenal insufficiency, estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73 m2, serum potassium above 5.0 mEq/L, severe (Child-Pugh class C) hepatic impairment, coadministration with strong CYP3A4 inhibitors or moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of estimated glomerular filtration rate (eGFR) and baseline serum potassium level.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. For approval, the patient must have documentation of a trial of Farxiga or Jardiance.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	Ketoconazole is being requested for the treatment of culture-proven systemic blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis, submission of baseline ALT, AST, total bilirubin, alkaline phosphatase, prothrombin time and INR, confirmation from the prescriber that the potential benefits of therapy outweigh the risks.
Age Restrictions	2 years of age or older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

KISQALI (ribociclib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome, QTcF interval greater than 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 and HER2-negative, submission of QTcF interval, serum potassium and magnesium within the previous 6 months, and pregnancy status for female patients of childbearing potential. For patients receiving Kisqali alone, confirmation 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

KORLYM (mifepristone)

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, submission of baseline serum potassium, AST, ALT, and alkaline phosphatase, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 Child-Pugh score or liver function testing results, 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	PA applies to new starts only. 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

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, submission of previous systemic treatment(s) tried.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LAPATINIB

Products Affected

- *lapatinib ditosylate*

PA Criteria	Criteria Details
Exclusion Criteria	Uncorrected hypokalemia, uncorrected hypomagnesemia
Required Medical Information	Diagnosis of covered use, submission of baseline potassium and magnesium levels, pregnancy status for female patients of childbearing potential, and depending on indication, confirmation that the treatment regimen will include concomitant use of either capecitabine or letrozole. For patients who will be using lapatinib with capecitabine, submission of prior therapies tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LAZCLUZE (lazertinib)

Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of required genetic mutations/deletions for indication, documentation that the medication will be used in combination with amivantamab, documentation that the patient has not received prior treatment for locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, attestation that females of reproductive potential are not pregnant and have been advised to use effective contraception during treatment and for 3 weeks after the last dose or that males with female partners of reproductive potential have been advised to use effective contraception during treatment and for 3 weeks after the last dose
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

LEDIPASVIR/SOFOSBUVIR

Products Affected

- HARVONI ORAL PACKET 45-200 MG
- HARVONI ORAL TABLET 90-400 MG
- *ledipasvir-sofosbuvir*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) genotype 1a, 1b, 4, 5, or 6 infection, submission of baseline HCV RNA level, documentation of whether cirrhosis is present or not and whether or not it is compensated or decompensated, confirmation of whether patient is treatment-naive or treatment-experienced, confirmation a test for HBV infection (HBsAg and anti-HBc) was completed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Treatment-experienced pts w/genotype 1 and compensated cirrhosis, 24 weeks. All others, 12 weeks.
Other Criteria	PA applies to all. For treatment-naive patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL, 8 weeks of therapy may be considered by the provider. For approval of brand Harvoni 90 mg/400 mg, the patient must have tried and failed to have an adequate response to or had an intolerance to ledipasvir/sofosbuvir 90 mg/400 mg.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LENALIDOMIDE

Products Affected

- *lenalidomide*
- REVLIMID

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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LIDOCAINE TRANSDERMAL PATCHES

Products Affected
- *lidocaine external patch 5 %*
- LIDOCAN
- LIDOCAN III
- 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	PA applies to all. FDA-approved only for postherpetic neuralgia. Requests for other indications will not be approved.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

LIVMARLI (maralixibat)

Products Affected

- LIVMARLI

PA Criteria	Criteria Details
Exclusion Criteria	History of liver transplant, clinical evidence of decompensated cirrhosis
Required Medical Information	Diagnosis of covered use confirmed by molecular genetic testing, attestation drug-induced pruritus has been ruled out, attestation patient has tried and failed at least two of the following medications for pruritus: ursodiol, cholestyramine, naltrexone, rifampin.
Age Restrictions	
Prescriber Restrictions	Restricted to gastroenterology and hepatology
Coverage Duration	1 year
Other Criteria	PA applies to all. Attestation of improvement in pruritus symptoms and confirmation the patient has not progressed to portal hypertension or has had a hepatic decompensation event since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 previous anti-CMV medication(s) patient has tried and failed (at least one of cidofovir, foscarnet, ganciclovir, valganciclovir).
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	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LODOCO (colchicine)

Products Affected

- LODOCO

PA Criteria	Criteria Details
Exclusion Criteria	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, (2) prior ischemic stroke, transient ischemic attack, or carotid artery stenosis greater than 50%, (3) prior coronary revascularization, (4) proven coronary artery disease on invasive coronary angiography or computer tomography angiography, (5) coronary-artery calcium score greater than or equal to 300 Agatston units, (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	PA applies to all. This product is not indicated for the treatment of gout and will not be authorized for this use.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	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 prior therapies used for indication, submission of ALT, AST, and bilirubin, pregnancy status for female patients of childbearing potential. For metastatic colorectal cancer, documentation of KRAS status.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LUMAKRAS (sotorasib)

Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 320 MG

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, submission of previous systemic treatment(s) tried.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LUPKYNIS (voclosporin)

Products Affected

- LUPKYNIS

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, coadministration with strong CYP3A4 inhibitors, moderate or strong CYP3A4 inducers, or cyclophosphamide, hypertensive emergency or a baseline blood pressure above 165/105 mmHg
Required Medical Information	Diagnosis of covered use including documentation of biopsy-proven Class III, IV, or V lupus nephritis, attestation patient will be taking concurrently with mycophenolate mofetil and corticosteroids, submission of estimated glomerular filtration rate (eGFR), urine protein to creatinine ratio (UPCR), baseline blood pressure, pregnancy status for female patients of childbearing potential, and any previous therapies tried.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. For approval, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to Benlysta (belimumab) and have a UPCR of at least 1.5 mg/mg. Documentation of a positive response to therapy will be required for initial reauthorization after the first 6 months. Maintenance of a clinical benefit, attestation that prescriber believes benefits of continuing therapy outweigh the potential risks to the patient, and updated eGFR and blood pressure since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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, confirmation patient has previously tried and failed, had an intolerance to, or had a contraindication to at least one generic second-generation antipsychotic with low incidence of metabolic side effects (e.g., aripiprazole, ziprasidone), attestation patient has had a trial of generic olanzapine with documentation showing a positive therapeutic benefit but unacceptable weight gain (greater than or equal to a 7% gain from baseline body weight) while using olanzapine.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and psychiatry
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. Reduction in or stabilization of body weight since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

LYNPARZA (olaparib)

