PRIOR AUTHORIZATION CRITERIA

This list is current as of November 1, 2022, and pertains to the following formularies:

2022 Pharmacy Benefit Dimensions PDP offered by Niagara County Formulary D0457 - 0464	Version 22
2022 Pharmacy Benefit Dimensions PDP offered by Niagara County Formulary D0465	Version 22

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

ACTHAR (corticotropin)

Products Affected

- ACTHAR

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	

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	

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, submission of negative pregnancy test result for female patients of childbearing age, 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 cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

AKYNZEO (netupitant/palonosetron)

Products Affected

- AKYNZEO ORAL

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, severe renal impairment, end-stage renal disease
Required Medical Information	Diagnosis of covered use, confirmation patient will receive concurrent dexamethasone therapy as indicated based on level of chemotherapy regimen emetogenicity.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. If the medication is being administered related to cancer treatment and is a full replacement for intravenous administration of antiemetic therapy within 48 hours of cancer treatment, it is covered as a Part B benefit. To be eligible for Part B coverage, the prescribing physician must indicate this on the prescription. Otherwise it may be covered as a Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	

ALECENSA (alectinib)

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of FDA-approved 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	

ALPHA-1-PROTEINASE INHIBITORS

Products Affected

- ARALAST NP INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG, 500 MG
- GLASSIA
- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED
- 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, confirmation that patient has clinically evident emphysema secondary to congenital alpha-1-PI deficiency by submission of pulmonary function testing (e.g., spirometry or body plethysmography), X-ray radiography, or diffusing capacity of the lung for carbon monoxide (DLCO).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved. A description of 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	

ALUNBRIG (brigatinib)

Products Affected

- ALUNBRIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of FDA-approved 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	

AMANTADINE EXTENDED-RELEASE PRODUCTS

Products Affected

- GOCOVRI

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	

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	

ANADROL-50 (oxymetholone)

Products Affected

- ANADROL-50

PA Criteria	Criteria Details
Exclusion Criteria	Carcinoma of the prostate or breast in male patients, carcinoma of the breast in females with hypercalcemia, women who are or may become pregnant, nephrosis or the nephrotic phase of nephritis, severe hepatic dysfunction
Required Medical Information	Diagnosis of covered use, submission of CBC, liver function tests, and pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	PA applies to all. Updated CBC since the previous authorization will be required for reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	

ARANESP (darbepoetin alfa)

Products Affected

- ARANESP (ALBUMIN FREE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 300 MCG/ML, 40 MCG/ML, 60 MCG/ML PREFILLED SYRINGE
- ARANESP (ALBUMIN FREE) INJECTION SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of hemoglobin or hematocrit level, serum iron, total iron-binding capacity (TIBC), and transferrin within 30 days of request date, documentation that the patient does not have uncontrolled hypertension.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	For non-ESRD-related conditions: 90 days. For ESRD-related conditions: 1 year.
Other Criteria	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	

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	

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.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	This medication is covered as a Part B benefit except for enrollees residing in a long-term care facility. PA applies to all when covered as a Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

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
Required Medical Information	Diagnosis of covered use. For gastrointestinal stromal tumor (GIST), submission of test result confirming presence of PDGFRA exon 18 mutation.
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	

BALVERSA (erdafitinib)

Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP2C9 or CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of FDA-approved companion test showing susceptible FGFR2 or FGFR3 genetic alterations, prior chemotherapy regimen(s) used.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

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.
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 Medically-accepted Indications.
Off Label Uses	

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: corticosteroids, NSAIDs, antimalarials, or immunosuppressants.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. A description of 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	

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	

BIOLOGIC RESPONSE MODIFIERS

Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS
- CIMZIA PREFILLED
- CIMZIA STARTER KIT
- CIMZIA SUBCUTANEOUS KIT 2 X 200 MG
- KEVZARA
- OTEZLA
- SIMPONI SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- SIMPONI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- TREMFYA
- 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 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 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	

BOSULIF (bosutinib)

Products Affected

- BOSULIF

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. For accelerated or blast phase Ph+ CML, documentation of resistance or intolerance to at least one of the following prior therapies: imatinib, dasatinib, or nilotinib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

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 FDA-approved test confirming presence of BRAF V600E or V600K mutation, serum potassium, and serum magnesium. For metastatic melanoma, 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	

BRIVIACT (brivaracetam)

Products Affected

- BRIVIACT ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
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	

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, attestation patient will not be using in combination with hypertonic (7%) sodium chloride nebulized solution.
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. For approval, the patient must must have tried and failed to have an adequate response to or had an intolerance to hypertonic (7%) sodium chloride nebulized solution.
Indications	All Medically-accepted Indications.
Off Label Uses	

BRUKINSA (zanubrutinib)

Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of prior chemotherapy regimen(s) used.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

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
- VTOL LQ
- 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	

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	

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

CABOMETYX (cabozantinib)

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment
Required Medical Information	Diagnosis of covered use.
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	

CALQUENCE (acalabrutinib)

Products Affected

- CALQUENCE

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, coadministration with strong CYP3A inhibitors or proton pump 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	

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 Medically-accepted Indications.
Off Label Uses	

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 moderate or strong CYP3A4 inhibitors or CYP3A4 inducers
Required Medical Information	Diagnosis of covered use.
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 (e.g., paliperidone, quetiapine, risperidone, etc.) or Latuda.
Indications	All Medically-accepted Indications.
Off Label Uses	

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, moderate or severe hepatic impairment, QTcF interval greater than 450 msec
Required Medical Information	Diagnosis of covered use, submission of baseline serum potassium, calcium, magnesium, ALT, AST, bilirubin, TSH, creatinine clearance (or serum creatinine, 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	

CARBAGLU (carglumic acid)

Products Affected

- *carglumic acid*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of plasma ammonia level.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated plasma ammonia level since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	

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, patients who are extensive or intermediate CYP2D6 metabolizers taking a strong CYP2D6 inhibitor with a strong or moderate CYP3A inhibitor, intermediate and poor CYP2D6 metabolizers taking a strong CYP3A inhibitor
Required Medical Information	Diagnosis of covered use, submission of CYP2D6 metabolizer status as detected by an FDA-cleared test for determining CYP2D6 genotype, 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	

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 treatment of migraine headache prevention, submission of baseline migraine days per month from medical chart, documentation patient has tried and failed at least two preferred FDA-approved (propranolol, timolol, topiramate, valproic acid) or compendial alternatives (e.g., amitriptyline, atenolol) for migraine prophylaxis, at least one alternative if they have contraindications to all other alternatives, or has contraindications to all alternatives. For Nurtec or Ubrelvy for the treatment of acute migraine, documentation of prior use of at least one triptan.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initially 3 months, then 1 year
Other Criteria	PA applies to all. For all drugs in this policy except Ubrelvy for migraine preventive treatment, submission of on-treatment headache days per month demonstrating improvement from baseline will be required for initial reauthorization after the first 3 months. Documentation of a clinically relevant response to therapy or maintenance of a clinical benefit will be required for subsequent reauthorizations. For approval of Nurtec for migraine headache prevention, the patient must have a diagnosis of episodic migraine, defined as 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 Ajovy, 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	

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	

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	

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	

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	

CORLANOR (ivabradine)

