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 D0457 - 0464
2027 Pharmacy Benefit Dimensions PDP offered by Niagara County Formulary D0465

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

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

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

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

ACTIMMUNE (interferon gamma-1b)

Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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

AIMOVIG (erenumab-aooe)

Products Affected

- AIMOVIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline headache days per month from medical chart.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For initial authorization for episodic migraine prevention, the patient must have documentation of fewer than 15 headache days per month. For the first reauthorization, submission of on-treatment headache days per month demonstrating improvement from baseline 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

AJOVY (fremanezumab-vfrm)

Products Affected

- AJOVY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline headache days per month from medical chart.
Age Restrictions	6 years of age or older
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For initial authorization for episodic migraine prevention, the patient must have documentation of fewer than 15 headache days per month. For the first reauthorization, submission of on-treatment headache days per month demonstrating improvement from baseline 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

AKEEGA (niraparib/abiraterone)

Products Affected

- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C)
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of deleterious BRCA mutation, liver function testing or Child-Pugh score.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and urology
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

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

AMBRISENTAN

Products Affected

- *ambrisentan oral tablet 10 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, moderate or severe hepatic impairment (Child-Pugh class B or C)
Required Medical Information	Diagnosis of covered use confirmed by right heart catheterization including a mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, and pulmonary vascular resistance greater than 2 Woods units, attestation patient is WHO Group 1, submission of liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	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

ARIKAYCE (amikacin inhalation)

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	Non-refractory Mycobacterium avium complex (MAC) lung disease
Required Medical Information	Diagnosis of covered use, documentation of multi-drug regimen for MAC (e.g., ethambutol, a macrolide, and a rifamycin) tried and failed for at least a 6-month trial period, submission of positive sputum culture result obtained after treatment with multi-drug regimen for MAC.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to infectious diseases and pulmonology
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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

AUGTYRO (repotrectinib)

Products Affected

- AUGTYRO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inhibitors or inducers or P-glycoprotein inhibitors
Required Medical Information	Diagnosis of covered use. For non-small cell lung cancer, submission of test confirming presence of ROS1-positive tumor. For other solid tumors, submission of test confirming tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, attestation patient has progressed following treatment or patient has no satisfactory alternative therapy.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	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
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HOUR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG, 48 MG, 6 MG
- AUSTEDO XR PATIENT TITRATION ORAL TABLET EXTENDED RELEASE THERAPY PACK 12 & 18 & 24 & 30 MG

PA Criteria	Criteria Details
Exclusion Criteria	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

AYVAKIT (avapritinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	For advanced or indolent systemic mastocytosis, platelet count below 50 x 10^9/L
Required Medical Information	Diagnosis of covered use. For gastrointestinal stromal tumor (GIST), submission of test result confirming presence of PDGFRA exon 18 mutation. For advanced or indolent systemic mastocytosis, submission of platelet count.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to allergy, hematology, immunology, and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

BALVERSA (erdafitinib)

Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	PD-1/PD-L1 inhibitor-eligible patients who have not received this therapy
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of susceptible FGFR3 genetic alterations, documentation showing patient has previously used a PD-1/PD-L1 inhibitor or explaining why patient is ineligible for this 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

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

BOSENTAN

Products Affected

- *bosentan oral tablet 125 mg, 62.5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use confirmed by right heart catheterization including a mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, and pulmonary vascular resistance greater than 2 Woods units, attestation patient is WHO Group 1, submission of pregnancy status for female patients of childbearing potential, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	For initial authorization in patients 18 years of age or older, the patient must have an intolerance or contraindication to the use of ambrisentan. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

BOSULIF (bosutinib)

Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 500 MG
- *bosutinib*

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

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

CAPLYTA (lumateperone)

Products Affected

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

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. For initial authorization for depressive episodes associated with bipolar disorder, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two of the following drugs: cariprazine, lurasidone, olanzapine, or quetiapine. For initial authorization for adjunctive therapy to antidepressants for major depressive disorder, the patient must have tried and failed to have an adequate response to or had an intolerance to (1) aripiprazole and (2) cariprazine or quetiapine. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