Products Affected

- LYNPARZA ORAL TABLET

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 applicable mutations and previous therapies tried and failed depending on cancer type as necessary.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and urology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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, submission of previous systemic treatment(s) 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MAVENCLAD (cladribine)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Current malignancy, pregnancy, HIV or other active chronic infection (e.g., hepatitis or tuberculosis), lymphocyte count below normal limit before first course or less than 800 cells/microliter before second course, creatinine clearance below 60 mL/min, Child-Pugh score greater than 6, patients with clinically isolated syndrome (CIS)
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential, submission of previous therapies tried and failed, lymphocyte count, 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	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to all. For approval, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two on-formulary medications for the maintenance treatment of relapsing forms of multiple sclerosis. Documentation of a positive response to therapy, confirmation the patient has no active infection, and updated lymphocyte count and creatinine clearance since the previous authorization will be required for reauthorization. After the completion of 2 treatment courses (2 years' treatment), additional treatment courses are not recommended over the following 2 years because of malignancy risk. Re-initiating treatment after those 2 years have passed has not been studied. Requests for therapy for a combined total of greater than 2 years will not be approved.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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), documentation of whether cirrhosis is present or not and whether or not it is compensated or decompensated, confirmation a test for HBV infection (HBsAg and anti-HBc) was completed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Criteria for coverage duration will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MECASERMIN

Products Affected
- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	Patients with closed epiphyses
Required Medical Information	Diagnosis of covered use, documentation of primary insulin-like growth factor (IGF-1) deficiency or growth hormone gene deletion in patients who have developed neutralizing antibodies to growth hormone, submission of IGF-1 level and growth hormone level.
Age Restrictions	
Prescriber Restrictions	Restricted to endocrinology and nephrology
Coverage Duration	6 months
Other Criteria	PA applies to all. Updated IGF-1 and growth hormone levels since the previous authorization will be required for subsequent reauthorizations. Mecasermin is not indicated as a growth hormone replacement and will not be approved for this indication.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MEGESTROL IN OLDER PATIENTS

Products Affected

- *megestrol acetate oral suspension 40 mg/ml, 400 mg/10ml, 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	PA applies to all except hematology and oncology.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MEKINIST (trametinib)

Products Affected

- MEKINIST

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 all indications except BRAF-inhibitor treatment-naïve patients with unresectable or metastatic melanoma, attestation that therapy will be used in combination with dabrafenib.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

METHOTREXATE INJECTABLE (SUBCUTANEOUS)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, documentation of intolerance or inadequate response to oral or non-subcutaneous injectable forms of methotrexate.
Age Restrictions	
Prescriber Restrictions	Restricted to rheumatology and dermatology
Coverage Duration	1 year
Other Criteria	PA applies to all. These medications are not approved for use in oncology and will not be approved for cancer diagnoses.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MYALEPT (metreleptin)

Products Affected

- MYALEPT

PA Criteria	Criteria Details
Exclusion Criteria	General obesity not associated with congenital leptin deficiency
Required Medical Information	Diagnosis of covered use, submission of leptin level laboratory test result confirming leptin deficiency, baseline HbA1c, fasting glucose, fasting triglyceride levels, and weight.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated patient weight, HbA1c, fasting glucose, and fasting triglyceride levels since the previous authorization will be required for subsequent annual reauthorizations. Metreleptin is not established as a treatment for nonalcoholic steatohepatitis, complications of partial lipodystrophy, HIV-related lipodystrophy, or metabolic disease without generalized lipodystrophy, and submissions for these uses will not be approved.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

MYCAPSSA (octreotide)

Products Affected

- MYCAPSSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of prior use of either injectable octreotide or lanreotide and attestation to its successful treatment of acromegaly using clinical biomarkers or chart notes.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NAMZARIC (memantine and donepezil)

Products Affected
- NAMZARIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of documentation that the patient has been stabilized on donepezil 10 mg daily.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NATPARA (parathyroid hormone)

Products Affected

- NATPARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation that (albumin-corrected) serum calcium is greater than 7.5 mg/dL and confirmation that 25-hydroxyvitamin D stores are sufficient.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NEXAVAR (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 carcinoma, attestation patient has disease refractory to radioactive iodine therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NITISINONE

Products Affected

- *nitisinone*
- ORFADIN ORAL SUSPENSION

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	PA applies to all. Updated liver function tests, urine succinylacetone levels, alpha-fetoprotein level, serum tyrosine level, and serum phenylalanine level since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	
Required Medical Information	Diagnosis of covered use. For eosinophilic asthma, documentation that patient's symptoms are poorly controlled with inhaled corticosteroids, submission of pulmonary function test results including FEV1, frequency of inhaled short-acting beta2-agonist therapy, frequency of daily and nighttime symptoms and exacerbations, and effect of exacerbations on activity, submission of blood eosinophil 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 chronic rhinosinusitis with nasal polyps, documentation of treatment with an intranasal corticosteroid for at least 8 weeks, a contraindication to the use of intranasal corticosteroids, or therapy is not otherwise advisable.
Age Restrictions	
Prescriber Restrictions	Restricted to allergy, hematology, immunology, otorhinolaryngology, pulmonology, and rheumatology
Coverage Duration	1 year
Other Criteria	PA applies to all. Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved. A description of 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

NUEDEXTA (dextromethorphan and quinidine)

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	Prolonged QT interval, congenital long QT syndrome, heart failure, history suggestive of torsades de pointes, AV block without implanted pacemaker, administration of non-selective monoamine oxidase inhibitors within 14 days of initiation
Required Medical Information	Diagnosis of covered use, submission of ECG (specifically QT interval).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and psychiatry
Coverage Duration	1 year
Other Criteria	PA applies to all. The medication will not be approved for agitation or Alzheimer's disease without pseudobulbar affect as this is considered an off-label use.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

NUPLAZID (pimavanserin)

Products Affected
- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related 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, hypokalemia, hypomagnesemia
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OCALIVA (obeticholic acid)

Products Affected

- OCALIVA ORAL TABLET 10 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Complete biliary obstruction, decompensated cirrhosis (Child-Pugh B or C) or prior decompensation event, compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
Required Medical Information	Diagnosis of covered use, documentation either (1) drug will be used in combination with ursodeoxycholic acid (UDCA) and UDCA has been used for at a stable dosage for at least 3 months or (2) patient had intolerance to UDCA, submission of baseline LFTs including ALP and total bilirubin, attestation patient does not have evidence of portal hypertension and has not had a prior decompensation event.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Documentation of a reduction in ALP will be required after the first 6 months. Maintenance of a clinical benefit will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OFEV (nintedanib)

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe (Child-Pugh class B or C) hepatic impairment, coadministration of a dual P-glycoprotein/CYP3A4 inducer
Required Medical Information	Diagnosis of covered use, submission of liver function tests or Child-Pugh status, 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 diagnoses, 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 or rheumatology
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated liver function testing or Child-Pugh score since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OGSIVEO (nirogacestat)

Products Affected

- OGSIVEO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inhibitors or inducers
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	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

OHTUVAYRE (ensifentrine)

Products Affected
- OHTUVAYRE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of chronic obstructive pulmonary disease (COPD), FEV1/FVC ratio less than 0.7, post-bronchodilator FEV1 % predicted of greater than or equal to 30% and less than or equal to 80%, modified Medical Research Council (mMRC) Dyspnea Scale score greater than or equal to 2. One of the following, 1) currently receiving dual therapy with a long-acting beta agonist (LABA) and a long-acting muscarinic agonist (LAMA) with or without an inhaled corticosteroid (ICS), OR 2) documentation that dual LABA-LAMA or triple LABA-LAMA-ICS therapy has been ineffective, not tolerated, or is contraindicated. Attestation drug will not be used in combination with roflumilast. Attestation that patient will continue current dual LABA-LAMA therapy with or without an ICS.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	6 months initially, then 1 year
Other Criteria	PA applies to all when covered as a Part D benefit. For reauthorization, documentation of proof of benefit (spirometry results from baseline and/or decreased symptoms from baseline) and documentation the patient remains on background LAMA-LABA therapy with or without an ICS.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	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	
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	PA applies to new starts only. 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