Products Affected

- CORLANOR

PA Criteria	Criteria Details
Exclusion Criteria	Acute decompensated heart failure, clinically significant hypotension, clinically significant bradycardia, severe hepatic impairment, pacemaker dependence (heart rate maintained exclusively by the pacemaker), or sick sinus syndrome, sinoatrial block, or 3rd degree AV block unless a functioning demand pacemaker is present, coadministration with strong CYP3A4 inhibitors
Required Medical Information	Diagnosis of covered use described as is indicated (1) to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use or (2) for stable symptomatic heart failure due to dilated cardiomyopathy in patients who are in sinus rhythm with an elevated heart rate. Submission of current baseline blood pressure reading, confirmation that patient does not have any of the following: (1) acute decompensated heart failure, (2) sick sinus syndrome, sinoatrial block, or 3rd degree AV block, unless a functioning demand pacemaker is present, (3) resting heart rate less than 60 bpm prior to treatment, (4) severe hepatic impairment, (5) pacemaker dependence (heart rate maintained exclusively by the pacemaker). For patients under 18 years old, (1) left ventricular ejection fraction less than or equal to 45% and (2) resting heart rate greater than or equal to the following age-stratified requirements: (a) 105 beats per minute in ages 6 to 12 months old, (b) 95 beats per minute in ages 1 to 3 years old, (c) 75 beats per minute in ages 3 to 5 years old, and (d) 70 beats per minute in ages 5 to 18 years old.
Age Restrictions	
Prescriber Restrictions	Restricted to cardiology
Coverage Duration	1 year
Other Criteria	PA applies to all. Continuation requires documentation of clinically relevant response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

COTELLIC/ZELBORAF (cobimetinib/vemurafenib)

Products Affected

- COTELLIC
- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inhibitors or inducers
Required Medical Information	Diagnosis of covered use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation, submission of left ventricular ejection fraction, ECG, and serum potassium, magnesium, and calcium levels. For patients using cobimetinib, confirmation that it will be co-administered with vemurafenib.
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	

CYSTEAMINE EYE DROPS

Products Affected

- CYSTADROPS
- CYSTARAN

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.
Indications	All Medically-accepted Indications.
Off Label Uses	

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) and objective measurement of walking speed, confirmation that patient is able to walk.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	Initially 3 months, then 1 year
Other Criteria	PA applies to all. Documentation the patient has demonstrated an improvement in walking speed from baseline measure (or maintenance of improvement if patient has been on long-term therapy) since starting medication will be required for initial reauthorization after the first 3 months. 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	

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	

DAYVIGO (lemborexant)

Products Affected

- DAYVIGO ORAL TABLET 10 MG, 5 MG

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	

DEFERASIROX

Products Affected

- *deferasirox granules*
- *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, serum creatinine, 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 will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	

DEFERIPRONE

Products Affected

- *deferiprone*
- FERRIPROX ORAL SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of serum ferritin levels, CBC, ANC, platelet count, and serum ALT.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	2 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. Monotherapy requests for Dravet syndrome will not be approved as there are no clinical data to support using stiripentol in this manner.
Indications	All Medically-accepted Indications.
Off Label Uses	

DICLOFENAC 1% GEL

Products Affected

- *diclofenac sodium external gel*

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

DICLOFENAC 1.5% TOPICAL SOLUTION

Products Affected

- *diclofenac sodium external solution 1.5 %*

PA Criteria	Criteria Details
Exclusion Criteria	Use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery
Required Medical Information	Diagnosis of covered use defined as the relief of pain of osteoarthritis of the knees.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. FDA-approved only for use on knee joints and therefore requests for other uses will not be approved.
Indications	All FDA-approved Indications.
Off Label Uses	

DICLOFENAC 3% GEL

Products Affected

- *diclofenac sodium external gel*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to dermatology
Coverage Duration	90 days
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

DIFICID (fidaxomicin)

Products Affected

- DIFICID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	10 days
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

DIGOXIN IN OLDER PATIENTS

Products Affected

- *digitek oral tablet 250 mcg*
- *digox oral tablet 250 mcg*
- *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	

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, submission of prior therapies tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to gastroenterology, hematology, hepatology, and surgery
Coverage Duration	5 days for undergoing a procedure or 1 year for immune thrombocytopenia
Other Criteria	PA applies to all. 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	

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 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	

DROXIDOPA

Products Affected

- *droxidopa*

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.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

DUOPA (carbidopa/levodopa enteral suspension)

Products Affected

- DUOPA ENTERAL

PA Criteria	Criteria Details
Exclusion Criteria	Administration of non-selective monoamine oxidase inhibitors within 14 days of initiation
Required Medical Information	Diagnosis of covered use, confirmation patient has a naso-jejunal tube for short-term administration or a PEG-J for long-term administration.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

DUPIXENT (dupilumab)

Products Affected

- DUPIXENT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For atopic dermatitis, documentation of treatment with at least a moderate strength topical corticosteroid for at least four weeks, a contraindication to the use of topical corticosteroids, or therapy is not otherwise advisable. For moderate-to-severe asthma, either (1) submission of blood eosinophil count of at least 150 cells/mcL obtained within 6 weeks of therapy initiation or (2) documentation asthma requires daily oral corticosteroid for control. For chronic rhinosinusitis with nasal polyposis, documentation of treatment with an intranasal corticosteroid for at least three months, a contraindication to the use of intranasal corticosteroids, or therapy is not otherwise advisable.
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. Continuation requires documentation of a positive response to therapy. 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	

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, use for weight loss
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	
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 Medically-accepted Indications.
Off Label Uses	

EMFLAZA (deflazacort)

Products Affected

- EMFLAZA

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, documentation of treatment failure with or intolerance to prednisone.
Age Restrictions	2 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

EMPAVELI (pegcetacoplan)

Products Affected

- EMPAVELI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use confirmed by high-sensitivity flow cytometry, proof of vaccination against Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B or 2 weeks of antibacterial drug prophylaxis if the vaccines were administered within the last 2 weeks and therapy is required immediately, submission of lactate dehydrogenase level.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology, immunology, and nephrology
Coverage Duration	1 year
Other Criteria	Because this medication is delivered subcutaneously through an infusion pump, it 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	

EMSAM (selegiline transdermal)

Products Affected

- EMSAM

PA Criteria	Criteria Details
Exclusion Criteria	Pheochromocytoma, coadministration with carbamazepine or serotonergic drugs
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	

ENDOTHELIN RECEPTOR ANTAGONISTS

Products Affected

- *ambrisentan*
- *bosentan*
- OPSUMIT
- 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, pregnancy status for female patients of childbearing potential, submission of baseline AST, ALT, and bilirubin. For ambrisentan and Opsumit, submission of baseline hemoglobin level.
Age Restrictions	For ambrisentan and Opsumit, 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.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

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	

ERIVEDGE (vismodegib)

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	
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	

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 FDA-approved 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	

ESBRIET (pirfenidone)

Products Affected

- ESBRIET ORAL CAPSULE
- *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	

EVEROLIMUS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with dual strong CYP3A4/P-glycoprotein inhibitors
Required Medical Information	Diagnosis of covered use and submission of pregnancy status for female patients of childbearing potential. For renal cell carcinoma, documented prior use of sunitinib or sorafenib. For postmenopausal women with advanced hormone receptor-positive, HER-2 negative breast cancer, documentation of treatment failure with letrozole or anastrozole and confirmation drug is being used in combination with exemestane.
Age Restrictions	1 year of age or older
Prescriber Restrictions	Restricted to neurology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