CAPRELSA (vandetanib)

Products Affected

- CAPRELSA

PA Criteria	Criteria Details
Exclusion Criteria	History of congenital long QT syndrome
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

CARGLUMIC ACID

Products Affected

- *carglumic acid oral tablet soluble*

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

CERDELGA (eliglustat)

Products Affected

- CERDELGA

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

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

CORTICOTROPIN

Products Affected

- CORTROPHIN
- CORTROPHIN GEL

PA Criteria	Criteria Details
Exclusion Criteria	Request for IV administration, patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, a history of or presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin
Required Medical Information	Diagnosis of covered use, submission of baseline serum sodium and potassium levels, attestation patient does not have uncontrolled hypertension.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 weeks
Other Criteria	For each reauthorization, updated blood pressure, sodium, and potassium levels since the previous authorization are required. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D.
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

DEFERASIROX

Products Affected

- *deferasirox oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C), estimated glomerular filtration rate (eGFR) less than 40 mL/min, platelet count below 50 x 10^9/L
Required Medical Information	Diagnosis of covered use, submission of platelet count, liver function testing (LFT) or Child-Pugh score, ferritin, and eGFR from the previous 3 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	For each reauthorization, updated ferritin level and platelet count drawn within last 3 months and updated LFT or Child-Pugh score, and eGFR drawn within the previous 6 months is required.
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

DOPTELET (avatrombopag)

Products Affected

- DOPTELET ORAL TABLET 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	Maintenance use for normalization of platelet counts in patients with chronic liver disease
Required Medical Information	Diagnosis of covered use. For thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure, submission of platelet count with a requirement it is less than 50 x 10^9/L. For immune thrombocytopenia (ITP), submission of platelet count with a requirement it is less than 30 x 10^9/L or less than 50 x 10^9/L with symptomatic bleeding, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	
Prescriber Restrictions	Restricted to gastroenterology, hematology, hepatology, and surgery
Coverage Duration	For patients undergoing a procedure, 5 days. For ITP, initially 2 months, then 1 year.
Other Criteria	For initial authorization for ITP, the patient must have tried and failed to have an adequate response to or had an intolerance to both eltrombopag and at least one other ITP therapy including a systemic corticosteroid, an immunoglobulin, danazol, or a cytotoxic/immunosuppressant such as rituximab. For first reauthorization for ITP, documentation of an improvement in platelet count greater than or equal to 50 x 10^9/L after at least 4 weeks on the maximum tolerated dose is required. For each annual reauthorization, documented maintenance of this clinical benefit is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

DRONABINOL

Products Affected

- *dronabinol 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

ELTROMBOPAG

Products Affected

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

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

EMGALITY (galcanezumab-gnlm) EGWP

Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline headache days per month from medical chart, 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	Initially 6 months, then 1 year
Other Criteria	For initial authorization for migraine prevention, the patient must have tried and failed to have an adequate response to or had an intolerance to Aimovig or Ajovy. For the first reauthorization, submission of on-treatment headache days per month demonstrating improvement from baseline 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	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

ENTYVIO (vedolizumab)

Products Affected

- ENTYVIO PEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline latent tuberculosis (TB) screening test or, if patient has been previously positive for TB (or if at high-risk for or had known exposure to TB), either baseline TB screening test or chest X-ray (CXR) from within the past year, 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. If TB screening test returns a positive result, coverage will be delayed until latent TB is treated and follow-up CXR confirms a negative result. For each annual reauthorization, yearly TB screening test or CXR required only for patients who live in, work in, or travel to areas where TB exposure is likely while on treatment or for those who have previously had a positive TB screening test.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

EPIDIOLEX (cannabidiol)

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	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

ERLEADA (apalutamide)

Products Affected

- ERLEADA

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 or had an intolerance to Xtandi. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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

EVRYSDI (risdiplam)

Products Affected

- EVRYSDI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use confirmed by genetic testing including either (a) homozygous deletion of SMN1 exon 7 or (b) compound heterozygosity for SMN1 exon 7 deletion and small mutation, documentation of two or more copies of the SMN2 gene confirmed by genetic testing.
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

