

PRIOR AUTHORIZATION CRITERIA

This list is current as of October 1, 2026, and pertains to the following formularies:

2027 Pharmacy Benefit Dimensions PDP offered by Niagara County Formulary – D0122
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Pharmacy Benefit Dimensions requires you (or your physician) to get prior authorization for certain drugs listed on the formularies above. This means that you will need to get approval from us before you fill your prescriptions. If you do not get approval, we may not cover the drug. These drugs are listed with a “PA” in the Requirements/Notes column on the formularies. This document contains the Prior Authorization requirements that are associated with the formularies listed above.

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

ADAPALENE

Products Affected

- *adapalene external cream*
- *adapalene external gel 0.3 %*

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

ALECENSA (alectinib)

Products Affected

- ALECENSA

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

ALUNBRIG (brigatinib)

Products Affected

- ALUNBRIG

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

ATTRUBY (acoramidis)

Products Affected

- ATTRUBY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of transthyretin amyloid cardiomyopathy (ATTRwt or ATTRm) confirmed by one of the following: (1) presence of amyloid deposits on cardiac biopsy, (2) presence of transthyretin precursor protein confirmed on immunohistochemical analysis, (3) technetium 99-labeled nuclear scintigraphy or single-photon emission computer tomography (SPECT), or (4) a TTR genetic mutation plus cardiac involvement defined as thickening of the interseptal ventricular wall.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

AUSTEDO (deutetrabenazine)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Hepatic impairment (Child-Pugh class A, B, or C)
Required Medical Information	Diagnosis of covered use, submission of liver function testing or Child-Pugh score. For treatment of chorea associated with Huntington's disease, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and psychiatry
Coverage Duration	1 year
Other Criteria	For initial authorization for treatment of chorea associated with Huntington's disease, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to tetrabenazine. For each annual reauthorization for tardive dyskinesia, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AUVELITY (dextromethorphan/bupropion)

Products Affected

- AUVELITY
- AUVELITY TITRATION PACK

PA Criteria	Criteria Details
Exclusion Criteria	Current or prior diagnosis of bulimia or anorexia nervosa
Required Medical Information	Diagnosis of covered use, attestation patient has been screened for and does not have bipolar disorder or contraindicated eating disorders. For major depressive disorder (MDD), submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and psychiatry
Coverage Duration	1 year
Other Criteria	For initial authorization for MDD, the patient must have tried and failed to have an adequate response to or had an intolerance to two generic on-formulary antidepressants (e.g., bupropion, SSRI, SNRI). This policy applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

AVMAPKI/FAKZYNJA (avutometinib/defactinib)

Products Affected

- AVMAPKI FAKZYNJA CO-PACK

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with warfarin, proton pump inhibitors, or H2 receptor antagonists
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of KRAS mutation, attestation patient has received at least one prior systemic therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BENLYSTA (belimumab)

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Severe active central nervous system lupus
Required Medical Information	Diagnosis of covered use, submission of current therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to immunology, nephrology, and rheumatology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must be using standard therapy, defined as at least one of the following: systemic corticosteroids (e.g., prednisone), antimalarials (e.g., hydroxychloroquine), or immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate mofetil). For each annual reauthorization, confirmation patient is still using some form of standard therapy (as defined above), unless contraindicated, is required.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BEXAROTENE GEL

Products Affected

- *bexarotene external*

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

BRAFTOVI (encorafenib)

Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

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

BRUKINSA (zanubrutinib)

Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For follicular lymphoma, submission of at least two prior systemic regimens tried and failed and attestation medication will be coadministered with obinutuzumab. For mantle cell lymphoma, submission of prior systemic regimen(s) used. For marginal zone lymphoma, documentation patient has tried and failed at least one anti-CD20-based regimen.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BUTALBITAL-ACETAMINOPHEN-CAFFEINE

Products Affected

- *butalbital-apap-caffeine oral capsule*
- *butalbital-apap-caffeine oral tablet 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	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BUTALBITAL-ASPIRIN-CAFFEINE

Products Affected

- *butalbital-aspirin-caffeine oral capsule*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient has tried and failed a preferred alternative such as ibuprofen or rizatriptan, or has contraindications to all alternatives.
Age Restrictions	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CABLIVI (caplacizumab-yhdp)

Products Affected

- CABLIVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, confirmation drug will be given with plasma exchange and immunosuppressive therapy. If the coverage determination request is not for the patient's first use of caplacizumab, submission of previous aTTP recurrences while on caplacizumab.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to cardiology, hematology, and immunology
Coverage Duration	3 months
Other Criteria	If the coverage determination request is not for the patient's first use of caplacizumab, coverage will not be authorized if the patient has had more than 2 recurrences of aTTP while on therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CABOMETYX (cabozantinib)

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For hepatocellular carcinoma, confirmation patient was previously treated with sorafenib. For differentiated thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible and submission of previous therapy or therapies tried and failed, which must include a VEGFR-targeted therapy at minimum.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CALQUENCE (acalabrutinib)

Products Affected

- CALQUENCE ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For previously untreated mantle cell lymphoma, attestation patient is ineligible for autologous hematopoietic stem cell transplantation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CAPRELSA (vandetanib)

Products Affected

- CAPRELSA

PA Criteria	Criteria Details
Exclusion Criteria	History of congenital long QT syndrome
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	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COBENFY (xanomeline/trospium)

Products Affected

- COBENFY
- COBENFY STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis, moderate to severe hepatic impairment (Child-Pugh class B or C)
Required Medical Information	Diagnosis of covered use, submission of liver function testing or Child-Pugh score, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to psychiatry
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to aripiprazole and at least one other generic second-generation atypical antipsychotic. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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	
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	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COPIKTRA (duvelisib)

Products Affected

- COPIKTRA ORAL CAPSULE 15 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of at least two prior systemic therapies tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

COTELLIC (cobimetinib)

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including verification of BRAF V600 mutation as needed for diagnosis.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CRESEMBA (isavuconazonium)

Products Affected

- CRESEMBA ORAL CAPSULE 186 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Restricted to hematology, infectious diseases, and oncology
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

CYSTEAMINE EYE DROPS

Products Affected

- CYSTADROPS
- CYSTARAN

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

DALFAMPRIDINE

Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe renal impairment (CrCl less than or equal to 50 mL/min)
Required Medical Information	Diagnosis of covered use, submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance), confirmation that patient is able to walk.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, updated creatinine clearance since the previous authorization and confirmation patient is able to walk is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DASATINIB

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with proton pump inhibitors or H2 receptor antagonists
Required Medical Information	Diagnosis of covered use. 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	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DAURISMO (glasdegib)

Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
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, 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	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIACOMIT (stiripentol)

Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	Requests for monotherapy
Required Medical Information	Diagnosis of covered use, confirmation patient is also receiving clobazam.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DICHLORPHENAMIDE

Products Affected

- *dichlorphenamide*
- ORMALVI

PA Criteria	Criteria Details
Exclusion Criteria	Severe pulmonary disease limiting compensation to metabolic acidosis, hepatic insufficiency
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initially 2 months, then 1 year
Other Criteria	For each reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DICLOFENAC PATCH