EXKIVITY (mobocertinib)

Products Affected

- EXKIVITY

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inducers, coadministration with strong CYP3A4 inhibitors
Required Medical Information	Diagnosis of covered use, submission of FDA-approved test confirming presence of EGFR exon 20 insertion mutation and previous therapies used, 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. Part B before Part D Step Therapy. For approval, the patient must have documentation of failure or contraindication to both platinum-based chemotherapy and amivantamab.
Indications	All Medically-accepted Indications.
Off Label Uses	

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, 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.
Indications	All Medically-accepted Indications.
Off Label Uses	

FINTEPLA (fenfluramine)

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	Hepatic impairment, moderate or severe renal impairment, 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	

FIRDAPSE (amifampridine)

Products Affected

- FIRDAPSE

PA Criteria	Criteria Details
Exclusion Criteria	History of seizure
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

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	

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	

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	

GATTEX (teduglutide)

Products Affected

- GATTEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline laboratory values including bilirubin, alkaline phosphatase, lipase, and amylase obtained within 6 months prior to starting therapy. 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	

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 FDA-approved 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	

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 positive FDA-approved test for 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	

GnRH ANTAGONISTS

Products Affected

- CAMCEVI
- ELIGARD
- FIRMAGON (240 MG DOSE)
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG
- *leuprolide acetate injection*
- LUPANETA PACK
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- LUPRON DEPOT-PED (1-MONTH) INTRAMUSCULAR KIT 11.25 MG, 15 MG
- LUPRON DEPOT-PED (3-MONTH) INTRAMUSCULAR KIT 30 MG (PED)
- TRELSTAR MIXJECT

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For prostate cancer, documentation of baseline prostate-specific antigen and serum testosterone level.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology, oncology, endocrinology, gynecology, and urology
Coverage Duration	For endometriosis and uterine fibroids, 6 months. For all other indications, 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	

GROWTH HORMONE

Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- 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

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	

HEREDITARY ANGIOEDEMA THERAPIES, ACUTE

Products Affected

- *icatibant acetate*
- RUCONEST
- *sajazir*

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	

HEREDITARY ANGIOEDEMA THERAPIES, MAINTENANCE

Products Affected

- HAEGARDA
- ORLADEYO
- *takhzyro*

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	

HETLIOZ (tasimelteon)

Products Affected

- HETLIOZ

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	

HYALURONATES

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient diagnosed with osteoarthritis of the knee joint and has tried and failed to respond to conservative non-pharmacologic therapy (exercise, physical therapy, weight loss) and simple analgesics (oral salicylates, non-steroidal anti-inflammatory drugs, and acetaminophen) within the previous 18 months.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Injection is being administered by an orthopedic surgeon, rheumatologist, physiatrist, or physician who has completed a formal sports medicine fellowship and is fully knowledgeable about the differential diagnosis of knee pain, is able to perform microscopic analysis of synovial fluid, and can recognize conditions such as pseudogout.
Coverage Duration	1 treatment cycle
Other Criteria	A maximum of 1 injection of Synvisc-One, Gel-One, or Monovisc, 3 injections of Euflexxa or Synvisc, 4 injections of Orthovisc, or 5 injections of Hyalgan per knee joint may be authorized per treatment cycle. Retreatment may be authorized, provided (1) previous treatment cycle was administered at least 6 months ago, (2) treating physician submits documentation of a favorable patient response including pain relief derived of more than 3 months in duration, (3) patient has demonstrated a reduction in analgesic use or increase in functional capacity, and (4) patient's progress and results of hyaluronate therapy is fully documented in the patient's record.
Indications	All FDA-approved Indications.
Off Label Uses	

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 showing that the primary tumor type is HR-positive, HER2-negative, confirmation that the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant, submission of baseline CBC.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

ICLUSIG (ponatinib)

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	Newly diagnosed chronic phase CML
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

IDHIFA (enasidenib)

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of FDA-approved 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	

ILARIS

Products Affected

- ILARIS SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Positive TB test, coadministration with TNF inhibitors
Required Medical Information	Diagnosis of covered use, submission of TB skin test result obtained within past 12 months, documentation that patient has received all recommended vaccinations as appropriate including pneumococcal vaccine and inactivated influenza vaccine prior to initiation of therapy. For CAPS, confirmed diagnosis including genetic testing for variant FCAS or MWS and documentation patient is not receiving concomitant TNF inhibitor therapy. For SJIA, submission of CBC including platelet count and confirmed diagnosis defined by prominence of systemic and inflammatory features including spiking fevers, rash, swelling and inflammation of lymph nodes, liver, and spleen, and high white blood cell and platelet counts.
Age Restrictions	2 years of age or older
Prescriber Restrictions	For SJIA, restricted to rheumatology
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated TB skin test result obtained within the past 12 months and objective documentation of positive patient response or maintenance of response 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	

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	18 years of age or older
Prescriber Restrictions	Restricted to hematology, oncology, and transplant specialty
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

IMCIVREE (setmelanotide)

Products Affected

- IMCIVREE

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe renal impairment, end-stage renal disease
Required Medical Information	Diagnosis of covered use, including submission of genetic testing showing homozygous or compound heterozygous gene variants in POMC, PCSK1, or LEPR genes interpreted as pathogenic, likely pathogenic, or of uncertain clinical significance and body mass index (BMI) greater than 30 kg/m2 in adults or greater than the 97th percentile in children.
Age Restrictions	6 years of age or older
Prescriber Restrictions	
Coverage Duration	Initially 16 weeks, then 1 year
Other Criteria	PA applies to all. For re-authorization at the 16-week point, submission of clinical documentation attesting to at least 5% weight loss from baseline (or at least 5% BMI from baseline in patients with continued growth potential) is required. Not FDA-approved for other types or causes of obesity, and therefore requests for these uses will not be approved.
Indications	All FDA-approved Indications.
Off Label Uses	

IMMUNE GLOBULIN

Products Affected

- BIVIGAM INTRAVENOUS SOLUTION 5 GM/50ML
- CARIMUNE NF INTRAVENOUS SOLUTION RECONSTITUTED 12 GM, 6 GM
- 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, 25 GM/500ML, 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. For IM forms, severe thrombocytopenia or coagulation disorder that would contraindicate an IM injection.
Required Medical Information	Diagnosis of covered use. For ITP, submission of platelet count. For CLL, IgG level less than 600 mg/dL and recent history of serious bacterial infection requiring either oral or IV antibiotic therapy. For CIDP, unequivocal diagnosis and documentation patient is refractory or intolerant to prednisone given in therapeutic doses over at least 3 months. For passive immunization against varicella, confirmation that the patient is immunosuppressed and cannot receive varicella-zoster immune globulin.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	For acute conditions/new starts, 3 months. For renewal of chronic conditions, 1 year.
Other Criteria	PA applies to all. For continuation of any diagnosis, documentation of the clinical response to therapy must be submitted. 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	

INJECTABLE TESTOSTERONE

Products Affected

- *testosterone cypionate injection solution 200 mg/ml*
- *testosterone cypionate intramuscular solution 100 mg/ml, 200 mg/ml*
- *testosterone enanthate intramuscular solution*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of serum testosterone level, documentation that patient has been evaluated for the presence of breast and prostate cancer prior to initiation of therapy.
Age Restrictions	
Prescriber Restrictions	PA not required for urology or endocrinology
Coverage Duration	1 year
Other Criteria	PA applies to all except when prescribed by urology or endocrinology. Documentation of clinically relevant response to therapy (including, but not limited to submission of updated serum testosterone level) 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	