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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ONUREG (azacitidine)

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	
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 cannot complete intensive curative therapy, submission of absolute neutrophil count, 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	PA applies to new starts only. This dosage form is not intended to be a substitute for or substituted for injectable azacitidine.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OPFOLDA (miglustat)

Products Affected

- OPFOLDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of previous enzyme replacement therapies tried and failed, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ORENITRAM (treprostinil)

Products Affected

- ORENITRAM
- ORENITRAM MONTH 1
- ORENITRAM MONTH 2
- ORENITRAM MONTH 3

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe (Child-Pugh class B or C) hepatic impairment
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OREXIN RECEPTOR ANTAGONISTS

Products Affected

- DAYVIGO ORAL TABLET 10 MG, 5 MG
- QUVIVIQ

PA Criteria	Criteria Details
Exclusion Criteria	Narcolepsy
Required Medical Information	Diagnosis of covered use. Patient must have tried and failed to tolerate or had an inadequate response to two covered alternative therapies recommended by the American Academy of Sleep Medicine (doxepin, eszopiclone, ramelteon, suvorexant, temazepam, zaleplon, zolpidem) including one non-suvorexant therapy for sleep maintenance (doxepin, eszopiclone, temazepam) if that is the 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	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology and gynecology
Coverage Duration	Up to 24 months based on liver function and coexisting dyspareunia. See "Other Criteria" section.
Other Criteria	PA applies to all. For endometriosis with dyspareunia or in women with moderate hepatic impairment, 6 months. For endometriosis without dyspareunia, 150 mg daily for 24 months. 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 Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ORKAMBI (lumacaftor/ivacaftor)

Products Affected

- ORKAMBI

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of cystic fibrosis mutation test confirming presence of two copies of the F508del mutation in the CFTR gene.
Age Restrictions	
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 presence of ESR1 mutation and liver function testing or Child-Pugh score, documentation of prior endocrine therapy/therapies patient has tried and failed. 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OXBRYTA (voxelotor)

Products Affected
- OXBRYTA

PA Criteria	Criteria Details
Exclusion Criteria	Hemoglobin greater than 10.5 g/dL
Required Medical Information	Diagnosis of covered use, submission of hemoglobin level, documentation of treatment failure with at least a three-month trial of hydroxyurea or a hematologic toxicity requiring discontinuation of a prior regimen of hydroxyurea therapy.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Submission of improved hemoglobin level from baseline will be required for initial reauthorization after the first 6 months. Documentation of continued hemoglobin level improvement or maintenance of initial hemoglobin level improvement will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OXERVATE (cenegermin-bkbj)

Products Affected

- OXERVATE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	Restricted to optometry and ophthalmology
Coverage Duration	8 weeks
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

OXYBATE SALT MEDICATIONS

Products Affected

- XYREM
- XYWAV

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with sedative hypnotics
Required Medical Information	Diagnosis of covered use confirmed with documentation from a sleep study, submission of previous therapies used for diagnosis (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	PA applies to all. For adults with excessive daytime sleepiness associated with narcolepsy, drugs in this policy will be authorized only if the patient previously tried and had an inadequate clinical response, intolerance, or contraindication to (1) armodafinil or modafinil and (2) solriamfetol. Medications covered in this policy are not indicated to treat insomnia and will not be approved for this use.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PALYNZIQ (pegvaliase-pqpz)

Products Affected

- PALYNZIQ

PA Criteria	Criteria Details
Exclusion Criteria	Blood phenylalanine concentration below 600 micromol/L
Required Medical Information	Diagnosis of covered use, submission of blood phenylalanine concentration, documentation patient has tried and failed to respond to at least 30 days of sapropterin therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. For initial approval, documentation of a phenylalanine concentration above 600 micromol/L while using sapropterin therapy is required. Reduction in blood phenylalanine concentration from pre-treatment baseline will be required for initial reauthorization after the first year. Documentation of continued phenylalanine level improvement or maintenance of initial phenylalanine level improvement will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PANRETIN (alitretinoin)

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, requirement for systemic Kaposi's sarcoma therapy (more than 10 new Kaposi's sarcoma lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary Kaposi's 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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, prescription claims or documentation from physician showing patient (a) has tried and failed or had an intolerance to medications from at least two different drug classes that can help to reduce "off" episodes (COMT inhibitors, dopamine agonists, monoamine oxidase B inhibitors), or (b) has tried and failed or had an intolerance to one medication from a drug class that can help to reduce "off" episodes if they have contraindications to two of these drug classes, or (c) has contraindications to all three drug classes that can help to reduce "off" episodes.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PCSK9 INHIBITORS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous lipid-lowering therapies (see Other Criteria).
Age Restrictions	For Repatha, 10 years of age or older. For Praluent, 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval, the patient must currently be using a statin plus ezetimibe or the patient must have tried and failed to have an adequate response to or had an intolerance to at least two statins or one statin and ezetimibe. At least one statin previously tried and failed must be a hydrophilic statin.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PDE5 INHIBITORS (PAH)

Products Affected

- ALYQ
- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate oral tablet 20 mg*
- *tadalafil (pah)*

PA Criteria	Criteria Details
Exclusion Criteria	For tadalafil, diagnosis of severe (Child-Pugh class C) hepatic impairment, creatinine clearance below 30 mL/min or on hemodialysis
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PEGFILGRASTIM

Products Affected

- NEULASTA ONPRO
- NEULASTA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- 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	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	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, submission of previous systemic treatment(s) 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PIRFENIDONE

Products Affected

- *pirfenidone oral tablet 267 mg, 801 mg*

PA Criteria	Criteria Details
Exclusion Criteria	End-stage renal disease on dialysis, severe (Child-Pugh class C) hepatic impairment
Required Medical Information	Diagnosis of covered use, submission of liver function tests or Child-Pugh status.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated liver function testing or Child-Pugh score since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 has used a lenalidomide-based treatment regimen. For Kaposi sarcoma, attestation patient is HIV-negative or patient is using 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PREVYMIS (letermovir)

Products Affected

- PREVYMIS ORAL

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, documentation of any previous doses of letermovir. 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	18 years of age or older
Prescriber Restrictions	Restricted to hematology, oncology, transplant specialist, and infectious diseases
Coverage Duration	Through 100 days post-transplant for HSCT or through 200 days post-transplant for kidney transplant
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PRIOR AUTHORIZATION TO OVERRIDE SPECIALTY RESTRICTIONS

Products Affected

- CORLANOR ORAL SOLUTION
- *diclofenac sodium external gel 3 %*
- *ivabradine hcl*
- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- SYMLINPEN 120 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- SYMLINPEN 60 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- *tazarotene external cream*
- *tazarotene external gel*
- TAZORAC EXTERNAL CREAM 0.05 %
- VABOMERE
- VEMLIDY