Products Affected

- *diclofenac epolamine external*

PA Criteria	Criteria Details
Exclusion Criteria	Treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery, use on non-intact or damaged skin resulting from any etiology including exudative dermatitis, eczema, infection lesions, burns, or wounds, pregnancy after 30 weeks gestation
Required Medical Information	Diagnosis of acute pain, defined as short-term pain not lasting longer than a 3-month period.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

DIGOXIN IN OLDER PATIENTS

Products Affected

- *digoxin oral tablet 250 mcg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. Patient must have tried and failed to respond adequately to 0.125 mg of digoxin.
Age Restrictions	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
Prescriber Restrictions	PA not required for cardiology
Coverage Duration	1 year
Other Criteria	PA not required for doses less than or equal to 0.125 mg per day. For each annual reauthorization, provider must attest patient is undergoing required laboratory testing to monitor kidney function and electrolytes and patient is not experiencing signs or symptoms of digoxin toxicity related to drug administration.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DRONABINOL

Products Affected

- *dronabinol oral capsule*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. If authorization is requested for treatment of nausea and vomiting associated with cancer therapy, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization for treatment of nausea and vomiting associated with cancer therapy, the patient must have tried and failed to have an adequate response to or had an intolerance to at least one 5-HT3 receptor antagonist (e.g., granisetron, ondansetron). If the medication is being administered related to cancer treatment and is a full replacement for intravenous administration of antiemetic therapy within 48 hours of cancer treatment, it is covered as a Part B benefit. To be eligible for Part B coverage, the prescribing physician must indicate this on the prescription.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ENSACOVE (ensartinib)

Products Affected

- ENSACOVE

PA Criteria	Criteria Details
Exclusion Criteria	Prior ALK-inhibitor use
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of ALK-positive tumor, pregnancy status for female patients of childbearing potential, attestation patient has not previously received an ALK-inhibitor.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

EPIDIOLEX (cannabidiol)

Products Affected

- EPIDIOLEX

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

ERIVEDGE (vismodegib)

Products Affected

- ERIVEDGE

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

ESZOPICLONE

Products Affected

- *eszopiclone*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation at least two of the following medications were tried and deemed ineffective or intolerable: Belsomra, doxepin tablets, ramelteon, and trazodone.
Age Restrictions	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Sedative hypnotic medications are high-risk medications in older patients due to increased risks of cognitive impairment, delirium, unsteady gait, syncope, falls, fractures, and motor vehicle accidents. This policy applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EVEROLIMUS

Products Affected

- everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg MG
- everolimus oral tablet soluble 2 mg, 3 mg, 5 mg
- TORPENZ ORAL TABLET 10 MG, 2.5 MG, 5 MG, 7.5 MG
- YULITHIRA ORAL TABLET 10 MG, 2.5 MG, 5 MG, 7.5

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer, documentation of treatment failure with letrozole or anastrozole and confirmation drug is being used in combination with exemestane.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EXXUA (gepirone)

Products Affected

- EXXUA
- EXXUA TITRATION PACK

PA Criteria	Criteria Details
Exclusion Criteria	QTc interval greater than 450 msec at treatment initiation, severe hepatic impairment (Child-Pugh class C)
Required Medical Information	Diagnosis of covered use, submission of baseline QTc interval, liver function testing or Child-Pugh score, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to psychiatry
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to medications with an indication for monotherapy of major depressive disorder from at least 2 of the following classes: (1) tricyclic antidepressants, (2) MAOIs, (3) selective serotonin reuptake inhibitors, (4) serotonin-norepinephrine reuptake inhibitors, or (5) atypical antidepressants (i.e., bupropion, mirtazapine, nefazodone, trazodone, vilazodone, vortioxetine). This policy applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FANAPT (iloperidone)

Products Affected

- FANAPT ORAL TABLET 1 MG, 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG
- FANAPT TITRATION PACK A
- FANAPT TITRATION PACK B ORAL TABLET
- FANAPT TITRATION PACK C ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to psychiatry
Coverage Duration	1 year
Other Criteria	For initial authorization for schizophrenia or acute treatment of manic/mixed episodes of bipolar I disorder, the patient must have tried and failed to have an adequate response to or had an intolerance to aripiprazole and at least one other generic second-generation atypical antipsychotic. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FINTEPLA (fenfluramine)

Products Affected

- FINTEPLA

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

FOTIVDA (tivozanib)

Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to a minimum of two previous systemic therapies, including the failure of at least one prior VEGFR inhibitor. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

FRUZAQLA (fruquintinib)

Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have documentation of previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GATTEX (teduglutide)

Products Affected

- GATTEX

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

GEFITINIB

Products Affected

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GILOTRIF (afatinib)

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For non-small cell lung cancer, submission of test confirming presence of non-resistant epidermal growth factor receptor mutations. For metastatic squamous non-small cell lung cancer, documentation of progression after platinum-based chemotherapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

GOMEKLI (mirdametinib)

Products Affected

- GOMEKLI

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

HAEGARDA (C1 esterase inhibitor)

Products Affected

- HAEGARDA

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

HYALURONATES

Products Affected

- EUFLEXXA INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE
- GEL-ONE INTRA-ARTICULAR PREFILLED SYRINGE
- GELSYN-3
- GENVISC 850
- HYALGAN
- HYMOVIS
- HYMOVIS ONE
- MONOVISC
- ORTHOVISC INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE
- SUPARTZ FX
- SYNVISIC INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE
- SYNVISIC 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, Monovisc, or Hymovis One, 2 injections of Hymovis, 3 injections of Euflexxa, Synvisc, or Gelsyn-3, 4 injections of Orthovisc, or 5 injections of Hyalgan, Genvisc, or Supartz FX per knee joint may be authorized per treatment cycle. Retreatment may be authorized, provided (1) previous treatment cycle was administered at least 6 months ago, (2) treating physician submits documentation of a favorable patient response including pain relief derived of more than 3 months in duration, (3) patient has demonstrated a reduction in analgesic use or increase in functional capacity, and (4) patient's progress and results of hyaluronate therapy is fully documented in the patient's record.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

HYRNUO (sevabertinib)

Products Affected

- HYRNUO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including documentation the tumor is nonsquamous, submission of test confirming primary tumor type is HER2-positive, documentation of at least one previous systemic therapy that was tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ICATIBANT

Products Affected

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

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

ICLUSIG (ponatinib)

Products Affected

- ICLUSIG

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

IMBRUVICA (ibrutinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For chronic graft-versus-host disease, documentation of treatment failure with any other systemic immunosuppressive agent.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology, oncology, and transplant specialty
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

IMKELDI (imatinib)

Products Affected

- *imkeldi*

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

INLYTA (axitinib)

Products Affected

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	Uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, attestation patient does not have uncontrolled hypertension and that axitinib will be used with either avelumab or pembrolizumab or, if being used as a single agent, documentation of at least one previous systemic therapy that was tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