INLYTA (axitinib)

Products Affected

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C), uncontrolled hypertension, evidence of untreated brain metastasis, recent active gastrointestinal bleeding, coadministration with strong CYP3A4/5 inducers
Required Medical Information	Diagnosis of covered use, submission of laboratory values including baseline ALT, AST, bilirubin, submission of baseline blood pressure reading. 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	

INQOVI (decitabine/cedazuridine)

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of complete blood 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	Initially 6 months, then 1 year
Other Criteria	PA applies to new starts only. Continuation of initial therapy beyond 6 months requires (a) confirmation of no disease progression and (b) attestation the patient is having no serious adverse events from treatment.
Indications	All Medically-accepted Indications.
Off Label Uses	

INREBIC (fedratinib)

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, coadministration with moderate or strong CYP3A4 inducers or dual CYP3A4/CYP2C19 inhibitors
Required Medical Information	Diagnosis of covered use, submission of thiamine level and platelet count.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval, the patient must have tried and failed to have an adequate response to or had an intolerance to ruxolitinib.
Indications	All Medically-accepted Indications.
Off Label Uses	

INTERLEUKIN-5 ANTAGONISTS

Products Affected

- FASENRA
- FASENRA PEN
- 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. For Nucala (eosinophilic asthma diagnosis only), 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 Nucala (for chronic rhinosinusitis with nasal polyps diagnosis only), 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. For Fasenra, submission of blood eosinophil count of at least 300 cells/mcL obtained within 6 weeks of therapy initiation or at least 150 cells/mcL within 6 weeks of therapy initiation if patient is dependent on a daily oral corticosteroid.
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	

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	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

INTRON A (interferon alfa-2b)

Products Affected

- INTRON A

PA Criteria	Criteria Details
Exclusion Criteria	Autoimmune hepatitis, decompensated liver disease
Required Medical Information	Diagnosis of covered use, submission of triglyceride levels, hemoglobin, complete and differential white blood cell counts, platelet count, serum electrolytes, ALT, serum bilirubin level, serum albumin level, and TSH. For malignant melanoma, submission of the date of surgical treatment. For AIDS-related Kaposi's sarcoma, submission of total CD4 count. For chronic hepatitis C, submission of HCV RNA, prothrombin time, baseline serum creatinine level, and laboratory confirmation of hepatitis C virus, and documentation of previous response to therapy if applicable. For chronic hepatitis B, submission of prothrombin time and documentation patient has been serum HBsAG positive for at least 6 months with evidence of HBV replication.
Age Restrictions	For hairy cell leukemia, malignant melanoma, follicular lymphoma, condylomata acuminata, or AIDS-related Kaposi's sarcoma, 18 years of age or older. For chronic hepatitis C, 3 years of age or older. For chronic hepatitis B, 1 year of age or older.
Prescriber Restrictions	
Coverage Duration	Depends on covered use. See "Other Criteria" section.
Other Criteria	PA applies to new starts only. For hairy cell leukemia, the coverage duration is 6 months. For condylomata acuminata, 3 weeks per course, and at least 12 weeks must pass in between multiple courses in order to be reauthorized. For Kaposi's sarcoma, 16 weeks. For hepatitis B infection, 24 weeks. For all other indications/uses, 1 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 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	

INVEGA HAFYERA (paliperidone 6-month injectable suspension)

Products Affected

- INVEGA HAFYERA

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use, documentation of at least 4 months' treatment with 1-month paliperidone palmitate extended-release injectable suspension 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	

INVEGA TRINZA (paliperidone 3-month injectable suspension)

Products Affected

- INVEGA TRINZA INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use, documentation of at least 4 months' treatment with 1-month paliperidone palmitate extended-release injectable suspension.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. A description of 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	

IRESSA (gefitinib)

Products Affected

- IRESSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, confirmation of EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test, 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	

ISTURISA (osilodrostat)

Products Affected

- ISTURISA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, 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 urine free cortisol level.
Indications	All Medically-accepted Indications.
Off Label Uses	

ITRACONAZOLE

Products Affected

- *itraconazole oral*
- TOLSURA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, fungal culture result identifying causative organism or positive KOH result.
Age Restrictions	
Prescriber Restrictions	PA not required for infectious diseases
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

JAKAFI (ruxolitinib)

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	For myelofibrosis, a platelet count less than 50 x 10^9/L with either concomitant estimated creatinine clearance between 15 and 59 mL/min, end-stage renal disease not on dialysis, or any degree of hepatic impairment
Required Medical Information	Diagnosis of covered use, submission of baseline platelet count, ALT, AST, and bilirubin, submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance). For polycythemia vera, documented intolerance or inadequate response to hydroxyurea. For acute graft-versus-host disease, documented inadequate response to systemic corticosteroids.
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	

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, 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, submission of renal indices, documentation of contraindication to or treatment failure with evolocumab.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology, lipidology, and endocrinology with experience in and a focus on lipid management
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Submission of LDL level 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.
Indications	All Medically-accepted Indications.
Off Label Uses	

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, 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	

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 result and baseline ALT and AST.
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	

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, severe (Child-Pugh class C) hepatic impairment, coadministration with strong CYP3A4 inhibitors
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.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

KEVEYIS (dichlorphenamide)

Products Affected

- KEVEYIS

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, submission of serum potassium.
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	

KISQALI (ribociclib)

Products Affected

- KISQALI (200 MG DOSE)
- KISQALI (400 MG DOSE)
- KISQALI (600 MG DOSE)
- KISQALI FEMARA (400 MG DOSE)
- KISQALI FEMARA (600 MG DOSE)
- KISQALI FEMARA(200 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 showing that the primary tumor type is HR-positive, HER2-negative, submission of ECG, serum electrolytes, CBC, 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	

KORLYM (mifepristone)

Products Affected

- KORLYM

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, severe hepatic impairment, uncorrected hypokalemia, female patients with a history of unexplained vaginal bleeding, 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	

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 left ventricular ejection fraction, Child-Pugh score or liver function testing results, and 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	Initially 6 months, then 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. Continuation of initial therapy beyond 6 months requires (a) documentation of any positive clinical response and (b) attestation the patient is having no serious adverse events to treatment.
Indications	All Medically-accepted Indications.
Off Label Uses	

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 left ventricular ejection fraction, 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	

LEDIPASVIR/SOFOSBUVIR

Products Affected

- HARVONI ORAL PACKET
- HARVONI ORAL TABLET 45-200 MG, 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	

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, comprehensive metabolic panel, 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	

LEUKINE (sargramostim, GM-CSF)

Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of WBC count and ANC.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	PA applies to all. A description of 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	

LIDOCAINE TRANSDERMAL PATCHES

Products Affected

- *lidocaine external patch 5 %*

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	

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	

LIVTENCITY (maribavir)

Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of previous anti-CMV medication(s) patient has tried and failed (at least one of cidofovir, foscarnet, ganciclovir, valganciclovir), documented history of hematopoietic stem cell or solid organ transplant.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to hematology, infectious disease specialty, oncology, and transplant specialty
Coverage Duration	8 weeks
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