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	(a) for ivabradine and Corlanor: cardiology exempt, (b) for diclofenac 3% gel: dermatology or oncology exempt, (c) for Pegasys: gastroenterology, hepatology, or infectious diseases exempt, (d) for Symlin: endocrinology exempt, (e) for tazarotene and Tazorac: dermatology exempt, (f) for Vabomere: infectious diseases or nephrology exempt, (g) for Vemlidy: gastroenterology, hepatology, or infectious diseases exempt
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PROCYSBI (cysteamine)

Products Affected

- PROCYSBI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation that patient has tried and failed or had an intolerance to immediate-release cysteamine.
Age Restrictions	1 year of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. For approval, the patient must have tried and failed to have an adequate response to, had an intolerance to, or have a contraindication to therapy with immediate-release cysteamine.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PROLIA (denosumab)

Products Affected

- PROLIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia, pregnancy
Required Medical Information	Diagnosis of covered use, submission of calcium level, pregnancy status for female patients of childbearing potential. "High risk for fracture" is defined as (1) a history of osteoporotic fracture or (2) multiple risk factors for fracture or (3) patients who have failed or are intolerant of other available osteoporosis therapies, confirmation of osteoporosis diagnosis either through densitometry (T-score less than or equal to -2.5 at the total hip, femoral neck, or lumbar spine) or clinically (documented presence of fragility fracture).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated serum calcium level since the previous authorization will be required for subsequent reauthorizations. 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

PROMACTA (eltrombopag)

Products Affected

- PROMACTA ORAL PACKET
- PROMACTA 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. 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 therapy or therapies tried and failed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	For ITP, initially 12 weeks, then 1 year. For AA, 6 months. For all other indications, 1 year.
Other Criteria	PA applies to all. Initial approval for ITP requires (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 and/or tried and failed two different ITP therapies including systemic corticosteroids, immunoglobulins, danazol, fostamatinib, or cytotoxics/immunosuppressants such as rituximab. For ITP, documentation of an improvement in platelet count will be required for initial reauthorization after the first 12 weeks. Maintenance of a clinical benefit will be required for subsequent annual reauthorizations. Initial approval in patients with chronic hepatitis C requires platelet count less than 75 x 10^9/L. Initial approval for aplastic anemia requires platelet count less than 30 x 10^9/L. Updated platelet count since the previous authorization will be required for subsequent reauthorizations. Not indicated for treatment of patients with myelodysplastic syndrome and will not be approved for this use.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

PROMETHAZINE IN OLDER PATIENTS

Products Affected

- *promethazine hcl oral*
- *promethazine hcl rectal suppository 12.5 mg, 25 mg*
- *promethazine vc plain*
- *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	PA applies to all. 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 Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PROSTATE CANCER ORAL MEDICATIONS

Products Affected

- *abiraterone acetate oral tablet 250 mg*
- ERLEADA
- NUBEQA
- XTANDI

PA Criteria	Criteria Details
Exclusion Criteria	For abiraterone, severe hepatic impairment (Child-Pugh class C), uncontrolled hypertension
Required Medical Information	Diagnosis of covered use. For Nubeqa, documentation of other treatments tried (see Other Criteria). For abiraterone, confirmation patient will receive concurrent prednisone, submission of baseline ALT, AST, bilirubin, and serum potassium level.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and urology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. Nubeqa will be authorized only if the patient previously tried and had an inadequate clinical response or an intolerance to both Erleada and Xtandi.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

PYRUKYND (mitapivat)

Products Affected

- PYRUKYND
- PYRUKYND TAPER PACK ORAL TABLET THERAPY PACK 5 MG, 7 X 20 MG & 7 X 5 MG, 7 X 50 MG & 7 X 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with hematopoietic stimulating agents or strong CYP3A4 inhibitors or inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of at least two mutant alleles in the PKLR gene, of which at least one is a missense mutation, and where the mutations are not a homozygous R479H mutation, hemoglobin level within the previous 3 months less than or equal to 10 mg/dL, number of red blood cell (RBC) transfusions in the previous 12 months (to establish baseline severity only).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology or specialists in inborn errors of metabolism
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. For initial reauthorization, improvement of hemoglobin level and/or reductions in annualized rate of RBC transfusions is required. Continued improvement/stability in either hemoglobin level or reductions in RBC transfusional burden from baseline will be required for subsequent reauthorizations.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RADICAVA ORS (edaravone)

Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT

PA Criteria	Criteria Details
Exclusion Criteria	ALS duration of greater than 2 years
Required Medical Information	Diagnosis of covered use, submission of ALS Functional Rating Scale-Revised (ALSFRS-R) scoring (patient is required to have 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	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

RAVICTI (glycerol phenylbutyrate)

Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline fasting plasma ammonia level, documentation patient has tried and failed, has a contraindication to, or could not tolerate sodium phenylbutyrate.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RECORLEV (levoketoconazole)

Products Affected

- RECORLEV

PA Criteria	Criteria Details
Exclusion Criteria	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, or 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, osilodrostat, pasireotide).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Continuation requires documentation of clinically relevant response to therapy, including, but not limited to 24-hour UFC level. Recorlev is not approved for the treatment of fungal infections and will not be approved for this use.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

RELYVRIO (sodium phenylbutyrate/taurursodiol)

Products Affected

- RELYVRIO

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment, moderate or severe renal impairment, tracheostomy, permanent assisted ventilation
Required Medical Information	Diagnosis of covered use, submission of ALS Functional Rating Scale-Revised (ALSFRS-R) scoring (patient is required to have ALSFRS-R score greater than 20), submission of chart data showing patient is starting drug within 18 months of symptom onset, documentation patient is currently using, has tried and failed, has a contraindication to, or could not tolerate riluzole.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

RETEVMO (selpercatinib)

Products Affected

- RETEVMO ORAL CAPSULE 40 MG, 80 MG
- 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 patients with RET fusion-positive thyroid cancer, documentation of previous radioactive iodine treatment or reason why radioactive iodine therapy is not appropriate.
Age Restrictions	2 years of age or older based on indication
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

REZUROCK (belumosudil)

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	
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	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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 estimated glomerular filtration rate (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	9 years of age or older
Prescriber Restrictions	Restricted to nephrology and urology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Reauthorization requires documentation of clinically relevant response to therapy as evidenced by reduced Uox or plasma oxalate levels.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ROZLYTREK (entrectinib)

Products Affected

- ROZLYTREK

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers
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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 maintenance treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer, documentation of response to platinum-based chemotherapy. For BRCA mutation-associated mCRPC, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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, documentation of other chemotherapy that will be coadministered with midostaurin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to all. Reduction in blood phenylalanine concentration from pre-treatment baseline will be required for initial reauthorization. Documentation of continued phenylalanine level improvement or maintenance of initial phenylalanine level improvement will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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. For use in patients without a T315I mutation, documentation of other tyrosine kinase inhibitors tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval in T315I-mutation-positive CML, the patient must have tried and failed to have an adequate response to or had an intolerance to ponatinib.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to new starts only. 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 Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SEROSTIM (somatropin)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Active malignancy, acute critical illness, active proliferative or severe non-proliferative diabetic retinopathy
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. Serostim is indicated only for the treatment of HIV-associated cachexia/wasting and uses outside of this indication will not be approved.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Continuation requires documentation of clinically relevant response to therapy including, but not limited to 24-hour UFC level.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SIMVASTATIN 80 mg per day