INQOVI (decitabine/cedazuridine)

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For acute myeloid leukemia, confirmation patient will also be receiving venetoclax as part of chemotherapeutic regimen, and, if patient is under 75 years of age, documentation of comorbidities that preclude use of intensive induction chemotherapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

INREBIC (fedratinib)

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	Thiamine deficiency
Required Medical Information	Diagnosis of covered use, submission of thiamine level (see Other Criteria), submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to ruxolitinib. If baseline thiamine level is low, coverage will be delayed until thiamine is repleted. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

JAKAFI (ruxolitinib)

Products Affected

- JAKAFI

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

JIDEYTRO (zidesamtinib)

Products Affected

- JIDEYTRO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of ROS1-positive tumor, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have had disease progression while using crizotinib, entrectinib, repotrectinib, or taletrectinib. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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 m ² , serum potassium above 5.0 mEq/L at initiation of therapy, severe hepatic impairment (Child-Pugh class C)
Required Medical Information	Diagnosis of covered use, submission of eGFR, liver function testing or Child-Pugh score, serum potassium level from within previous 6 months, and current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to dapagliflozin or empagliflozin. For each annual reauthorization, documented maintenance or further improvement of a clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

KISQALI (ribociclib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	QTcF interval greater than or equal to 450 msec at treatment initiation
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HR-positive, HER2-negative, submission of QTcF interval with the requirement it is less than 450 msec at treatment initiation, attestation that the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

KOSELUGO (selumetinib)

Products Affected

- KOSELUGO

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

LAZCLUZE (lazertinib)

Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, attestation that the medication will be used in combination with amivantamab and will be given with anticoagulant prophylaxis for the first four months of therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

LEUKINE (sargramostim, GM-CSF)

Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

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

L-GLUTAMINE

Products Affected

- *l-glutamine oral packet*

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

LIDOCAINE TRANSDERMAL PATCHES

Products Affected

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

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

LIPFENDRA (enlicitide)

Products Affected

- LIPFENDRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization for reducing major adverse cardiovascular events or heterozygous familial hypercholesterolemia, the patient must (1) have tried and failed to achieve an LDL below 70 mg/dL despite at least 8 weeks of high-intensity statin therapy, or (2) experienced rhabdomyolysis while using a statin, or (3) had a skeletal muscle intolerance to both atorvastatin and rosuvastatin that resolved upon discontinuation. For initial authorization for homozygous familial hypercholesterolemia, the patient must (1) have tried and failed to have an adequate response to achieve an LDL below goal despite at least 8 weeks of high-intensity statin therapy, or (2) experienced rhabdomyolysis while using a statin, or (3) had an skeletal muscle intolerance to both atorvastatin and rosuvastatin that resolved upon discontinuation, or (4) are statin-intolerant for reasons other than (2) or (3). This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LIVTENCITY (maribavir)

Products Affected

- LIVTENCITY

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

LONSURF (trifluridine/tipiracil)

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment (Child-Pugh class B or C)
Required Medical Information	Diagnosis of covered use, submission of liver function testing or Child-Pugh score. For colorectal cancer, documentation of KRAS status and attestation patient was previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and, depending on KRAS status, an anti-EGFR therapy. For gastric cancer, attestation patient was previously treated with at least two lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LORBRENA (lorlatinib)

Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

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

MAVYRET (glecaprevir/pibrentasvir)

Products Affected

- MAVYRET ORAL PACKET
- MAVYRET ORAL TABLET

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

MEGESTROL IN OLDER PATIENTS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
Prescriber Restrictions	PA not required for hematology or oncology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MEMANTINE/DONEPEZIL

Products Affected

- *memantine hcl-donepezil hcl er oral capsule extended release 24 hour 14-10 mg, 21-10 mg, 28-10 mg*
- NAMZARIC ORAL CAPSULE EXTENDED RELEASE 24 HOUR 7-10 MG

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

MOUNJARO (tirzepatide)

Products Affected

- MOUNJARO SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.5ML, 12.5 MG/0.5ML, 15 MG/0.5ML, 2.5 MG/0.5ML, 5 MG/0.5ML, 7.5 MG/0.5ML

PA Criteria	Criteria Details
Exclusion Criteria	Off-label use for weight management
Required Medical Information	Diagnosis of type 2 diabetes confirmed through one of the following: (1) medical record, or (2) ICD-10 on medical claims, or (3) laboratory results (hemoglobin A1c, fasting plasma glucose, 2-hour postprandial blood glucose after an oral glucose tolerance test, or random plasma blood glucose combined with classic signs/symptoms of hyperglycemia or hyperglycemic crisis).
Age Restrictions	Age must be consistent with the prescribing information of the drug and condition being treated
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MYTESI (crofelemer)

Products Affected

- MYTESI

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

NILOTINIB

Products Affected

- *nilotinib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	Uncorrected hypokalemia or hypomagnesemia, long QT syndrome, coadministration with proton pump inhibitors
Required Medical Information	Diagnosis of covered use, confirmation of positive Philadelphia chromosome (Ph) status, serum potassium and magnesium levels from within previous 6 months.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NINLARO (ixazomib)

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, attestation that medication will be administered concomitantly with lenalidomide and dexamethasone, documentation of prior therapy regimen for multiple myeloma.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUEDEXTA (dextromethorphan/quinidine)

Products Affected

- *dextromethorphan-quinidine*

PA Criteria	Criteria Details
Exclusion Criteria	Agitation or Alzheimer's disease without pseudobulbar affect, prolonged QT interval, heart failure, uncorrected hypokalemia or hypomagnesemia
Required Medical Information	Diagnosis of covered use, submission of serum potassium and magnesium levels from within previous 6 months. In patients with an increased risk of QT prolongation, including patients taking drugs that prolong the QT interval, taking moderate or strong CYP3A4 inhibitors, with left ventricular hypertrophy, or with left ventricular dysfunction, submission of electrocardiographic (ECG) evaluation of baseline QT interval.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and psychiatry
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, submission of updated potassium and magnesium levels and confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

NUPLAZID (pimavanserin)

Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	Psychosis unrelated to Parkinson's disease psychosis, uncorrected hypokalemia or hypomagnesemia
Required Medical Information	Diagnosis of covered use, submission of serum potassium and magnesium levels from within previous 6 months.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ODOMZO (sonidegib)

Products Affected

- ODOMZO

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

OGSIVEO (nirogacestat)

Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with proton pump inhibitors or H2 receptor antagonists
Required Medical Information	Diagnosis of covered use with documentation of tumor progression.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and sarcoma specialty
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

OJJAARA (mometotinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Active infection
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	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ORGOVYX (relugolix)

Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and urology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to Eligard or Trelstar or have contraindications to both Eligard and Trelstar. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ORIAHNN (elagolix/estradiol/norethindrone)

Products Affected

- ORIAHNN

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

OZEMPIC/RYBELSUS (semaglutide)