LONSURF (trifluridine/tipiracil)

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment, febrile neutropenia
Required Medical Information	Diagnosis of covered use, submission of prior therapies used, submission of baseline CBC, absolute neutrophil count, ALT, AST, and bilirubin, pregnancy status for female patients of childbearing potential, 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	

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 FDA-approved 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	

LUCEMYRA (lofexidine)

Products Affected

- LUCEMYRA

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome, severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure
Required Medical Information	Diagnosis of covered use, attestation patient will be using medication in conjunction with a comprehensive management program for the treatment of opioid use disorder.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	14 days
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

LUMAKRAS (sotorasib)

Products Affected

- LUMAKRAS

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers, coadministration with proton pump inhibitors or H2 receptor antagonists
Required Medical Information	Diagnosis of covered use, submission of test result confirming presence of KRAS G12C mutations, 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	

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, attestation patient will be taking concurrently with mycophenolate mofetil and corticosteroids, submission of estimated glomerular filtration rate (eGFR), baseline blood pressure, pregnancy status for female patients of childbearing potential. If the patient's eGFR is less than or equal to 45 mL/min/1.73 m2, attestation that prescriber believes benefits of therapy outweigh the potential risks to the patient.
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). 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 estimated glomerular filtration rate (eGFR) and blood pressure since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	

LYBALVI (olanzapine/samidorphan)

Products Affected

- LYBALVI

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis, coadministration with opioids 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	
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	

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 FDA-approved test confirming presence of applicable mutations and previous therapies tried and failed depending on cancer type as necessary, submission of baseline CBC.
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	

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
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential, submission of 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. 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	

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	

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	

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	

MEKINIST (trametinib)

Products Affected

- MEKINIST

PA Criteria	Criteria Details
Exclusion Criteria	Progression of disease on prior BRAF-inhibitor therapy
Required Medical Information	Diagnosis of covered use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation. For non-small cell lung cancer and thyroid cancer, attestation that therapy will be used in combination with dabrafenib.
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	

METHAMPHETAMINE

Products Affected

- *methamphetamine hcl*

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

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

- REDITREX

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.
Indications	All Medically-accepted Indications.
Off Label Uses	

METHYLTESTOSTERONE

Products Affected

- METHITEST
- *methyltestosterone oral*

PA Criteria	Criteria Details
Exclusion Criteria	Male patients with breast or prostate cancer, women who are or may become pregnant
Required Medical Information	Diagnosis of covered use. For patients 65 years of age and older, attestation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services (CMS) and that the benefits of methyltestosterone therapy outweigh the potential risks to the patient.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

MIGLUSTAT

Products Affected

- *miglustat*

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.
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	

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	

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	

MYFEMBREE (relugolix/estradiol/norethindrone)

Products Affected

- MYFEMBREE

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, known liver impairment or disease, known osteoporosis, undiagnosed abnormal uterine bleeding, women at increased risk of or current/a history of 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, 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	

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	

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	

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	

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 showing that the primary tumor type is HER2-positive, confirmation member has completed adjuvant trastuzumab-based therapy or will be using in combination with capecitabine, submission of baseline liver function tests, 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	

NEXAVAR (sorafenib)

Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use.
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	

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, submission of baseline platelet count, absolute neutrophil count, 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	Initially 3 months, then 1 year
Other Criteria	PA applies to new starts only. For continuation, documentation of platelet count greater than 30,000/mm3, ANC greater than 500/mm3, and Grade 1 or lower non-hematological toxicities (including rash, peripheral neuropathies) required.
Indications	All Medically-accepted Indications.
Off Label Uses	

NITISINONE

Products Affected

- *nitisinone*
- NITYR
- ORFADIN ORAL CAPSULE 20 MG
- ORFADIN ORAL SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. 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	

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	

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, congential QT prolongation, coadministration with moderate or strong CYP3A4 inducers, 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	

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 1 year 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 3 months, then 1 year
Other Criteria	PA applies to all. Updated ALP obtained within the previous 3 months will be required for subsequent authorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

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 in 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 affecting at least 10% 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	

ONUREG (azacitidine)

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, 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	Initially 6 months, then 1 year
Other Criteria	PA applies to new starts only. Attestation of clinical benefit or stabilization and absence of unacceptable toxicity will be required for reauthorization. This dosage form is not intended to be a substitute for or substituted for injectable azacitidine.
Indications	All Medically-accepted Indications.
Off Label Uses	

ORENITRAM (treprostinil)

Products Affected

- ORENITRAM

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	

ORGOVYX (relugolix)

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
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	

ORIAHNN (elagolix/estradiol/norethindrone)

Products Affected

- ORIAHNN

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, known liver impairment or disease, known osteoporosis, undiagnosed abnormal uterine bleeding, women at increased risk of or a history of 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, coadministration with OATP1B1 inhibitors or strong CYP3A4 inhibitors
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	18 years of age or older
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	

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	

ORKAMBI (lumacaftor/ivacaftor)

Products Affected

- ORKAMBI

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, documentation that the patient is homozygous for the F508del mutation in the CFTR gene provided from an FDA-cleared CF mutation test, attestation baseline and follow-up ophthalmologic exams will be performed in pediatric patients starting on therapy.
Age Restrictions	2 years of age or older
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

OSMOLEX (amantadine)

Products Affected

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

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.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology
Coverage Duration	6 months
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	

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	

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.
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, Xyrem will be authorized only if the patient previously tried and had an inadequate clinical response or an intolerance to armodafinil or modafinil. Xywav will be authorized only if the patient has used Xyrem and prescriber submits a clinical reason detailing the need to switch to Xywav. Neither medication covered in this policy is indicated to treat insomnia and will not be approved for this use.
Indications	All Medically-accepted Indications.
Off Label Uses	

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.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. 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	

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	

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

Products Affected

- *apomorphine hcl subcutaneous*
- INBRIJA
- KYNMOBI
- KYNMOBI TITRATION KIT

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. For Kynmobi, severe renal impairment or end-stage renal disease, severe hepatic impairment.
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 is (a) currently taking at least one other medication to help reduce "off" episodes (from COMT inhibitor, dopamine agonist, or monoamine oxidase B inhibitor drug classes) or (b) has tried and failed, had an intolerance to, or has a contraindication to medications from at least two different drug classes (COMT inhibitors, dopamine agonists, monoamine oxidase B inhibitors) that can help 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	

PCSK9 INHIBITORS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For all indications, submission of LDL level obtained within the previous 6 months. For primary hyperlipidemia (including HeFH) and ASCVD indications, submission of current or previous lipid-lowering therapies. For HeFH, documentation of genetic test result documenting HeFH or diagnosis by clinical criteria using Simon Broom or WHO/Dutch Lipid Network criteria. For ASCVD, documented history of MI, ACS, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or PAD.
Age Restrictions	For Repatha, 13 years of age or older. For Praluent, 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval for primary hyperlipidemia (including HeFH) and ASCVD indications, 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	

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. For tadalafil, 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 cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

PEGFILGRASTIM

Products Affected

- NEULASTA ONPRO
- NEULASTA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- UDENYCA

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	

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 result 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	

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 showing that the primary tumor type is HR-positive, HER2-negative, PIK3CA-mutated, attestation that patient has advanced or metastatic disease and will be taking concurrently with fulvestrant, submission of prior therapies tried, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

POMALYST (pomalidomide)