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

GAVRETO (pralsetinib)

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of RET gene fusion or mutation. For thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

GEFITINIB

Products Affected

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.
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

GROWTH HORMONE

Products Affected

- NORDITROPIN FLEXPRO SUBCUTANEOUS SOLUTION PEN-INJECTOR 10 MG/1.5ML, 15 MG/1.5ML, 5 MG/1.5ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation of growth failure, submission of IGF-1 levels, height, weight, creatinine clearance (or serum creatinine), fasting blood glucose, and bone age if applicable based on patient age and diagnosis.
Age Restrictions	
Prescriber Restrictions	Restricted to endocrinology and nephrology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, submission of updated IGF-1 level, bone age (if applicable based on patient age and diagnosis), height, weight, creatinine clearance (or serum creatinine), fasting glucose, and confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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

HERNEXEOS (zongertinib)

Products Affected

- HERNEXEOS

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.
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

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
- SYNVISC INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE
- SYNVISC ONE INTRA-ARTICULAR SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient diagnosed with osteoarthritis of the knee joint and has tried and failed to respond to conservative non-pharmacologic therapy (exercise, physical therapy, weight loss) and simple analgesics (oral salicylates, non-steroidal anti-inflammatory drugs, and acetaminophen) within the previous 18 months.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Injection is being administered by an orthopedic surgeon, rheumatologist, physiatrist, or physician who has completed a formal sports medicine fellowship and is fully knowledgeable about the differential diagnosis of knee pain, is able to perform microscopic analysis of synovial fluid, and can recognize conditions such as pseudogout.
Coverage Duration	1 treatment cycle
Other Criteria	A maximum of 1 injection of Synvisc-One, Gel-One, 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

IBRANCE (palbociclib)

Products Affected

- IBRANCE ORAL CAPSULE 100 MG, 125 MG
- IBRANCE ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming primary tumor type is HR-positive, HER2-negative, attestation the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant. For endocrine-resistant breast cancer, submission of genetic tumor testing confirming primary tumor type is PIK3CA-mutated, attestation patient will be taking palbociclib concurrently with inavolisib.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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

IDHIFA (enasidenib)

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of IDH2 mutation.
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

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

INBRIJA (levodopa)

Products Affected

- INBRIJA

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

INLURIYO (imlunestrant)

Products Affected

- INLURIYO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming primary tumor type is ER-positive, HER2-negative, and has an ESR1 mutation, attestation patient has progressed on at least one endocrine-based regimen.
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

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

INVEGA INJECTABLE (paliperidone injectable suspension)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use. For the 3-month injection, documentation of at least 4 months' treatment with 1-month paliperidone palmitate extended-release injectable suspension. For the 6-month injection, documentation of at least 4 months' treatment with 1-month paliperidone palmitate extended-release injectable suspension or at least one 3-month injection of 3-month paliperidone palmitate extended-release injectable suspension.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ITOVEBI (inavolisib)

Products Affected

- ITOVEBI ORAL TABLET 3 MG, 9 MG

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

IWILFIN (eflornithine)

Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient demonstrated at least a partial response to prior multiagent, multimodal therapy including an anti-GD2 immunotherapy.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	2 years (see Other Criteria)
Other Criteria	Per the prescribing information, the maximum length of therapy with eflornithine is 2 years and reauthorizations for use longer than 2 years will not be approved. 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 x 10^9/L
Required Medical Information	Diagnosis of covered use. For myelofibrosis, submission of baseline platelet count. For polycythemia vera, documented intolerance or inadequate response to hydroxyurea. For acute graft-versus-host disease, documented inadequate response to systemic corticosteroids. For chronic graft-versus-host-disease, documented failure of at least one previous line of systemic therapy.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology, oncology, and transplant specialty
Coverage Duration	1 year
Other Criteria	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

KALYDECO (ivacaftor)

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	
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.
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

KERENDIA (finerenone)