Products Affected

- OZEMPIC (0.25 OR 0.5 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/3ML
- OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 4 MG/3ML
- OZEMPIC (2 MG/DOSE)
- OZEMPIC ORAL TABLET 1.5 MG, 4 MG, 9 MG
- RYBELSUS ORAL TABLET 14 MG, 3 MG, 7 MG

PA Criteria	Criteria Details
Exclusion Criteria	Off-label use for weight management
Required Medical Information	Diagnosis of type 2 diabetes confirmed through one of the following: (1) medical record, or (2) ICD-10 on medical claims, or (3) laboratory results (hemoglobin A1c, fasting plasma glucose, 2-hour postprandial blood glucose after an oral glucose tolerance test, or random plasma blood glucose combined with classic signs/symptoms of hyperglycemia or hyperglycemic crisis).
Age Restrictions	Age must be consistent with the prescribing information of the drug and condition being treated
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PEGFILGRASTIM

Products Affected

- UDENYCA
- UDENYCA ONBODY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of FDA-approved indication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

PRETOMANID

Products Affected

- *pretomanid*

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

PROMETHAZINE IN OLDER PATIENTS

Products Affected

- *promethazine hcl oral solution 6.25 mg/5ml*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal suppository 12.5 mg, 25 mg*
- 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	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

QINLOCK (ripretinib)

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of previous kinase inhibitor therapies.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

REVCOVI (elapegademase-lvlr)

Products Affected

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	Severe thrombocytopenia
Required Medical Information	Diagnosis of covered use confirmed by either biochemical testing showing less than 1% of adenosine deaminase (ADA) catalytic activity in red blood cells or genetic testing showing biallelic ADA pathogenic variants, submission of baseline plasma ADA level (if genetic testing was submitted as confirmation of diagnosis) and platelet count, with the requirement it is at least $50 \times 10^9/L$.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology, immunology, and specialists in genetic diseases
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, submission of updated plasma ADA level demonstrating an improvement from baseline and updated platelet count of at least $50 \times 10^9/L$ is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REZUROCK (belumosudil)

Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment (Child-Pugh class B or C) without liver graft-versus-host disease
Required Medical Information	Diagnosis of covered use, submission of at least 2 previous therapies tried and failed for chronic graft-versus-host disease, liver function testing or Child-Pugh score.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to hematology, oncology, and transplant specialty
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ROMVIMZA (vimseltinib)

Products Affected

- ROMVIMZA

PA Criteria	Criteria Details
Exclusion Criteria	Active liver or biliary tract disease (including increased ALP), pre-existing increased serum transaminases, total or direct bilirubin greater than the upper limit of normal
Required Medical Information	Diagnosis of covered use (and attestation 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	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SAPROPTERIN

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of blood phenylalanine concentration with the requirement it exceeds 360 micromol/L.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For the first reauthorization, documentation of reduction in blood phenylalanine concentration from pre-treatment baseline is required. For each annual reauthorization, documented maintenance of a clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SCEMBLIX (asciminib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For use in patients with a T315I mutation, documentation patient has first tried and failed or become intolerant to ponatinib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SECUADO (asenapine)

Products Affected

- SECUADO TRANSDERMAL PATCH 24 HOUR 3.8 MG/24HR, 5.7 MG/24HR, 7.6 MG/24HR

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis, severe hepatic impairment (Child-Pugh class C)
Required Medical Information	Diagnosis of covered use, submission of liver function testing or Child-Pugh score, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to psychiatry
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to aripiprazole and at least one other generic second-generation atypical antipsychotic. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SIGNIFOR (pasireotide)

Products Affected

- SIGNIFOR

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

SORAFENIB

Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome, coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use. For differentiated thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SPECIALTY RESTRICTIONS - DICLOFENAC 3% GEL

Products Affected

- *diclofenac sodium external gel 3 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	PA not required for dermatology or oncology
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SPECIALTY RESTRICTIONS - IVABRADINE

Products Affected

- *ivabradine hcl oral tablet 5 mg, 7.5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	PA not required for cardiology
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SPECIALTY RESTRICTIONS - NAYZILAM

Products Affected

- NAYZILAM

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	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SPECIALTY RESTRICTIONS - PEGASYS

Products Affected

- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	PA not required for gastroenterology, hepatology, or infectious diseases
Coverage Duration	1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SPECIALTY RESTRICTIONS - VALTOCO

Products Affected

- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE NASAL LIQUID THERAPY PACK
2 X 7.5 MG/0.1ML
- VALTOCO 20 MG DOSE NASAL LIQUID THERAPY PACK
2 X 10 MG/0.1ML
- VALTOCO 5 MG DOSE

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

STIVARGA (regorafenib)

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For metastatic colorectal cancer, documentation of previous treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy. For gastrointestinal stromal tumor, documentation of previous treatment with imatinib and sunitinib. For hepatocellular carcinoma, documentation of previous treatment with sorafenib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

SUNITINIB

Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For gastrointestinal stromal tumor, documentation of prior use of imatinib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TAFINLAR (dabrafenib)

Products Affected

- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of BRAF V600E or V600K mutation.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TAKHZYRO (lanadelumab-flyo)

Products Affected

- TAKHZYRO SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 300 MG/2ML

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

TAZAROTENE

Products Affected

- *tazarotene external cream*
- *tazarotene external gel*
- TRILITAS

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

TESTOSTERONE REPLACEMENT PRODUCTS

Products Affected

- *testosterone transdermal gel 12.5 mg/act (1%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 50 mg/5gm (1%)*
- *testosterone transdermal solution*

PA Criteria	Criteria Details
Exclusion Criteria	Breast cancer or known or suspected prostate cancer
Required Medical Information	Diagnosis of covered use, submission of serum testosterone level below the normal range, attestation that patient has been evaluated for the presence of prostate cancer prior to initiation of therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, submission of increased serum testosterone level (or maintenance of a previous increase in serum testosterone level) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRETINOIN TOPICAL

Products Affected

- *tretinoin external cream*
- *tretinoin external gel 0.01 %, 0.025 %*

PA Criteria	Criteria Details
Exclusion Criteria	Cosmetic use (e.g., hyperpigmentation, keloids, photoaging, wrinkles)
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of improvement previously achieved) is required. Tretinoin products will not be approved for cosmetic uses as these uses are currently excluded from coverage under Medicare Part D.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C)
Required Medical Information	Diagnosis of covered use, submission of cystic fibrosis (CF) mutation test confirming presence of CFTR gene mutations as indicated in the prescribing information, liver function testing or Child-Pugh score.
Age Restrictions	Age must be consistent with the prescribing information of the drug
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TRULICITY (dulaglutide)

Products Affected

- TRULICITY SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Off-label use for weight management
Required Medical Information	Diagnosis of type 2 diabetes confirmed through one of the following: (1) medical record, or (2) ICD-10 on medical claims, or (3) laboratory results (hemoglobin A1c, fasting plasma glucose, 2-hour postprandial blood glucose after an oral glucose tolerance test, or random plasma blood glucose combined with classic signs/symptoms of hyperglycemia or hyperglycemic crisis).
Age Restrictions	Age must be consistent with the prescribing information of the drug and condition being treated
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