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, submission of baseline serum bilirubin, AST, ALT, CBC including ANC and platelet count, prior therapies, when prior therapy was completed, 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	

PRETOMANID

Products Affected

- PRETOMANID

PA Criteria	Criteria Details
Exclusion Criteria	Inability to use bedaquiline or linezolid
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	

PREVYMIS (letermovir)

Products Affected

- PREVYMIS ORAL

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, coadministration with ergot alkaloids, pimozide, pitavastatin, or simvastatin
Required Medical Information	Diagnosis of covered use, submission of day number post-HSCT, documentation of any previous doses of letermovir.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology, oncology, transplant specialist, and infectious diseases
Coverage Duration	100 days
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

PRIOR AUTHORIZATION TO OVERRIDE SPECIALTY RESTRICTIONS

Products Affected

- FABIOR
- PEG-INTRON REDIPEN SUBCUTANEOUS KIT 50 MCG/0.5ML
- PEG-INTRON SUBCUTANEOUS KIT 50 MCG/0.5ML
- PEGASYS PROCLICK SUBCUTANEOUS SOLUTION 135 MCG/0.5ML
- PEGASYS PROCLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR 135 MCG/0.5ML
- PEGASYS SUBCUTANEOUS SOLUTION
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- PEGINTRON SUBCUTANEOUS KIT 50 MCG/0.5ML
- *tazarotene external cream*
- *tazarotene external foam*
- TAZORAC EXTERNAL CREAM 0.05 %
- TAZORAC EXTERNAL GEL
- VABOMERE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	The following physician specialties are exempt from prior authorization (by drug): (a) for Fabior, tazarotene, and Tazorac: dermatology exempt, (b) for Pegasys: gastroenterology, hepatology, or infectious diseases exempt, (c) for Vabomere: infectious diseases or nephrology exempt
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	

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	

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	

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 (including cause of thrombocytopenia if being used for that indication), documentation of previous therapies tried (corticosteroids, immunoglobulins), submission of platelet count.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	PA applies to all. 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 Medically-accepted Indications.
Off Label Uses	

PROMETHAZINE IN OLDER PATIENTS

Products Affected

- *promethazine hcl oral solution*
- PROMETHAZINE HCL ORAL SYRUP
- PROMETHAZINE HCL ORAL TABLET
- 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	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	

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)
Required Medical Information	Diagnosis of covered use. For Nubeqa, documentation of other treatments tried. 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	

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
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, past-year history of red blood cell (RBC) transfusions.
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. Positive history of RBC transfusions is required for initial coverage. For initial reauthorization, improvement of hemoglobin level and/or reductions in annualized rate of RBC transfusions is required. Continued improvement in either hemoglobin level or reductions in RBC transfusional burden from baseline will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	

QINLOCK (ripretinib)

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of previous kinase inhibitor therapies, baseline blood pressure reading, attestation patient does not have uncontrolled hypertension, 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	

QUVIVIQ (daridorexant)

Products Affected

- *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	

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 Medically-accepted Indications.
Off Label Uses	

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.
Age Restrictions	2 months of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

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, attestation pituitary gland surgery is not an option for the patient or has not been curative, submission of cortisol level (e.g., 24-hour urine free cortisol test), 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 urine free cortisol 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	

RETACRIT (epoetin alfa-epbx)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of hemoglobin or hematocrit level, serum iron, total iron-binding capacity (TIBC), and transferrin within 30 days of request date, documentation that the patient does not have uncontrolled hypertension.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	For non-ESRD-related conditions: 90 days. For ESRD-related conditions: 1 year.
Other Criteria	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	

RETEVMO (selpercatinib)

Products Affected

- RETEVMO ORAL CAPSULE 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 FDA-approved 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, submission of date or year of previous previous radioactive iodine treatment or reason why radioactive iodine therapy is not appropriate.
Age Restrictions	12 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	

REVCOVI (elapegademase-lvlr)

Products Affected

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	Severe thrombocytopenia
Required Medical Information	Diagnosis of covered use, submission of plasma ADA activity and platelet count.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated plasma ADA level and platelet count 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 FDA-approved Indications.
Off Label Uses	

REVLIMID (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, submission of CBC including ANC and platelet count, pregnancy status for female patients of childbearing potential. 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.
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	

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	

ROZLYTREK (entrectinib)

Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

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 results showing tumor is ROS1-positive as detected by an FDA-approved test. For solid tumors, submission of evidence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

RUBRACA (rucaparib)

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline CBC. For BRCA mutation-associated ovarian, fallopian tube, primary peritoneal or metastatic castration-resistant prostate cancer, confirmation of deleterious BRCA mutation as detected by FDA-approved companion diagnostic test, documentation that the patient has been treated with two or more chemotherapies.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and urology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For initial approval, patient must have recovered from hematological toxicity caused by previous chemotherapy (Grade 1 or less).
Indications	All Medically-accepted Indications.
Off Label Uses	

RYDAPT (midostaurin)

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use. For acute myeloid leukemia, submission of FDA-approved 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	

SAPROPTERIN

Products Affected

- *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 level.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Submission of blood phenylalanine concentration documenting a 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	

SCEMBLIX (asciminib)

Products Affected

- SCEMBLIX ORAL TABLET 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	

SEDATIVE HYPNOTICS IN OLDER PATIENTS

Products Affected

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

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	

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	

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 ALT, aspartate aminotransferase, alkaline phosphatase, total bilirubin, and serum potassium and magnesium levels, attestation that pituitary radiation/surgery was not curative or is not an option.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated liver function testing and serum potassium and magnesium 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	

SIMVASTATIN 80 mg per day

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Any new start to therapy. Not recommended as initial therapy nor for patients already taking lower doses of simvastatin whose response is inadequate.
Required Medical Information	Diagnosis of covered use, documentation that patient has been taking simvastatin 80 mg daily for 12 months or longer without ill effect, submission of lipid panel, liver function tests, and serum creatinine level all obtained within the past 12 months.
Age Restrictions	10 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	

SIRTURO (bedaquiline)

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline ECG, serum potassium, calcium, magnesium, ALT, AST, alkaline phosphatase, and bilirubin, confirmation that Sirturo will be co-administered with 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	

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	

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	

SOMATULINE DEPOT (lanreotide)

Products Affected

- SOMATULINE DEPOT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation of baseline serum GH, IGF-1, TSH, and blood glucose levels. For acromegaly, attestation that pituitary radiation/surgery was not curative or is not an option.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology and oncology
Coverage Duration	Initially 3 months, then up to 1 year
Other Criteria	PA applies to new starts only. Continuation of therapy requires documentation of a positive clinical response. A description of 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	

SOMAVERT (pegvisomant)

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline IGF-1, ALT, AST, alkaline phosphatase, and serum total bilirubin, attestation that surgery or radiation was not curative or is not an option.
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 and liver function tests since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

SPRYCEL (dasatinib)

Products Affected

- 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
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	

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, submission of baseline ALT, AST, serum bilirubin, 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	

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	

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.
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. 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	

SUTENT (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.
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	

SYMDEKO (tezacaftor/ivacaftor)

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use. Documentation that the patient is homozygous for the F508del mutation or has at least one mutation in the CTFR gene responsive to the drug (see section 12.1, table 4 of package insert for full list) provided from an FDA-cleared CF mutation test. Submission of documentation that baseline and follow-up ophthalmologic exams will be performed in pediatric patients starting on therapy.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