Products Affected

- KERENDIA

PA Criteria	Criteria Details
Exclusion Criteria	Adrenal insufficiency, estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73 m2, serum potassium above 5.0 mEq/L 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

KINERET (anakinra)

Products Affected

- KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline latent tuberculosis (TB) screening test or, if patient has been previously positive for TB (or if at high-risk for or had known exposure to TB), either baseline TB screening test or chest X-ray (CXR) from within the past year. For rheumatoid arthritis indication only, 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 for rheumatoid arthritis, 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, Enbrel, Rinvoq, a tocilizumab biosimilar, and Xeljanz/Xeljanz XR). If TB screening test returns a positive result, coverage will be delayed until latent TB is treated and follow-up CXR confirms a negative result. For each annual reauthorization, yearly TB screening test or CXR required only for patients who live in, work in, or travel to areas where TB exposure is likely while on treatment or for those who have previously had a positive TB screening test.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
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

KOMZIFTI (ziftomenib)

Products Affected

- KOMZIFTI

PA Criteria	Criteria Details
Exclusion Criteria	QTcF interval greater than 480 msec at treatment initiation, white blood cell (WBC) count greater than 25 x 10^9/L, coadministration with proton pump inhibitors
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of a susceptible nucleophosmin 1 (NPM1) mutation, submission of baseline QTcF interval with the requirement it is less than 480 msec at treatment initiation, baseline WBC count.
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

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

KRAZATI (adagrasib)

Products Affected

- KRAZATI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of KRAS G12C mutation. For non-small cell lung cancer, documentation of at least one previous therapy that was tried and failed. For colorectal cancer, documentation of previous therapy with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LAPATINIB

Products Affected

- *lapatinib ditosylate*

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

LAZCLUZE (lazertinib)

Products Affected

- LAZCLUZE ORAL TABLET 240 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
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

LENALIDOMIDE

Products Affected

- *lenalidomide*

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

LEQEMBI (lecanemab-irmb)

Products Affected

- LEQEMBI IQLIK
- LEQEMBI IQLIK (500 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	Use of drug outside of an FDA-approved randomized controlled trial, studies approved by the Centers for Medicare and Medicaid Services, or studies supported by the National Institutes of Health
Required Medical Information	Diagnosis of covered use, documentation patient has amyloid beta pathology confirmed by brain imaging, lumbar puncture, or other laboratory tests.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Medicare coverage of monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease, including lecanemab, is dictated by a National Coverage Determination (NCD) that requires use of the drug through a clinical study.
Indications	All FDA-approved 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

LIFYORLI (relacorilant)

Products Affected

- LIFYORLI (125 MG DOSE)
- LIFYORLI (150 MG DOSE)

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, documentation showing patient has previously used bevacizumab, attestation that the medication will be used in combination with nab-paclitaxel.
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

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

LUMAKRAS (sotorasib)

Products Affected

- LUMAKRAS

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with proton pump inhibitors or H2 receptor antagonists
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of KRAS G12C mutation. For non-small cell lung cancer, attestation patient has received at least one prior systemic therapy. For colorectal cancer, attestation patient was treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and will be using sotorasib with panitumumab.
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

LYBALVI (olanzapine/samidorphan)

Products Affected

- LYBALVI

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

LYNPARZA (olaparib)

Products Affected

- LYNPARZA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of current or previous therapies used to treat the condition (see Other Criteria). For ovarian cancer with a homologous recombination deficiency-positive status, submission of test confirming presence of BRCA mutation and/or genomic instability. For non-BRCA-mutated metastatic castration-resistant prostate cancer, submission of test confirming presence of germline or somatic homologous recombination repair gene mutation. For all other indications, submission of test confirming presence of BRCA mutation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and urology
Coverage Duration	1 year
Other Criteria	For initial authorization for ovarian cancer, attestation patient is in complete or partial response to platinum-based chemotherapy. If the patient has a homologous recombination deficiency-positive status, attestation patient will be using olaparib in combination with bevacizumab. For initial authorization for breast cancer, attestation patient has been previously treated with chemotherapy. If the patient has hormone receptor-positive tumor, attestation patient has been or cannot be treated with endocrine therapy. For initial authorization for pancreatic cancer, attestation patient has not progressed after at least 16 weeks of platinum-based chemotherapy. For initial authorization for castration-resistant prostate cancer, attestation patient has progressed after using abiraterone or enzalutamide or will be using olaparib in combination with abiraterone with a corticosteroid. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