UBRELVY (ubrogepant)

Products Affected

- UBRELVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization for acute migraine treatment, the patient must have have tried and failed to have an adequate response to one triptan or have a documented contraindication to triptan use.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VALCHLOR (mechlorethamine)

Products Affected

- VALCHLOR

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

VELSIPITY (etrasimod)

Products Affected

- VELSIPITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two preferred agents (an adalimumab biosimilar, Rinvoq, Skyrizi, an ustekinumab biosimilar, and Xeljanz/Xeljanz XR) for the indication submitted, where possible.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VENCLEXTA (venetoclax)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For newly-diagnosed acute myeloid leukemia, if patient is under 75 years of age, documentation of comorbidities that preclude use of intensive induction chemotherapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VEOZAH (fezolinetant)

Products Affected

- VEOZAH

PA Criteria	Criteria Details
Exclusion Criteria	Estimated glomerular filtration rate (eGFR) less than 30 mL/min, known cirrhosis, any aminotransferase or total bilirubin at or above 2 times the upper limit of normal
Required Medical Information	Diagnosis of covered use, submission of eGFR, liver function testing, current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two prior systemic hormone therapies or FDA-approved or compendia-supported non-hormonal therapies (e.g., SSRI, SNRI, clonidine, gabapentin, etc.) for the treatment of vasomotor symptoms due to menopause. The drugs tried must come from different medication classes. For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VEPPANU (vepdegestrant)

Products Affected

- VEPPANU

PA Criteria	Criteria Details
Exclusion Criteria	QTc interval greater than 470 msec at treatment initiation
Required Medical Information	Diagnosis of covered use, submission of test confirming the primary tumor type is ER-positive, HER2-negative, and ESR1-mutated, submission of baseline QTc interval with the requirement it is less than or equal to 470 msec at treatment initiation, attestation patient had disease progression after at least one prior endocrine therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VERZENIO (abemaciclib)

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming that the primary tumor type is HR-positive, HER2-negative.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VIVJOA (oteseconazole)

Products Affected

- VIVJOA

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

VIZIMPRO (dacomitinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with a proton pump inhibitor
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of EGFR exon 19 deletions or exon 21 L858R substitution mutations.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)

Products Affected

- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient has a contraindication to or is otherwise not a candidate for a regimen recommended by the AASLD-IDSA guidance containing Mavyret or sofosbuvir/velpatasvir.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to gastroenterology, hepatology, and infectious diseases
Coverage Duration	Criteria for coverage duration will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

VTAMA (tapinarof)

Products Affected

- VTAMA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to dermatology
Coverage Duration	1 year
Other Criteria	For initial authorization for atopic dermatitis, the patient must have tried and failed to have an adequate response to or had an intolerance to at least (1) a Class/Group 3 high potency or stronger topical corticosteroid for at least 4 weeks, and (2) a topical calcineurin inhibitor (CNI) for at least 4 weeks, unless clinical documentation is submitted as to why a topical corticosteroid and/or topical CNI cannot be used. For initial authorization for plaque psoriasis, the patient must (1) have tried and failed to have an adequate response to or had an intolerance to at least (a) one Class/Group 3 high potency or stronger topical corticosteroid, and (b) one other prescription topical agent indicated for plaque psoriasis (e.g., calcipotriene, calcitriol, tazarotene), or (2) be using a systemic medication (biologic or otherwise) to manage plaque psoriasis. For each annual reauthorization, confirmation of a symptomatic or clinical improvement or maintenance of an improvement previously achieved is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

WEIGHT LOSS MEDICATIONS

Products Affected

- ADIPEX-P
- CONTRAVE
- FOUNDAYO
- *liraglutide -weight management*
- *phentermine hcl oral capsule*
- *phentermine hcl oral tablet 37.5 mg*
- *phentermine-topiramate er*
- WEGOVY HD
- WEGOVY ORAL
- WEGOVY SUBCUTANEOUS SOLUTION AUTO-INJECTOR 0.25 MG/0.5ML, 0.5 MG/0.5ML, 1 MG/0.5ML, 1.7 MG/0.75ML, 2.4 MG/0.75ML

PA Criteria	Criteria Details
Exclusion Criteria	Body mass index (BMI) less than 30 kg/m ² or less than 27 kg/m ² if the patient also has diabetes, high blood pressure, or dyslipidemia. For Wegovy, indication of risk reduction for major adverse cardiovascular events in cardiovascular disease or for metabolic dysfunction-associated steatohepatitis (see Other Criteria).
Required Medical Information	Submission of BMI, body weight and patient's exercise/diet plan.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	After initial 1-year approval, documentation the patient has maintained a loss of 5 percent body weight will be required for further 1-year reauthorizations. Medication will not be approved if patient does not have a diet/exercise plan. Criteria for use of Wegovy to reduce risk of major adverse cardiovascular events (MACE) or to treat metabolic dysfunction-associated steatohepatitis (MASH) are located in the Wegovy (semaglutide) NC EGWP policy.
Indications	Some FDA-approved Indications Only.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

WELIREG (belzutifan)

Products Affected

- WELIREG

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

XALKORI (crizotinib)

Products Affected

- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of ALK or ROS1-positive tumor.
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	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

XERMELO (telotristat)

Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient has been on at least 12 weeks of prior somatostatin analog therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each reauthorization, documentation patient remains on somatostatin analog therapy (unless contraindicated) and confirmation that the patient has not experienced episodes of severe constipation is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XPOVIO (selinexor)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For multiple myeloma in combination with bortezomib and dexamethasone, documented failure of at least one previous therapy. For relapsed or refractory multiple myeloma, documented failure of at least four previous lines of systemic therapy including at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

XTANDI (enzalutamide)

Products Affected

- XTANDI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For metastatic castration-resistant prostate cancer (mCRPC) only, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and urology
Coverage Duration	1 year
Other Criteria	For initial authorization of Xtandi for mCRPC, the patient must have an intolerance or contraindication to abiraterone. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZALEPLON

Products Affected

- *zaleplon*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation at least two of the following medications were tried and deemed ineffective or intolerable: Belsomra, doxepin tablets, ramelteon, and trazodone.
Age Restrictions	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Sedative hypnotic medications are high-risk medications in older patients due to increased risks of cognitive impairment, delirium, unsteady gait, syncope, falls, fractures, and motor vehicle accidents. This policy applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZENBEXUS (iberdomide)

Products Affected

- ZENBEXUS

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, attestation patient was previously treated with at least one prior line of therapy including a proteasome inhibitor and an immunomodulatory agent, attestation patient does not have disease that was refractory to previous receipt of an anti-CD38 monoclonal antibody, attestation patient will be taking iberdomide concurrently with and daratumumab-hyaluronidase and dexamethasone, 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	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZEPBOUND (tirzepatide) NC EGWP

Products Affected

- ZEPBOUND KWIKPEN
- ZEPBOUND SUBCUTANEOUS SOLUTION AUTO-INJECTOR

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

ZILRETTA (triamcinolone intra-articular injection)