Products Affected

- *ezetimibe-simvastatin oral tablet 10-80 mg*
- *simvastatin oral tablet 80 mg*
- VYTORIN ORAL TABLET 10-80 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 12 months or longer without adverse effects.
Age Restrictions	10 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. Not recommended as initial therapy nor for patients already taking lower doses of simvastatin whose response is inadequate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SIRTURO (bedaquiline)

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	Drug-sensitive tuberculosis, latent infection, extra-pulmonary tuberculosis
Required Medical Information	Diagnosis of covered use, confirmation that Sirturo will be co-administered with pretomanid and linezolid or at least 3 other drugs proven to be or at least 4 other drugs suspected to be effective against the patient's M. tuberculosis isolate and submission of susceptibility testing, if available.
Age Restrictions	5 years of age or older
Prescriber Restrictions	Restricted to infectious diseases and pulmonology
Coverage Duration	26 weeks
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	12 years of age or older
Prescriber Restrictions	Restricted to infectious diseases
Coverage Duration	6 days
Other Criteria	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SKYCLARYS (omaveloxolone)

Products Affected

- SKYCLARYS

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment
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	PA applies to all. Documentation of a positive response to therapy will be required for initial reauthorization after the first year. Maintenance of a clinical benefit and attestation that prescriber believes benefits of continuing therapy outweigh the potential risks to the patient will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SOFOSBUVIR/VELPATASVIR

Products Affected

- EPCLUSA ORAL PACKET
- EPCLUSA ORAL TABLET 200-50 MG, 400-100 MG
- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) infection, submission of baseline HCV RNA level, documentation of whether cirrhosis is present or not and whether it is compensated or decompensated, confirmation that patients with decompensated cirrhosis will receive concomitant ribavirin therapy unless ribavirin therapy is otherwise clinically not indicated, submission of eGFR (safety and efficacy of sofosbuvir/velpatasvir has not been established in patients with eGFR less than 30 mL/min/1.73 m2), confirmation a test for HBV infection (HBsAg and anti-HBc) was completed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	PA applies to all. For approval of brand Epclusa 400 mg/100 mg, the patient must have tried and failed to have an adequate response to or had an intolerance to sofosbuvir/velpatasvir 400 mg/100 mg.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SOHONOS (palovarotene)

Products Affected

- SOHONOS

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inhibitors, coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of R206H ACVR1 mutation and 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	PA applies to all. Attestation patient is benefitting from treatment and continues to undergo regular pregnancy testing (as necessary for patients of childbearing potential) will be required for all annual reauthorizations.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	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 either (a) are less than or equal to 3 times the upper limit of normal (ULN), or (b) if 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	PA applies to all. 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) will be required for initial reauthorization. Updated IGF-1 level demonstrating continued improvement or maintenance of initial effect will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SOVALDI (sofosbuvir)

Products Affected

- SOVALDI ORAL PACKET
- SOVALDI ORAL TABLET 200 MG, 400 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) genotype 1a, 1b, 2, 3, or 4 infection, documentation of whether cirrhosis is present or not and whether or not it is compensated or decompensated, confirmation a test for HBV infection (HBsAg and anti-HBc) was completed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Criteria for coverage duration will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SPRYCEL (dasatinib)

Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*
- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	Uncorrected hypokalemia, uncorrected 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 previous therapies to match indication, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SUNOSI (solriamfetol)

Products Affected

- SUNOSI ORAL TABLET 150 MG, 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	End-stage renal disease, administration of non-selective monoamine oxidase inhibitors within 14 days of initiation, serious arrhythmias, unstable cardiovascular disease including uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, submission of baseline blood pressure reading and previous therapies used for diagnosis (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and sleep medicine
Coverage Duration	1 year
Other Criteria	PA applies to all. This medication will be authorized only if the patient previously tried and had an inadequate clinical response, intolerance, or contraindication to armodafinil or modafinil. Solriamfetol is not indicated to treat the underlying airway obstruction in obstructive sleep apnea and will not be approved for this use.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SYMDEKO (tezacaftor/ivacaftor)

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of cystic fibrosis mutation test confirming presence of two copies of the F508del mutation in the CFTR gene or at least one mutation in the CTFR gene responsive to the drug (see section 12.1 of package insert for full list).
Age Restrictions	
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SYMPROIC (naldemedine)

Products Affected

- SYMPROIC

PA Criteria	Criteria Details
Exclusion Criteria	Known or suspected gastrointestinal obstruction or increased risk of recurrent obstruction, severe hepatic impairment (Child-Pugh class C)
Required Medical Information	Diagnosis of covered use, documentation patient has been using opioids at a morphine milligram equivalent of at least 30 mg daily for at least 4 weeks prior to initiation, provider attestation that if opioid medication is stopped for any reason, naldemedine will be discontinued.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

SYNAREL (nafarelin)

Products Affected

- SYNAREL

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy/breast-feeding, undiagnosed abnormal vaginal bleeding
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	For endometriosis, 6 months. For all other diagnoses, 1 year.
Other Criteria	PA applies to all. Re-treatment for endometriosis is not recommended because safety data are not available.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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, scintigraphy, or mass spectrometry, or (3) a TTR genetic mutation plus cardiac involvement defined as thickening of the interseptal ventricular wall, 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	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TAFINLAR (dabrafenib)

Products Affected

- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP2C8 or CYP3A4 inhibitors
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 all indications except unresectable/metastatic melanoma with a BRAF V600E mutation, attestation that therapy will be used in combination with trametinib.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 required genetic mutations/deletions for indication, pregnancy status for female patients of childbearing potential. For EGFR T790M mutation-positive NSCLC, documentation that the patient has progressed on or after EGFR TKI therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TARPEYO (budesonide)

Products Affected

- TARPEYO

PA Criteria	Criteria Details
Exclusion Criteria	Severe (Child-Pugh class C) hepatic impairment, estimated glomerular filtration rate (eGFR) less than 35 mL/min/1.73 m2
Required Medical Information	Diagnosis of primary IgA nephropathy confirmed by biopsy, submission of 24-hour urine protein of at least 1 g/day or 24-hour urine protein-to-creatinine ratio of at least 0.8 g/g, eGFR, liver function testing or Child-Pugh class, attestation patient is stable on a maximally-tolerated renin-angiotensin system antagonist (ACE inhibitor or ARB), documentation patient has progressed on at least one immunosuppressant (e.g., azathioprine, mycophenolate, etc.).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to immunology and nephrology
Coverage Duration	41 weeks
Other Criteria	PA applies to all. Approval for additional 41-week courses requires documentation of clinically relevant response to therapy, including, but not limited to stabilization or improvement of urine protein-to-creatinine ratio or eGFR.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

TASIGNA (nilotinib)