LYTGOBI (futibatinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of FGFR2 fusion or rearrangement, attestation previous systemic treatment has been tried.
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

MACITENTAN

Products Affected

- *macitentan*

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use confirmed by right heart catheterization including a mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, and pulmonary vascular resistance greater than 2 Woods units, attestation patient is WHO Group 1, submission of pregnancy status for female patients of childbearing potential, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have an intolerance to ambrisentan or bosentan or a contraindication to both ambrisentan and bosentan. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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

MECASERMIN

Products Affected

- INCRELEX

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

MEGESTROL IN OLDER PATIENTS

Products Affected

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

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

MEKINIST (trametinib)

Products Affected

- MEKINIST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of BRAF V600E or V600K mutation.
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

MEKTOVI (binimetinib)

Products Affected

- MEKTOVI

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), confirmation that binimetinib will be co-administered with encorafenib.
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

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

MIFEPRISTONE (CUSHING'S SYNDROME)

Products Affected

- *mifepristone oral tablet 300 mg*

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

MIGLUSTAT

Products Affected

- *miglustat*
- YARGESA

PA Criteria	Criteria Details
Exclusion Criteria	Severe renal impairment (CrCl less than 30 mL/min)
Required Medical Information	Diagnosis of covered use, documentation that enzyme replacement is not a therapeutic option (e.g., allergy, poor central venous access, hypersensitivity), submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

MODEYSO (dordaviprone)

Products Affected

- MODEYSO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming an H3K27M mutation, documentation of at least one previous therapy.
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	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

NERLYNX (neratinib)

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with proton pump inhibitors
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HER2-positive, confirmation member has completed adjuvant trastuzumab-based therapy or will be using in combination with capecitabine. For advanced or metastatic breast cancer, submission of previous anti-HER2 regimens used.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NEXLETOL (bempedoic acid)

Products Affected

- NEXLETOL

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, the patient must (1) currently be using a statin (unless contraindicated) plus ezetimibe, or (2) have tried and failed to have an adequate response to or had an intolerance to (a) at least two statins or (b) one statin and ezetimibe. At least one statin previously tried and failed must be a hydrophilic statin. For each annual reauthorization, documentation that the patient remains on previously-used lipid-lowering therapies since the previous approval, unless there is documentation of a new contraindication or intolerance requiring discontinuation of a therapy (or therapies) since the previous approval, is required.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

NEXLIZET (bempedoic acid/ezetimibe)

Products Affected

- NEXLIZET

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, the patient must (1) currently be using a statin (unless contraindicated) plus ezetimibe, or (2) have tried and failed to have an adequate response to or had an intolerance to (a) at least two statins or (b) one statin and ezetimibe. At least one statin previously tried and failed must be a hydrophilic statin. For each annual reauthorization, documentation that the patient remains on previously-used lipid-lowering therapies since the previous approval, unless there is documentation of a new contraindication or intolerance requiring discontinuation of a therapy (or therapies) since the previous approval, is required.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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

NINTEDANIB

Products Affected

- *nintedanib esylate*
- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For chronic fibrosing interstitial lung diseases with a progressive phenotype and systemic sclerosis-associated interstitial lung disease, submission of HRCT scan showing fibrosis of the lungs within the previous 12 months.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to pulmonology and rheumatology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, 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

NITISINONE

Products Affected

- *nitisinone*

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

NUBEQA (darolutamide)

Products Affected

- NUBEQA

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 or had an intolerance to Xtandi. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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

NURTEC (rimegepant)