SYMLIN (pramlintide)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Gastroparesis
Required Medical Information	Diagnosis of covered use, confirmation of current use of a mealtime insulin.
Age Restrictions	
Prescriber Restrictions	PA not required for endocrinology
Coverage Duration	1 year
Other Criteria	PA applies to all except when prescribed by endocrinology.
Indications	All Medically-accepted Indications.
Off Label Uses	

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 equivalent dose of at least 30 mg daily for at least 4 weeks prior to initiation, provider must attest that if opioid medication is stopped for any reason, naldemedine will be discontinued.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

SYNRIBO (omacetaxine)

Products Affected

- SYNRIBO

PA Criteria	Criteria Details
Exclusion Criteria	Poor glycemic control
Required Medical Information	Diagnosis of covered use, submission of prior therapies tried and failed, 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. 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	

TABRECTA (capmatinib)

Products Affected

- TABRECTA ORAL TABLET 150 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of FDA-approved 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	

TAFAMIDIS

Products Affected

- VYNDAMAX
- VYNDAQEL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

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 FDA-approved test confirming presence of BRAF V600E or V600K mutation. For non-small cell lung cancer, thyroid cancer, or unresectable/metastatic melanoma with a BRAF V600K mutation, attestation that therapy will be used in combination with trametinib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

TAGRISSO (osimertinib)

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, confirmation of the presence of required genetic mutations/deletions as detected by an FDA-approved test, 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	Initially 3 months, then 1 year
Other Criteria	PA applies to new starts only. Continuation of approval requires affirmation of absence of unacceptable toxicities.
Indications	All Medically-accepted Indications.
Off Label Uses	

TALZENNA (talazoparib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of FDA-approved companion test results showing patient is a candidate for therapy 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	

TARGRETIN (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	

TARPEYO (budesonide)

Products Affected

- TARPEYO

PA Criteria	Criteria Details
Exclusion Criteria	Severe (Child-Pugh class C) hepatic impairment, eGFR less than 35 mL/min/1.73 m2
Required Medical Information	Diagnosis of covered use, primary IgA nephropathy confirmed by biopsy, submission of 24-hour urine protein of at least 1 gram/day or 24-hour urine protein-to-creatinine ratio of at least 1.5 g/g, submission of eGFR and 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 Medically-accepted Indications.
Off Label Uses	

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 or strong CYP3A4 inhibitors
Required Medical Information	Diagnosis of covered use, submission of baseline ECG, 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	

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, documentation patient had an insufficient response to prior treatment (including at least one of the following: corticosteroids, immunoglobulins, splenectomy, and/or a thrombopoietin receptor agonist).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology
Coverage Duration	Initially 12 weeks, then 1 year
Other Criteria	PA applies to all. 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	

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	

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.
Age Restrictions	16 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	Initially 16 weeks, then 1 year
Other Criteria	PA applies to new starts only. Continuation of therapy requires (a) documentation of a positive clinical response and (b) attestation no known secondary malignancies have developed.
Indications	All Medically-accepted Indications.
Off Label Uses	

TEGSEDI (inotersen)

Products Affected

- TEGSEDI

PA Criteria	Criteria Details
Exclusion Criteria	Platelet count less than 100 x 10^9 L
Required Medical Information	Diagnosis of covered use, submission of platelet count.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated platelet count since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	

TEPMETKO (tepotinib)

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers or dual strong CYP3A4/P-glycoprotein inhibitors
Required Medical Information	Diagnosis of covered use, submission of FDA-approved 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	

TERIPARATIDE

Products Affected

- FORTEO SUBCUTANEOUS SOLUTION 600 MCG/2.4ML
- FORTEO SUBCUTANEOUS SOLUTION PEN-INJECTOR
- TERIPARATIDE (RECOMBINANT)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, postmenopausal status, submission of serum calcium level, documentation that other treatment options have failed (or are contraindicated), submission of a value, condition, or past medical history that assesses fracture risk (e.g., DEXA scan results or prior fracture), submission of number of total months of all prior use of parathyroid hormone analogs and parathyroid hormone related peptides.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated serum calcium since the previous authorization will be required for reauthorization.
Indications	All Medically-accepted Indications.
Off Label Uses	

TESTOSTERONE REPLACEMENT PRODUCTS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of serum testosterone level, documentation that patient has been evaluated for the presence of breast and prostate cancer prior to initiation of therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. 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	

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 FDA-approved test confirming presence of IDH1 mutation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

TOBI PODHALER (tobramycin)

Products Affected

- TOBI PODHALER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	6 years of age or older
Prescriber Restrictions	
Coverage Duration	1 month
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

TOLVAPTAN (HYPONATREMIA)

Products Affected

- SAMSCA ORAL TABLET 15 MG
- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	History of signs or symptoms of significant liver impairment or injury, 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 serum sodium.
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	

TOPICAL ONYCHOMYCOSIS TREATMENTS

Products Affected

- JUBLIA
- *tavaborole*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of culture-proven Trichophyton rubrum or Trichophyton mentagrophytes infection, documentation patient has (1) tried and failed to respond to or tolerate oral terbinafine therapy or a documented contraindication to its use exists, and (2) tried and failed therapy with topical ciclopirox nail solution.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	48 weeks
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

TOPICAL PSORIASIS TREATMENTS

Products Affected

- VTAMA
- ZORYVE

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: (a) a vitamin D analog such as calcipotriene or calcitriol, (b) tazarotene, or (c) a topical calcineurin inhibitor, 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, 12 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 FDA-approved Indications.
Off Label Uses	

TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, documentation that the patient has at least one mutation in the CFTR gene responsive to the drug (see section 12.1, table 4 of package insert for full list) or a mutation that is responsive based on in vitro data provided from an FDA-cleared CF mutation test, submission of documentation that baseline and follow-up ophthalmologic exams will be performed in pediatric patients starting on therapy.
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	

TRUSELTIQ (infigratinib)

Products Affected

- TRUSELTIQ (100MG DAILY DOSE)
- TRUSELTIQ (125MG DAILY DOSE)
- TRUSELTIQ (50MG DAILY DOSE)
- TRUSELTIQ (75MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers or inhibitors, coadministration with proton pump inhibitors
Required Medical Information	Diagnosis of covered use, submission of test result confirming presence of FGFR2 fusion or rearrangement, 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	

TUKYSA (tucatinib)

Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, coadministration with strong CYP3A inducers, strong CYP2C8 inhibitors, 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, confirmation that the treatment regimen will include concomitant use of capecitabine and trastuzumab.
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	

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.
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	

TYMLOS (abaloparatide)

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	Male patients, 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, postmenopausal status, documentation that at least one bisphosphonate was tried and failed (or a bisphosphonate is contraindicated), submission of a value, condition, or past medical history that assesses fracture risk (e.g., DEXA scan results or prior fracture), submission of number of total months of all prior use of parathyroid hormone analogs and parathyroid hormone related peptides.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 years maximum dependent on patient's prior use of all PTH analogs and PTH-related peptides
Other Criteria	PA applies to all. Use of parathyroid hormone analogs and/or parathyroid hormone related peptides for more than 2 years during a patient's lifetime is not recommended and requests for therapy with any of these agents for a combined total of greater than 2 years will not be approved.
Indications	All Medically-accepted Indications.
Off Label Uses	