Products Affected

- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	Uncorrected hypokalemia, uncorrected 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, submission of Philadelphia chromosome (Ph) status, potassium and magnesium levels.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 Smith-Magenis Syndrome patients only, documentation of genetic testing results confirming diagnosis is required.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology and sleep medicine
Coverage Duration	1 year
Other Criteria	PA applies to all. For non-24-hour sleep-wake disorder, patients are required to be totally blind to match the population in which tasimelteon was studied.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TAVALISSE (fostamatinib)

Products Affected

- TAVALISSE ORAL TABLET 100 MG, 150 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, 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 documented increased risk of bleeding, documentation patient has undergone splenectomy and/or tried and failed two different ITP therapies including systemic corticosteroids, immunoglobulins, danazol, fostamatinib, or cytotoxics/immunosuppressants such as rituximab.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology
Coverage Duration	Initially 12 weeks, then 1 year
Other Criteria	PA applies to all. Documentation of an improvement in platelet count will be required for initial reauthorization after the first 12 weeks. Maintenance of a clinical benefit will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 (GPA or MPA variant of ANCA-associated vasculitis) and confirmation 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	PA applies to all. Reauthorization requires 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.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

TAZVERIK (tazemetostat)

Products Affected
- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inhibitors or moderate or strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TEGSEDI (inotersen)

Products Affected

- TEGSEDI

PA Criteria	Criteria Details
Exclusion Criteria	Platelet count less than 100 x 10^9/L, urine protein to creatinine ratio (UPCR) above 1,000 mg/g
Required Medical Information	Diagnosis of covered use, submission of genetic testing confirming presence of TTR gene mutation, submission of platelet count and urine protein to creatinine ratio.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated platelet count since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TERIPARATIDE

Products Affected

- FORTEO SUBCUTANEOUS SOLUTION PEN-INJECTOR 600 MCG/2.4ML
- *teriparatide subcutaneous solution pen-injector 600 mcg/2.4ml, 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 (1) a history of osteoporotic fracture or (2) multiple risk factors for fracture or (3) patients who have failed or are intolerant of other available osteoporosis therapies, submission of baseline serum calcium, postmenopausal status, documentation that at least one bisphosphonate was tried and failed (or all bisphosphonates, including zoledronic acid, are contraindicated), submission of a value, condition, or past medical history that assesses fracture risk (e.g., DEXA scan results or prior fracture), submission of number of total months of all prior use of parathyroid hormone analogs and parathyroid hormone related peptides.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 years unless patient is at high risk for fracture after 2 years of therapy (see Other Criteria)
Other Criteria	PA applies to all. A trial of teriparatide is required for new starts to therapy. Forteo will be approved only if the patient has (1) tried and failed teriparatide or (2) been previously stabilized on Forteo. Updated serum calcium since the previous authorization will be required for reauthorization. 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. Requests for continuation of therapy beyond a total of 2 years must be accompanied by evidence that patient remains at high risk for fracture.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TESTOSTERONE REPLACEMENT PRODUCTS

Products Affected

- ANDRODERM TRANSDERMAL PATCH 24 HOUR
- *testosterone transdermal gel 1.62 %, 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, documentation 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	PA applies to all. Documentation of clinically relevant response to therapy (including, but not limited to submission of updated serum testosterone level) will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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, submission of previous therapies.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TOLVAPTAN (HYPONATREMIA)

Products Affected

- *tolvaptan*

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
Other Criteria	PA applies to all. 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) because the tolvaptan formulation approved for ADPKD has a mandatory REMS program.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TOPICAL PSORIASIS TREATMENTS

Products Affected

- VTAMA
- ZORYVE EXTERNAL CREAM 0.3 %

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of percent body surface area affected (with a requirement BSA affected is less than or equal to 20 percent), documentation patient either (1) has tried and failed, had an incomplete response to, had an intolerance to, or has contraindications to at least one Class/Group 3 high potency or stronger topical corticosteroid and at least one of the following other topical agents: tazarotene or a vitamin D analog such as calcipotriene or calcitriol, or (2) patient is currently using a systemic medication (biologic or otherwise) to manage psoriasis.
Age Restrictions	For Vtama, 18 years of age or older. For Zoryve, 6 years of age or older.
Prescriber Restrictions	For Vtama, restricted to dermatology. For Zoryve, PA not required for dermatology.
Coverage Duration	1 year
Other Criteria	PA applies to all. Documentation of a positive response to therapy will be required for reauthorization.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)

Products Affected

- 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	Severe hepatic impairment, coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of cystic fibrosis mutation test confirming presence of at least one mutation in the CFTR gene responsive to the drug (see section 12.1 of package insert for full list) or a mutation that is responsive based on in vitro data.
Age Restrictions	
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 pregnancy status for female patients of childbearing potential, genetic tumor testing showing that the primary tumor type is HR-positive, HER2-negative, submission of test confirming presence of PIK3CA, AKT1, and/or PTEN mutation, submission of previous systemic treatment(s) tried to match the indication, and confirmation drug will be given with fulvestrant. In patients with a PIK3CA mutation and no AKT1 and/or PTEN mutation, documentation patient has tried and failed, had an intolerance to, or has a contraindication to alpelisib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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 showing that the primary tumor type is HER2-positive, submission of previous systemic treatment including prior HER2-directed therapy, pregnancy status for female patients of childbearing potential. For metastatic colon cancer, documentation tumor is RAS wild-type.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TURALIO (pexidartinib)

Products Affected

- TURALIO

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 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

TYMLOS (abaloparatide)

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	Female patients of childbearing potential, 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 (1) a history of osteoporotic fracture or (2) multiple risk factors for fracture or (3) patients who have failed or are intolerant of other available osteoporosis therapies, submission of baseline serum calcium, documentation that at least one bisphosphonate was tried and failed (or all bisphosphonates, including zoledronic acid, are contraindicated), submission of a value, condition, or past medical history that assesses fracture risk (e.g., DEXA scan results or prior fracture), submission of number of total months of all prior use of parathyroid hormone analogs and parathyroid hormone related peptides. For females, attestation of postmenopausal status. For males not at high risk for fracture, documentation of all other treatments tried and failed or intolerant to or contraindicated.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 years maximum dependent on patient's prior use of all PTH analogs and PTH-related peptides
Other Criteria	PA applies to all. Use of parathyroid hormone analogs and/or parathyroid hormone related peptides for more than 2 years during a patient's lifetime is not recommended. Requests for continuation of therapy beyond a total of 2 years must be accompanied by evidence that patient remains at high risk for fracture.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

UPTRAVI (selexipag)

Products Affected

- UPTRAVI ORAL TABLET 1000 MCG, 1200 MCG, 1400 MCG, 1600 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG
- UPTRAVI TITRATION

PA Criteria	Criteria Details
Exclusion Criteria	Severe (Child-Pugh class C) hepatic impairment, coadministration with strong CYP2C8 inhibitors
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

UTERINE FIBROID ORAL THERAPIES

Products Affected

- MYFEMBREE
- 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	1 year
Other Criteria	PA applies to all. 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 Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VANFLYTA (quizartinib)

Products Affected

- VANFLYTA

PA Criteria	Criteria Details
Exclusion Criteria	Uncorrected hypokalemia or hypomagnesemia, 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 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VENTAVIS (iloprost)