Products Affected

- NURTEC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For migraine prevention, submission of baseline headache days per month from medical chart. For acute migraine treatment, 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	For migraine headache prevention, initially 6 months, then 1 year. For acute migraine, 1 year.
Other Criteria	For initial authorization for episodic migraine prevention, the patient must have documentation of fewer than 15 headache days per month. 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. For the first reauthorization for migraine prevention, submission of on-treatment headache days per month demonstrating improvement from baseline is required. For each annual reauthorization for migraine prevention, documented maintenance of a clinical benefit is required.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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

OJEMDA (tovorafenib)

Products Affected

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

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

OJJAARA (momelotinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Active infection
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

ONUREG (azacitidine)

Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	Diagnosis of myelodysplastic syndrome
Required Medical Information	Diagnosis of covered use, documentation patient achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and attestation patient cannot complete intensive curative therapy, submission of absolute neutrophil count (with the requirement it is at least 500/mcL).
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

ORENITRAM (treprostinil)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment (Child-Pugh class B or C)
Required Medical Information	Diagnosis of covered use confirmed by right heart catheterization including a mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, and pulmonary vascular resistance greater than 2 Woods units, attestation patient is WHO Group 1, submission of liver function testing or Child-Pugh score.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and 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

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

ORILISSA (elagolix)

Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

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

ORKAMBI (lumacaftor/ivacaftor)

Products Affected

- ORKAMBI ORAL PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
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.
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

ORSERDU (elacestrant)

Products Affected

- ORSERDU

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

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

PANRETIN (alitretinoin)

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	Instances where systemic Kaposi sarcoma therapy is required (more than 10 new Kaposi's sarcoma lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary Kaposi sarcoma, or symptomatic visceral involvement)
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to dermatology and oncology
Coverage Duration	1 year
Other Criteria	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

PEMAZYRE (pemigatinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of either FGFR1 rearrangement or FGFR2 fusion or rearrangement depending on the indication, attestation patient has used previous systemic treatment for the indication.
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

PIQRAY (alpelisib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming the primary tumor type is HR-positive, HER2-negative, and PIK3CA-mutated, attestation that patient has advanced or metastatic disease and will be taking concurrently with fulvestrant, submission of at least one endocrine-based (e.g., anastrozole, exemestane, letrozole, tamoxifen, etc.) regimen tried and failed.
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

PIRFENIDONE

Products Affected

- *pirfenidone oral tablet 267 mg, 801 mg*

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

POMALIDOMIDE

Products Affected

- *pomalidomide*
- POMALYST

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

PRETOMANID

Products Affected

- *pretomanid*

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

PROLASTIN-C (alpha-1-proteinase inhibitor)

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Individuals with immunoglobulin A (IgA) deficiency who have known antibodies against IgA
Required Medical Information	Diagnosis of covered use, submission of pre-treatment alpha-1-antitrypsin (AAT) showing levels below 11 mmol/L (80 mg/dL), confirmation that patient has clinically evident emphysema secondary to congenital alpha-1-PI deficiency by submission of pulmonary function testing (e.g., spirometry or body plethysmography), X-ray radiography, or diffusing capacity of the lung for carbon monoxide (DLCO).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	For each reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D.
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

QULIPTA (atogepant)

Products Affected

- QULIPTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline headache days per month from medical chart.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For initial authorization for episodic migraine prevention, the patient must have documentation of fewer than 15 headache days per month. For the first reauthorization, submission of on-treatment headache days per month demonstrating improvement from baseline 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

RADICAVA ORS (edaravone)

Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT

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

REDEMPLO (plozasiran)

Products Affected

- REDEMPLO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of pathogenic lipoprotein lipase (LPL) gene variant or other genetic variant known to negatively impact the function of LPL, baseline serum triglycerides (TG) drawn within the previous 6 months with the requirement the value is equal to or greater than 880 mg/dL, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology, endocrinology, and lipidology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have tried and failed to have an adequate response to a traditional TG-lowering medication such as a fibrate, statin, omega-3 fatty acids, or prescription-strength niacin. For each reauthorization, confirmation of a reduction of serum TG level from baseline 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