Products Affected

- ZILRETTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 treatment only
Other Criteria	PA applies to all. Use for hip and shoulder osteoarthritis were not evaluated in trials and PA will not be approved for this use. Re-authorization will not be approved. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

ZOLPIDEM

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation at least two of the following medications were tried and deemed ineffective or intolerable: Belsomra, doxepin tablets, ramelteon, and trazodone.
Age Restrictions	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Sedative hypnotic medications are high-risk medications in older patients due to increased risks of cognitive impairment, delirium, unsteady gait, syncope, falls, fractures, and motor vehicle accidents. This policy applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZTALMY (ganaxolone)

Products Affected

- ZTALMY

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

ZYDELIG (idelalisib)

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, attestation therapy will be coadministered with rituximab, documentation of at least one previous line of systemic therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZYKADIA (ceritinib)

Products Affected

- ZYKADIA ORAL TABLET

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

Index

ACTIMMUNE	2	COBENFY	36
<i>adapalene external cream</i>	3	COBENFY STARTER PACK	36
<i>adapalene external gel 0.3 %</i>	3	COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG	37
ADEMPAS ORAL TABLET 0.5 MG, 1 MG, 1.5 MG, 2 MG, 2.5 MG	4	COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG	37
ADIPEX-P	266	COMETRIQ (60 MG DAILY DOSE)	37
AIMOVIG	5	CONTRACE	266
AJOVY	6	COPIKTRA ORAL CAPSULE 15 MG, 25 MG	38
AKEEGA	7	CORTROPHIN	39
ALECENSA	8	CORTROPHIN GEL	39
ALUNBRIG	9	COTELLIC	40
ALYQ	219	CRESEMBA ORAL CAPSULE 186 MG	41
AMBIEN	282	CYSTADROPS	42
AMBIEN CR	282	CYSTARAN	42
<i>ambrisentan oral tablet 10 mg, 5 mg</i>	10	<i>dalfampridine er</i>	43
ARIKAYCE	11	<i>dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg</i>	44
ATTRUBY	12	DAURISMO ORAL TABLET 100 MG, 25 MG	45
AUGTYRO	13	<i>deferasirox oral tablet soluble</i>	46
AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG	14	<i>dextromethorphan-quinidine</i>	150
AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HOUR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG, 48 MG, 6 MG	14	DIACOMIT	47
AUSTEDO XR PATIENT TITRATION ORAL TABLET EXTENDED RELEASE THERAPY PACK 12 & 18 & 24 & 30 MG	14	<i>dichlorphenamide</i>	48
AUVELITY	15	<i>diclofenac epolamine external</i>	49
AUVELITY TITRATION PACK	15	<i>diclofenac sodium external gel 3 %</i>	208
AVMAPKI FAKZYNJA CO-PACK	16	<i>digoxin oral tablet 250 mcg</i>	50
AYVAKIT ORAL TABLET 100 MG, 200 MG, 25 MG, 300 MG, 50 MG	17	DOPTLET ORAL TABLET 20 MG	51
BALVERSA	18	<i>dronabinol oral capsule</i>	52
BENLYSTA SUBCUTANEOUS	19	DUPIXENT SUBCUTANEOUS SOLUTION AUTO- INJECTOR	53
BESREMI	20	DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 200 MG/1.14ML, 300 MG/2ML	53
BESREMI PEN	20	<i>eltrombopag olamine oral packet</i>	55
<i>bexarotene external</i>	21	<i>eltrombopag olamine oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg</i>	55
<i>bosentan oral tablet 125 mg, 62.5 mg</i>	22	EMGALITY	56
BOSULIF ORAL CAPSULE 100 MG, 50 MG	23	EMGALITY (300 MG DOSE)	56
BOSULIF ORAL TABLET 100 MG, 500 MG	23	ENSACOVE	57
<i>bosutinib</i>	23	ENTYVIO PEN	58
BRAFTOVI ORAL CAPSULE 75 MG	24	EOHILIA	59
BRUKINSA	25	EPIDIOLEX	60
<i>butalbital-apap-caffeine oral capsule</i>	26	ERIVEDGE	61
<i>butalbital-apap-caffeine oral tablet 50-325-40 mg</i>	26	ERLEADA	62
<i>butalbital-aspirin-caffeine oral capsule</i>	27	<i>eszopiclone</i>	63
CABLIVI	28	EUFLEXXA INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE	80
CABOMETYX	29	<i>everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg</i> ..	64
CALQUENCE ORAL TABLET	30	<i>everolimus oral tablet soluble 2 mg, 3 mg, 5 mg</i>	64
CAMZYOS	31	EVRYSDI	65
CAPLYTA ORAL CAPSULE 10.5 MG, 21 MG, 42 MG	32	EXXUA	66
CAPRELSA	33	EXXUA TITRATION PACK	66
<i>carglumic acid oral tablet soluble</i>	34		
CERDELGA	35		