Products Affected

- VENTAVIS

PA Criteria	Criteria Details
Exclusion Criteria	Systolic blood pressure below 85 mmHg
Required Medical Information	Diagnosis of covered use, submission of baseline systolic blood pressure.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	This medication is covered as a Part B benefit except for enrollees residing in a long-term care facility. PA applies to new starts only when covered as a Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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
Required Medical Information	Diagnosis of covered use, submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance), documentation patient has tried and had an inadequate response to at least one prior systemic hormone therapy or FDA-approved or compendia-supported non-hormonal therapy (e.g., SSRI, SNRI, clonidine, gabapentin, etc.) for the treatment of vasomotor symptoms due to menopause.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

VERQUVO (vericiguat)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	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 and pregnancy status for female patients of childbearing potential. Prescribers are also required to submit current regimen for the treatment of HFrEF, which must include (1) a renin-angiotensin system (RAS) inhibitor (ACE inhibitor, ARB, or sacubitril/valsartan), (2) a beta-blocker (BB), and (3) a mineralocorticoid receptor antagonist (MRA), each at maximally-tolerated doses. If any of these three therapies are not currently being used, prescriber is required to submit documentation as to why (e.g., contraindications, intolerances, etc.). 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, the prescriber is required to submit documentation as to why (e.g., intolerances, physiologic parameters, 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).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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 showing 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	PA applies to all. Submission of objective documentation of a clinical benefit (e.g., reductions in target lesion size, pain, vascular malformations, limb enlargements, etc.) in the absence of unacceptable toxicity will be required for subsequent reauthorizations.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	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 and attestation tumor is metastatic or surgical resection/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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 (a) postmenopausal or (b) infertile.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	PA applies to all.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	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 deletion or exon 21 L858R substitution 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VMAT2 INHIBITORS

Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO PATIENT TITRATION KIT
- 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, 6 & 12 & 24 MG
- INGREZZA ORAL CAPSULE 40 MG, 60 MG, 80 MG
- INGREZZA ORAL CAPSULE SPRINKLE 40 MG, 60 MG, 80 MG
- INGREZZA ORAL CAPSULE THERAPY PACK
- *tetrabenazine oral tablet 12.5 mg, 25 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. For tetrabenazine and Austedo, actively suicidal or untreated/undertreated depression, hepatic impairment. For Ingrezza, coadministration with strong CYP3A4 inducers.
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and psychiatry
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VONJO (pacritinib)

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe (Child-Pugh class B or C) hepatic impairment, 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, documentation from a physical exam patient has splenomegaly.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology or oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VOQUEZNA (vonoprazan)

Products Affected

- VOQUEZNA ORAL TABLET 10 MG, 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of (1) erosive esophagitis confirmed by endoscopy, (2) non-erosive gastroesophageal reflux disease (GERD), or (3) Helicobacter pylori infection. For erosive esophagitis only, documentation of treatment failure with at least one proton pump inhibitor or a contraindication to the proton pump inhibitor class. For non-erosive GERD, (1) the patient must have tried and failed to have an adequate response to, or had an intolerance/contraindication to, at least two proton pump inhibitors and (2) attestation that prescriber will use only the 10 mg daily dose for treatment of non-erosive GERD. 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	Restricted to gastroenterology for non-erosive GERD only.
Coverage Duration	For non-erosive GERD, initially 4 weeks, then 20 weeks. For all other indications, 32 weeks.
Other Criteria	PA applies to all.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

VORANIGO (vorasidenib)

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed diagnosis of grade 2 oligodendroglioma or grade 2 astrocytoma, confirmed isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation, patient has had at least one prior surgery (including 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	PA applies to all
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

VOSEVI (sofosbuvir, velpatasvir, voxilaprevir)

Products Affected

- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment, coadministration with rifampin or drugs that are strong P-glycoprotein inducers or moderate to strong CYP2B6, CYP2C8, or CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) and genotype, documentation of whether cirrhosis is present or not and whether or not it is compensated or decompensated, submission of previous treatment regimen, confirmation a test for HBV infection (HBsAg and anti-HBc) was completed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VOTRIENT (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 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, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

VOWST (fecal microbiota, live-jslm)

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, confirmation patient has had prior therapy with bezlotoxumab or has a contraindication to its use, confirmation patient has had prior therapy with either fecal microbiota, live-jslm rectal suspension or a fecal microbiota transplant from a reputable source or has a contraindication to use of a fecal microbiota transplant.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 course (3 days)
Other Criteria	PA applies to all.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

VOYDEYA (danicopan) EGWP

Products Affected

- VOYDEYA ORAL TABLET
- VOYDEYA ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient has clinically significant extravascular hemolysis, defined as a hemoglobin level less than or equal to 9.5 g/dL and an absolute reticulocyte count greater than 120 x 10^9/L after having used a complement C5 inhibitor at a stable dose (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. For approval, the patient should have been on a stable regimen of eculizumab or ravulizumab for the previous 6 months. Danicopan has not been shown to be effective as monotherapy and should only be prescribed as an add-on to complement C5 inhibitor therapy. For initial reauthorization after 6 months of therapy, documentation of therapeutic effect without incidence of intolerable toxicity will be required. Subsequent annual continuation of therapy requests require confirmation of the maintenance of therapeutic effect without incidence of intolerable toxicity.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

WAINUA (eplontersen)

Products Affected

- WAINUA

PA Criteria	Criteria Details
Exclusion Criteria	Prior or scheduled liver transplant, New York Heart Association (NYHA) heart failure classification greater than 2
Required Medical Information	Diagnosis of covered use confirmed by (1) genetic testing including a mutation in the TTR gene and (2) signs and/or symptoms of peripheral or autonomic polyneuropathy, including submission of baseline polyneuropathy disability (PND) score (required to be less than or equal to IIIb), submission of NYHA heart failure classification (required to be less than or equal to 2), attestation patient is not currently using a TTR stabilizer such as tafamidis or diflunisal or another TTR gene-silencing or mRNA degrading therapy such as inotersen, patisiran, or vutrisiran.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and specialists in genetic diseases
Coverage Duration	1 year
Other Criteria	PA applies to all. Documentation of a positive response to therapy will be required for initial reauthorization after the first year.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

WAKIX (pitolisant)

Products Affected

- WAKIX ORAL TABLET 17.8 MG, 4.45 MG

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, end-stage renal disease, known QT interval prolongation, symptomatic bradycardia, uncorrected hypokalemia or hypomagnesemia, coadministration with medications that prolong the QT interval
Required Medical Information	Diagnosis of covered use, submission of serum potassium and magnesium and previous therapies used for diagnosis (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and sleep medicine
Coverage Duration	1 year
Other Criteria	PA applies to all. For excessive daytime sleepiness associated with narcolepsy, pitolisant will be authorized only if the patient previously tried and had an inadequate clinical response, an intolerance, or contraindication to (1) armodafinil or modafinil and (2) solriamfetol. Updated serum potassium and magnesium since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

WHITE BLOOD CELL STIMULATORS

Products Affected

- NIVESTYM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For approval of Nivestym, the patient must have tried and failed to have an adequate response to or had an intolerance to Zarxio. 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

WINREVAIR (sotatercept-csrk)