REPATHA (evolocumab)

Products Affected

- REPATHA
- REPATHA SURECLICK

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	10 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

RETACRIT (epoetin alfa-epbx)

Products Affected

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

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

RETEVMO (selpercatinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of RET gene fusion or mutation. For RET fusion-positive thyroid cancer, attestation patient is radioactive iodine-refractory or ineligible. For solid tumors with a RET gene fusion, documentation of previous systemic therapy tried or reason why patient has no satisfactory alternative treatment options.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REVCOVI (elapegademase-lvlr)

Products Affected

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	Severe thrombocytopenia
Required Medical Information	Diagnosis of covered use confirmed by either biochemical testing showing less than 1% of adenosine deaminase (ADA) catalytic activity in red blood cells or genetic testing showing biallelic ADA pathogenic variants, submission of baseline plasma ADA level (if genetic testing was submitted as confirmation of diagnosis) and platelet count, with the requirement it is at least 50 x 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 x 10^9/L is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

REXULTI (brexpiprazole)

Products Affected

- REXULTI ORAL TABLET 0.25 MG, 0.5 MG, 1 MG, 2 MG, 3 MG, 4 MG

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use. For schizophrenia or adjunctive therapy in major depressive disorder (MDD) indications only, 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, the patient must have tried and failed to have an adequate response to or had an intolerance to aripiprazole and at least one other generic second-generation atypical antipsychotic. For initial authorization for adjunctive therapy to antidepressants for MDD, the patient must have tried and failed to have an adequate response to or had an intolerance to (1) aripiprazole and (2) cariprazine or quetiapine. This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

REZLIDHIA (olutasidenib)

Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of IDH1 mutation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted 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

ROZLYTREK (entrectinib)

Products Affected

- ROZLYTREK

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 ROS1-positive tumor. For solid tumors, submission of evidence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation and attestation tumor is metastatic or surgical resection/other systemic therapies are unsatisfactory treatment options.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

RUBRACA (rucaparib)

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of deleterious BRCA mutation. For ovarian, fallopian tube, or primary peritoneal cancer, documentation of response to platinum-based chemotherapy. For BRCA mutation-associated metastatic castration-resistant prostate cancer, confirmation patient is using a gonadotropin-releasing hormone analog or has had a bilateral orchiectomy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology and urology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

RYDAPT (midostaurin)

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For acute myeloid leukemia, submission of test confirming presence of FLT3 mutation, attestation patient will be receiving cytarabine and daunorubicin induction and cytarabine consolidation with midostaurin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to allergy, hematology, and oncology
Coverage Duration	1 year
Other Criteria	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

SILDENAFIL FOR PAH

Products Affected

- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use confirmed by right heart catheterization including a mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, and pulmonary vascular resistance greater than 2 Woods units, attestation patient is WHO Group 1.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
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

SIRTURO (bedaquiline)

Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	Drug-sensitive tuberculosis, latent infection, extra-pulmonary tuberculosis
Required Medical Information	Diagnosis of covered use, confirmation that Sirturo will be co-administered with pretomanid and linezolid or at least 3 other drugs proven to be or at least 4 other drugs suspected to be effective against the patient's M. tuberculosis isolate and submission of susceptibility testing, if available. Alternatively, Sirturo may be used as one drug of a 3-drug regimen if the patient has a documented intolerance, a contraindication, or documented resistance to a fluoroquinolone or rifampin.
Age Restrictions	
Prescriber Restrictions	Restricted to infectious diseases and pulmonology
Coverage Duration	26 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SKYCLARYS (omaveloxolone)

Products Affected

- SKYCLARYS

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

SODIUM OXYBATE

Products Affected

- *sodium oxybate*

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

SOFOSBUVIR/VELPATASVIR

Products Affected

- *sofosbuvir-velpatasvir*

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

SOMAVERT (pegvisomant)

Products Affected

- SOMAVERT

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

SORAFENIB

Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome, coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use. 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

SOTYKTU (deucravacitinib)