UPNEEQ (oxymetazoline)

Products Affected

- UPNEEQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to ophthalmologic surgery
Coverage Duration	Initially 90 days, then 1 year
Other Criteria	PA applies to all. Submission of clinically significant response to therapy will be required for reauthorization. Not FDA-approved for cosmetic use and therefore uses outside of acquired blepharoptosis will not be approved.
Indications	All FDA-approved Indications.
Off Label Uses	

UPTRAVI (selexipag)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Severe (Child-Pugh class C) hepatic impairment
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	Initially 6 months, then 1 year
Other Criteria	PA applies to new starts only. Submission of clinically significant response to therapy will be required for reauthorization.
Indications	All Medically-accepted Indications.
Off Label Uses	

VECAMYL (mecamylamine)

Products Affected

- VECAMYL

PA Criteria	Criteria Details
Exclusion Criteria	Mild, moderate, labile hypertension, coronary insufficiency or history of recent myocardial infarction, uremia, glaucoma, organic pyloric stenosis
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and neurology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

VEMLIDY (tenofovir alafenamide)

Products Affected

- VEMLIDY

PA Criteria	Criteria Details
Exclusion Criteria	End-stage renal disease patients not receiving chronic hemodialysis, decompensated (Child-Pugh class B or C) hepatic impairment
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 of HIV test and that drug will not be used by itself in the case of HIV co-infection.
Age Restrictions	18 years of age or older
Prescriber Restrictions	PA not required for gastroenterology or infectious diseases
Coverage Duration	1 year
Other Criteria	PA applies to all except gastroenterology or infectious diseases. Updated creatinine clearance since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	

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.
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	

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	

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	

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, submission of baseline liver function tests and CBC, 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	

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	

VIJOICE (alpelisib)

Products Affected

- *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, 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.
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	

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 the solid tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, 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	

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 Medically-accepted Indications.
Off Label Uses	

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 FDA-approved 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	

VMAT2 INHIBITORS

Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- INGREZZA ORAL CAPSULE 40 MG, 60 MG, 80 MG
- INGREZZA ORAL CAPSULE THERAPY PACK
- *tetrabenazine*

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	

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, coadministration with strong CYP3A4 inducers or strong CYP3A4 inhibitors
Required Medical Information	Diagnosis of covered use, submission of platelet count, 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	

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	

VOTRIENT (pazopanib)

Products Affected

- VOTRIENT

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, ALT, AST, bilirubin, and 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	

VRAYLAR (cariprazine)

Products Affected

- VRAYLAR ORAL CAPSULE
- VRAYLAR ORAL CAPSULE THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis, severe hepatic impairment, severe renal impairment (creatinine clearance less than 30 mL/min), coadministration with 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 new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

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, sympatomatic 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.
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. Updated serum potassium and magnesium since the previous authorization will be required for subsequent annual reauthorizations. For excessive daytime sleepiness associated with narcolepsy, pitolisant will be authorized only if the patient previously tried and had an inadequate clinical response or an intolerance to armodafinil or modafinil.
Indications	All Medically-accepted Indications.
Off Label Uses	

WEIGHT LOSS MEDICATIONS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Body mass index (BMI) less than 30 kg/m2 or less than 27 kg/m2 if the patient also has diabetes, high blood pressure, or dyslipidemia.
Required Medical Information	Submission of BMI and patient's exercise/diet plan.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Medication will not be approved if patient does not have a diet/exercise plan.
Indications	All Medically-accepted Indications.
Off Label Uses	

WELIREG (belzutifan)

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including confirmation patient does not require immediate surgery, 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	

WHITE BLOOD CELL STIMULATORS

Products Affected

- NIVESTYM
- ZARXIO

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	

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 results showing tumor is ALK or ROS1-positive as detected by an FDA-approved test, 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	

XATMEP (methotrexate oral solution)

Products Affected

- XATMEP

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy (for polyarticular juvenile idiopathic arthritis [pJIA] indication only)
Required Medical Information	Diagnosis of covered use. For acute lymphoblastic leukemia, confirmation that medication is being used as a component of a combination chemotherapy maintenance regimen.
Age Restrictions	2 years of age through 18 years of age
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

XCOPRI (cenobamate)

Products Affected

- XCOPRI (250 MG DAILY DOSE)
- XCOPRI (350 MG DAILY DOSE)
- XCOPRI ORAL TABLET 100 MG, 150 MG, 200 MG, 50 MG
- XCOPRI ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	Familial short QT syndrome, patients with end-stage renal disease (creatinine clearance less than 15 mL/min) undergoing dialysis, severe hepatic impairment
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

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	

XOLAIR (omalizumab)

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	Patients whose pre-treatment serum IgE level and body weight place them in the "insufficient data to recommend a dose" category based on dosing charts in the prescribing information
Required Medical Information	Diagnosis of covered use. For asthma, documentation that patient's symptoms are poorly controlled with inhaled corticosteroids, submission of patient's current body weight, pre-treatment serum IgE level, pulmonary function test results including FEV1, positive skin test result or demonstrated in vitro reactivity (RAST test) to a perennial aeroallergen, frequency of inhaled short-acting beta2-agonist therapy, frequency of daily and nighttime symptoms and exacerbations, and effect of exacerbations on activity. For chronic idiopathic urticaria, documentation that the patient continues to experience severe itching and hives despite the use of an H1 antihistamine at an approved dose. For nasal polyps, documentation that patient's symptoms are poorly controlled with intranasal corticosteroids and current intranasal corticosteroid therapy.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Restricted to allergy, dermatology, immunology, otolaryngology/otorhinolaryngology, and pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to all. Submission of objective documentation of symptomatic improvement and updated patient weight will be required for subsequent annual 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	

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 FDA-approved test confirming presence of FLT3 mutation, serum calcium 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	

XPOVIO (selinexor)

Products Affected

- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 40 MG
- XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 40 MG
- XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 60 MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 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	

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	

ZEJULA (niraparib)

Products Affected

- ZEJULA

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 oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

ZERBAXA (ceftolozane/tazobactam)

Products Affected

- ZERBAXA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For complicated intra-abdominal infections, confirmation patient will receive concurrent metronidazole therapy.
Age Restrictions	18 years of age or older
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	

ZILEUTON ER

Products Affected

- ZILEUTON ER

PA Criteria	Criteria Details
Exclusion Criteria	Active liver disease or persistent hepatic function elevation enzyme greater than or equal to 3 times the upper limit of normal
Required Medical Information	Diagnosis of covered use, submission of hepatic function enzymes and serum bilirubin.
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated hepatic function enzymes and serum bilirubin since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	

ZILRETTA (triamcinolone intra-articular injection)

Products Affected

- ZILRETTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 treatment only
Other Criteria	PA applies to all. Use for hip and shoulder osteoarthritis were not evaluated in trials and PA will not be approved for this use. Re-authorization will not be approved. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	

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
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	

ZONTIVITY (vorapaxar)

Products Affected

- ZONTIVITY

PA Criteria	Criteria Details
Exclusion Criteria	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, documentation of concurrent use with aspirin and/or clopidogrel.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

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	

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.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to new starts only. Submission of documentation demonstrating a sustained reduction in monthly major motor seizure frequency is required for reauthorization.
Indications	All Medically-accepted Indications.
Off Label Uses	

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, 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	

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 FDA-approved 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	

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