Products Affected

- WINREVAIR SUBCUTANEOUS KIT 2 X 45 MG, 2 X 60 MG, 45 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including documentation patient has a pulmonary capillary wedge pressure less than or equal to 15 mm Hg and pulmonary vascular resistance greater than or equal to 5 Wood units, submission of background PAH therapy with a requirement the patient is using, unless contraindicated or not tolerated, one drug in at least two of the following classes: (a) nitric oxide pathway mediator, (b) endothelin receptor antagonist, and (c) prostacyclin pathway agonist, submission of baseline 6-minute walk distance, baseline brain natriuretic peptide (BNP) and/or N-terminal pro b-type natriuretic peptide (NT-proBNP) level, and patient's WHO functional class or New York Heart Association functional class, with a requirement the patient falls into Class II or III, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Initial reauthorization after 6 months of therapy requires any response to therapy including (1) functional class status improvement or remaining in WHO/NYHA functional class II, (2) right ventricular functional improvement as evidenced by echocardiogram or cardiac MRI, (3) 6-minute walk distance improvement, (4) BNP and/or NT-proBNP decreases from baseline.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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	12 weeks
Other Criteria	PA applies to all. Continuation of therapy requires that symptoms have stabilized or improved and that the patient has not experienced episodes of severe constipation.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

XGEVA (denosumab)

Products Affected
- XGEVA

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia
Required Medical Information	Diagnosis of covered use, submission of serum calcium level, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. 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

XOLAIR (omalizumab)

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	Weight greater than 150 kg
Required Medical Information	Diagnosis of covered use. For asthma, documentation that patient's symptoms are poorly controlled with at least a 30-day trial of inhaled corticosteroids plus at least one of the following: a long-acting beta-agonist, long-acting muscarinic antagonist, leukotriene inhibitor, or theophylline, submission of pre-treatment serum IgE level between 30 and 700 IU/mL in patients 12 years of age and older, documentation patient has a pre-bronchodilator FEV1 less than 80 percent predicted, positive skin test result or demonstrated in vitro reactivity (RAST test) to a perennial aeroallergen, frequency of daily and nighttime symptoms and exacerbations, and effect of exacerbations on activity. For chronic spontaneous urticaria, documentation that the patient continues to experience severe itching and hives despite the use of an H1 antihistamine at an approved dose for at least 30 days. For nasal polyps, documentation of treatment with an intranasal corticosteroid for at least 30 days, a contraindication to the use of intranasal corticosteroids, or why therapy is not otherwise advisable, and if the patient does not have an intolerance or contraindication to intranasal corticosteroids, attestation omalizumab will be used in addition to this therapy.
Age Restrictions	
Prescriber Restrictions	Restricted to allergy, dermatology, immunology, otolaryngology/otorhinolaryngology, and pulmonology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Submission of objective documentation of symptomatic improvement (i.e., a reduction in asthma exacerbations) will be required for subsequent reauthorizations. 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

XOLREMDI (mavorixafor)

Products Affected

- XOLREMDI

PA Criteria	Criteria Details
Exclusion Criteria	Several hepatic impairment, severe renal impairment
Required Medical Information	Diagnosis of covered use, documentation of CXCR4 mutation, submission of baseline absolute neutrophil count (ANC) with a requirement it is less than or equal to 400 cells/mcL, submission of baseline absolute lymphocyte count (ALC), pregnancy status for female patients of childbearing potential.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to hematology, immunology, dermatology, and specialists in genetic diseases
Coverage Duration	Initially 3 months, then 1 year
Other Criteria	PA applies to all. Initial reauthorization after 3 months requires documentation of response to therapy as evidenced by improvements in ANC and/or ALC from baseline. Subsequent annual reauthorizations require maintenance of ANC/ALC benefit.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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, serum potassium and magnesium, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 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, documentation of treatment failure with or intolerance to all prior therapies to match 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	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to all. Updated urine orotic acid level and CBC including neutrophil count and mean corpuscular volume since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZEJULA (niraparib)

Products Affected

- ZEJULA ORAL CAPSULE
- ZEJULA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZERBAXA (ceftolozane/tazobactam)

Products Affected

- ZERBAXA

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. For complicated intra-abdominal infections, confirmation patient will receive concurrent metronidazole therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	For UTI including pyelonephritis, 7 days. For all other FDA-approved indications, 14 days.
Other Criteria	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 MG and baseline MG-ADL score with a requirement the score is at least 6, attestation patient will not concurrently use rituximab or eculizumab, confirmation patient has failed to respond to at least one drug in two of the following three drug groups: (1) acetylcholinesterase inhibitors (e.g., pyridostigmine), (2) corticosteroids (e.g., prednisone), or (3) non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate), 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	PA applies to all. Documentation of any positive response to therapy will be required for initial reauthorization after the first 6 months. Maintenance of a clinical benefit, attestation the patient is up to date on all vaccinations, and attestation that prescriber believes benefits of continuing therapy outweigh the potential risks to the patient will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZOKINVY (lonafarnib)

Products Affected

- ZOKINVY ORAL CAPSULE 50 MG, 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	Body surface area less than 0.39 m^2, coadministration with moderate or strong CYP3A inhibitors or inducers, midazolam, atorvastatin, lovastatin, or simvastatin
Required Medical Information	Diagnosis of covered use including results of genetic testing supporting diagnosis, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ZONTIVITY (vorapaxar)

Products Affected

- ZONTIVITY

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, history of stroke, transient ischemic attack, or intracranial hemorrhage, active pathological bleeding, severe hepatic impairment, coadministration with strong CYP3A inhibitors or inducers
Required Medical Information	Diagnosis of covered use, confirmation that patient has not had prior stroke, transient ischemic attack, or intracranial hemorrhage, attestation therapy will be coadministered with aspirin and/or clopidogrel.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZORBTIVE (somatropin)

Products Affected

- ZORBTIVE

PA Criteria	Criteria Details
Exclusion Criteria	Active malignancy, acute critical illness, active proliferative or severe non-proliferative diabetic retinopathy
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	4 weeks
Other Criteria	PA applies to all. Zorbtive is indicated only for the treatment of short bowel syndrome and uses outside of this indication will not be approved.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	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 (a) a CDKL5 gene that is pathogenic or likely to be pathogenic or (b) CDKL5 deficiency, documentation of failure of at least two previous anticonvulsant therapies, submission of baseline monthly major motor seizure (defined as bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, or focal to bilateral tonic-clonic seizure) frequency, with the requirement that the frequency is at least 16 major motor seizures per month.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

ZURZUVAE (zuranolone)

Products Affected
- ZURZUVAE

PA Criteria	Criteria Details
Exclusion Criteria	Current pregnancy, bipolar disorder, schizophrenia, or schizoaffective disorder, coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use (with provider attestation of moderate to severe postpartum depression), attestation patient is within 12 months postpartum.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to gynecology, obstetrics, and psychiatry
Coverage Duration	14 days
Other Criteria	PA applies to all. As there are no safety or efficacy data beyond one 14-day course for postpartum depression, only one 14-day course will be allowed per plan year.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

ZYDELIG (idelalisib)

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	History of serious hypersensitivity reactions, including toxic epidermal necrolysis with any drug, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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