FANAPT ORAL TABLET 1 MG, 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG	67	IWILFIN	98
FANAPT TITRATION PACK A	67	JAKAFI	99
FANAPT TITRATION PACK B ORAL TABLET	67	JAVYGTOR	196
FANAPT TITRATION PACK C ORAL TABLET	67	JAYPIRCA	100
FILSPARI	68	JIDEYTRO ORAL TABLET 100 MG, 25 MG	101
FINTEPLA	69	JOENJA ORAL TABLET 70 MG	102
FOTIVDA	70	JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG	103
FOUNDAYO	266	KALYDECO	104
FRUZAQLA ORAL CAPSULE 1 MG, 5 MG	71	KERENDIA	105
GAMASTAN S/D	89	KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE	106
GAMMAGARD	89	KISQALI (200 MG DOSE)	107
GAMMAGARD ERC	89	KISQALI (400 MG DOSE)	107
GAMMAGARD S/D LESS IGA	89	KISQALI (600 MG DOSE)	107
GATTEX	72	KOMZIFTI	108
GAVRETO	73	KOSELUGO	109
<i>gefitinib</i>	74	KRAZATI	110
GEL-ONE INTRA-ARTICULAR PREFILLED SYRINGE	80	<i>lapatinib ditosylate</i>	111
GELSYN-3	80	LAZCLUZE ORAL TABLET 240 MG, 80 MG	112
GENVISC 850	80	<i>lenalidomide</i>	113
GILOTRIF	75	LENVIMA (10 MG DAILY DOSE)	114
GOMEKLI	76	LENVIMA (12 MG DAILY DOSE)	114
HAEGARDA	78	LENVIMA (14 MG DAILY DOSE)	114
HERNEXEOS	79	LENVIMA (18 MG DAILY DOSE)	114
HYALGAN	80	LENVIMA (20 MG DAILY DOSE)	114
HYMOVIS	80	LENVIMA (24 MG DAILY DOSE)	114
HYMOVIS ONE	80	LENVIMA (4 MG DAILY DOSE)	114
HYRNUO	81	LENVIMA (8 MG DAILY DOSE)	114
IBRANCE ORAL CAPSULE 100 MG, 125 MG	82	LEQEMBI IQLIK	115
IBRANCE ORAL TABLET	82	LEQEMBI IQLIK (500 MG DOSE)	115
IBTROZI	83	LEUKINE INJECTION SOLUTION RECONSTITUTED	116
<i>icatibant acetate subcutaneous solution prefilled syringe</i>	84	<i>l-glutamine oral packet</i>	117
ICLUSIG	85	<i>lidocaine external patch 5 %</i>	118
IDHIFA	86	LIDOCAN	118
IMBRUVICA ORAL CAPSULE	87	LIFYORLI (125 MG DOSE)	119
IMBRUVICA ORAL SUSPENSION	87	LIFYORLI (150 MG DOSE)	119
IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG	87	LIPFENDRA	120
<i>imkeldi</i>	88	<i>liraglutide -weight management</i>	266
INBRIJA	90	LIVTENCITY	121
INCRELEX	130	LONSURF	122
INLURIYO	91	LORBRENA ORAL TABLET 100 MG, 25 MG	123
INLYTA	92	LUMAKRAS	124
INQOVI	93	LYBALVI	125
INREBIC	94	LYNPARZA ORAL TABLET	126
INVEGA HAFYERA	95	LYTGOBI (12 MG DAILY DOSE)	127
INVEGA TRINZA INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE 273 MG/0.88ML, 410 MG/1.32ML, 546 MG/1.75ML, 819 MG/2.63ML	95	LYTGOBI (16 MG DAILY DOSE)	127
ISTURISA ORAL TABLET 1 MG, 5 MG	96	LYTGOBI (20 MG DAILY DOSE)	127
ITOVEBI ORAL TABLET 3 MG, 9 MG	97	<i>macitentan</i>	128
<i>ivabradine hcl oral tablet 5 mg, 7.5 mg</i>	209	MAVYRET ORAL PACKET	129
		MAVYRET ORAL TABLET	129
		<i>megestrol acetate oral suspension 40 mg/ml, 625 mg/5ml</i>	131

MEKINIST	132	ORGOVYX	161
MEKTOVI	133	ORIAHNN	162
<i>memantine hcl-donepezil hcl er oral capsule</i>		ORILISSA ORAL TABLET 150 MG, 200 MG	163
<i>extended release 24 hour 14-10 mg, 21-10 mg, 28-</i>		ORKAMBI ORAL PACKET	164
<i>10 mg</i>	134	ORKAMBI ORAL TABLET	164
<i>mifepristone oral tablet 300 mg</i>	135	ORMALVI	48
<i>miglustat</i>	136	ORSERDU	165
MODEYSO	137	ORTHOVISC INTRA-ARTICULAR SOLUTION	
MONOVISC	80	PREFILLED SYRINGE	80
MOUNJARO SUBCUTANEOUS SOLUTION AUTO-		OZEMPIC (0.25 OR 0.5 MG/DOSE) SUBCUTANEOUS	
INJECTOR 10 MG/0.5ML, 12.5 MG/0.5ML, 15		SOLUTION PEN-INJECTOR 2 MG/3ML	166
MG/0.5ML, 2.5 MG/0.5ML, 5 MG/0.5ML, 7.5		OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION	
MG/0.5ML	138	PEN-INJECTOR 4 MG/3ML	166
MYTESI	139	OZEMPIC (2 MG/DOSE)	166
NAMZARIC ORAL CAPSULE EXTENDED RELEASE 24		OZEMPIC ORAL TABLET 1.5 MG, 4 MG, 9 MG	166
HOOR 7-10 MG	134	PANRETIN	167
NAYZILAM	210	<i>pazopanib hcl oral tablet 200 mg</i>	168
NERLYNX	140	PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML	211
NEXLETOL	141	PEGASYS SUBCUTANEOUS SOLUTION PREFILLED	
NEXLIZET	142	SYRINGE	211
<i>nilotinib hcl</i>	143	PEMAZYRE ORAL TABLET 13.5 MG, 4.5 MG, 9 MG ...	170
NINLARO	144	<i>phentermine hcl oral capsule</i>	266
<i>nintedanib esylate</i>	145	<i>phentermine hcl oral tablet 37.5 mg</i>	266
<i>nitisinone</i>	146	<i>phentermine-topiramate er</i>	266
NORDITROPIN FLEXPPO SUBCUTANEOUS SOLUTION		PIQRAY (200 MG DAILY DOSE)	171
PEN-INJECTOR 10 MG/1.5ML, 15 MG/1.5ML, 5		PIQRAY (250 MG DAILY DOSE)	171
MG/1.5ML	77	PIQRAY (300 MG DAILY DOSE)	171
NUBEQA	147	<i>pirfenidone oral tablet 267 mg, 801 mg</i>	172
NUCALA SUBCUTANEOUS SOLUTION AUTO-		<i>pomalidomide</i>	173
INJECTOR	148	POMALYST	173
NUCALA SUBCUTANEOUS SOLUTION PREFILLED		<i>pretomanid</i>	174
SYRINGE 100 MG/ML	148	PREVMIS ORAL TABLET	175
NUCALA SUBCUTANEOUS SOLUTION		PROLASTIN-C INTRAVENOUS SOLUTION	176
RECONSTITUTED	148	<i>promethazine hcl oral solution 6.25 mg/5ml</i>	177
NUPLAZID ORAL CAPSULE	151	<i>promethazine hcl oral tablet</i>	177
NUPLAZID ORAL TABLET 10 MG	151	<i>promethazine hcl rectal suppository 12.5 mg, 25 mg</i>	177
NURTEC	152	PROMETHEGAN RECTAL SUPPOSITORY 25 MG, 50	
OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML,		MG	177
10 GM/100ML, 10 GM/200ML, 2 GM/20ML, 2.5		QINLOCK	178
GM/50ML, 20 GM/200ML, 5 GM/100ML, 5		QULIPTA	179
GM/50ML	89	RADICAVA ORS	180
ODOMZO	153	RADICAVA ORS STARTER KIT	180
OFEV	145	REDEMPLO	181
OGSIVEO ORAL TABLET 100 MG, 150 MG	154	REPATHA	182
OJEMDA ORAL SUSPENSION RECONSTITUTED	155	REPATHA SURECLICK	182
OJEMDA ORAL TABLET 100 MG, 100 MG (16 PACK),		RETACRIT INJECTION SOLUTION 10000 UNIT/ML,	
100 MG (24 PACK)	155	2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML,	
OJJAARA ORAL TABLET 100 MG, 150 MG, 200 MG ...	156	4000 UNIT/ML, 40000 UNIT/ML	183
ONUREG	159	RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG,	
ORENITRAM	160	80 MG	184
ORENITRAM MONTH 1	160	REVCovi	185
ORENITRAM MONTH 2	160	REVUFORJ ORAL TABLET 110 MG, 160 MG, 25 MG ..	186
ORENITRAM MONTH 3	160		

REXULTI ORAL TABLET 0.25 MG, 0.5 MG, 1 MG, 2 MG, 3 MG, 4 MG	187	<i>testosterone transdermal gel 12.5 mg/act (1%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 50 mg/5gm (1%)</i>	230
REZDIFFRA	188	<i>testosterone transdermal solution</i>	230
REZLIDHIA	189	TIBSOVO	231
REZUROCK	190	<i>tolvaptan (hyponatremia) oral tablet 15 mg, 30 mg</i>	233
RIVFLOZA	191	<i>tolvaptan oral tablet 15 mg, 30 mg</i>	232
ROMVIMZA	192	<i>tolvaptan oral tablet therapy pack 15 mg, 30 & 15 mg, 45 & 15 mg, 60 & 30 mg, 90 & 30 mg</i>	232
ROZLYTREK	193	TORPENZ ORAL TABLET 10 MG, 2.5 MG, 5 MG, 7.5 MG	64
RUBRACA	194	<i>tretinoin external cream</i>	234
RYBELSUS ORAL TABLET 14 MG, 3 MG, 7 MG	166	<i>tretinoin external gel 0.01 %, 0.025 %</i>	234
RYDAPT	195	TRIDACAINA II	118
SAJAZIR SUBCUTANEOUS SOLUTION PREFILLED		TRIKAFTA ORAL TABLET THERAPY PACK 100-50-75 & 150 MG, 50-25-37.5 & 75 MG	235
SYRINGE	84	TRIKAFTA ORAL THERAPY PACK	235
<i>sapropterin dihydrochloride oral packet</i>	196	TRILITAS	226
<i>sapropterin dihydrochloride oral tablet</i>	196	TRULICITY SUBCUTANEOUS SOLUTION AUTO-INJECTOR	236
SCSEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG	197	TRUQAP ORAL TABLET 200 MG	237
SECUADO TRANSDERMAL PATCH 24 HOUR 3.8 MG/24HR, 5.7 MG/24HR, 7.6 MG/24HR	198	TRUQAP ORAL TABLET THERAPY PACK	237
SIGNIFOR	199	TUKYSA ORAL TABLET 150 MG, 50 MG	238
<i>sildenafil citrate oral suspension reconstituted</i>	200	TURALIO ORAL CAPSULE 125 MG	239
<i>sildenafil citrate oral tablet 20 mg</i>	200	UBRELVY	240
SIRTURO	201	UDENYCA	169
SKYCLARYS	202	UDENYCA ONBODY	169
<i>sodium oxybate</i>	203	<i>ustekinumab subcutaneous</i>	241
<i>sofosbuvir-velpatasvir</i>	204	UZEDY	242
SOMAVERT	205	VALCHLOR	243
<i>sorafenib tosylate</i>	206	VALTOCO 10 MG DOSE	212
SOTYKTU	207	VALTOCO 15 MG DOSE NASAL LIQUID THERAPY PACK 2 X 7.5 MG/0.1ML	212
STIVARGA	213	VALTOCO 20 MG DOSE NASAL LIQUID THERAPY PACK 2 X 10 MG/0.1ML	212
SUCRAID	214	VALTOCO 5 MG DOSE	212
<i>sunitinib malate</i>	215	VANFLYTA	244
SUNOSI ORAL TABLET 150 MG, 75 MG	216	VANRAFIA	245
SUPARTZ FX	80	VELSIPITY	246
SYMDEKO	217	VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG ..	247
SYNVISC INTRA-ARTICULAR SOLUTION PREFILLED		VENCLEXTA STARTING PACK	247
SYRINGE	80	VEOZAH	248
SYNVISC ONE INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE	80	VEPPANU	249
TABRECTA	218	VERQUVO ORAL TABLET 10 MG, 2.5 MG, 5 MG	250
<i>tadalafil (pah)</i>	219	VERZENIO	251
TAFINLAR	220	VIBERZI	252
TAGRISSO	221	VIJOICE ORAL PACKET	253
TAKHZYRO SUBCUTANEOUS SOLUTION PREFILLED		VIJOICE ORAL TABLET THERAPY PACK 125 MG, 200 & 50 MG, 50 MG	253
SYRINGE 300 MG/2ML	222	VITRAKVI ORAL CAPSULE 100 MG, 25 MG	254
TALZENNA ORAL CAPSULE 0.1 MG, 0.25 MG, 0.35 MG, 0.5 MG, 0.75 MG, 1 MG	223	VITRAKVI ORAL SOLUTION	254
TARPEYO	224	VIVJOA	255
<i>tasimelteon</i>	225	VIZIMPRO ORAL TABLET 15 MG, 30 MG, 45 MG	256
<i>tazarotene external cream</i>	226		
<i>tazarotene external gel</i>	226		
TEPMETKO	227		
<i>teriparatide subcutaneous solution pen-injector 560 mcg/2.24ml, 620 mcg/2.48ml</i>	228		

VONJO	257	ZYMFENTRA (2 PEN)	288
VOQUEZNA ORAL TABLET 10 MG, 20 MG	258	ZYMFENTRA (2 SYRINGE)	288
VORANIGO ORAL TABLET 10 MG, 40 MG	259		
VOSEVI	260		
VOWST	261		
VOYXACT	262		
VTAMA	263		
WEGOVY HD	266		
WEGOVY ORAL	264, 266		
WEGOVY SUBCUTANEOUS SOLUTION AUTO- INJECTOR 0.25 MG/0.5ML, 0.5 MG/0.5ML, 1 MG/0.5ML, 1.7 MG/0.75ML, 2.4 MG/0.75ML..	264, 266		
WELIREG	267		
WINREVAIR SUBCUTANEOUS KIT 2 X 45 MG, 2 X 60 MG, 45 MG, 60 MG	268		
XALKORI	269		
XDEMVI	270		
XERMELO	271		
XIFAXAN ORAL TABLET 550 MG	272		
XOLAIR	157		
XOSPATA	273		
XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 50 MG	274		
XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 10 MG	274		
XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 40 MG	274		
XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 60 MG	274		
XPOVIO (60 MG TWICE WEEKLY)	274		
XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 40 MG, 80 MG	274		
XPOVIO (80 MG TWICE WEEKLY)	274		
XTANDI	275		
YARGESA	136		
YULITHIRA ORAL TABLET 10 MG, 2.5 MG, 5 MG, 7.5 MG	64		
<i>zaleplon</i>	276		
ZEJULA ORAL TABLET	277		
ZELBORAF	278		
ZELVYSIA	196		
ZENBEXUS	279		
ZEPBOUND KWIKPEN	280		
ZEPBOUND SUBCUTANEOUS SOLUTION AUTO- INJECTOR	280		
ZILRETTA	281		
<i>zolpidem tartrate er</i>	282		
<i>zolpidem tartrate oral tablet</i>	282		
ZORYVE EXTERNAL CREAM 0.3 %	283		
ZTALMY	284		
ZURZUVAE	285		
ZYDELIG	286		
ZYKADIA ORAL TABLET	287		