Products Affected

- SOTYKTU

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline latent tuberculosis (TB) screening test or, if patient has been previously positive for TB (or if at high-risk for or had known exposure to TB), either baseline TB screening test or chest X-ray (CXR) from within the past year, 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, Cosentyx, Enbrel, Otezla, Rinvoq, Skyrizi, an ustekinumab biosimilar, and Xeljanz/Xeljanz XR) for the indication submitted, where possible. If TB screening test returns a positive result, coverage will be delayed until latent TB is treated and follow-up CXR confirms a negative result. For each annual reauthorization, yearly TB screening test or CXR required only for patients who live in, work in, or travel to areas where TB exposure is likely while on treatment or for those who have previously had a positive TB screening test.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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

SUCRAID (sacrosidase)

Products Affected

- SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of laboratory-confirmed congenital sucrase-isomaltase deficiency via differential urinary disaccharide test or measurement of intestinal disaccharides following small bowel biopsy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

SUNITINIB

Products Affected

- *sunitinib malate*

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

SUNOSI (solriamfetol)

Products Affected

- SUNOSI ORAL TABLET 150 MG, 75 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 neurology and sleep medicine
Coverage Duration	1 year
Other Criteria	For initial authorization, if the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to armodafinil or modafinil. For each annual 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	Yes

SYMDEKO (tezacaftor/ivacaftor)

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	
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.
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

TABRECTA (capmatinib)

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of MET exon 14 skipping mutation.
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

TADALAFIL FOR PAH

Products Affected

- ALYQ
- *tadalafil (pah)*

PA Criteria	Criteria Details
Exclusion Criteria	Creatinine clearance below 30 mL/min or on hemodialysis
Required Medical Information	Diagnosis of covered use confirmed by right heart catheterization including a mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, and pulmonary vascular resistance greater than 2 Woods units, attestation patient is WHO Group 1, submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance)..
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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

TAGRISSO (osimertinib)

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of EGFR exon 19 deletions, exon 21 L858R mutations, or T790M mutations. For EGFR T790M mutation-positive NSCLC, submission of previous EGFR tyrosine kinase inhibitor therapy used for indication.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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

TALZENNA (talazoparib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For breast cancer, submission of test results confirming germline BRCA mutation-positive, human epidermal growth factor receptor 2 (HER2) negative disease. For prostate cancer, submission of test results confirming HRR gene-mutated disease, attestation talazoparib will be used in combination with enzalutamide.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

TASIMELTEON

Products Affected

- *tasimelteon*

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

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

TEPMETKO (tepotinib)

Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of MET exon 14 skipping mutation.
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

TERIPARATIDE

Products Affected

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

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

PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

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

TIBSOVO (ivosidenib)

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of IDH1 mutation. For newly-diagnosed acute myeloid leukemia, if patient is under 75 years of age, documentation of comorbidities that preclude use of intensive induction chemotherapy. For cholangiocarcinoma, documentation of at least one previous therapy that was tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TOLVAPTAN (ADPKD)

Products Affected

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

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

TOLVAPTAN (HYPONATREMIA)

Products Affected

- *tolvaptan (hyponatremia) oral tablet 15 mg, 30 mg*

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

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

TRUQAP (capivasertib)

Products Affected

- TRUQAP ORAL TABLET 200 MG
- TRUQAP ORAL TABLET THERAPY PACK

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 and has at least one PIK3CA, AKT1, and/or PTEN mutation, attestation patient has (1) progressed on at least one endocrine-based regimen in the metastatic setting, or (2) has recurrent disease on or within 12 months of completing adjuvant therapy, attestation drug will be given with fulvestrant.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

TURALIO (pexidartinib)

Products Affected

- TURALIO ORAL CAPSULE 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	Active liver or biliary tract disease (including increased ALP), pre-existing increased serum transaminases, total or direct bilirubin greater than the upper limit of normal, coadministration with proton pump inhibitors
Required Medical Information	Diagnosis of covered use and attestation surgical intervention is not possible or practical, documentation of patient's severe morbidity or functional limitations, submission of serum transaminases, total and direct bilirubin, and ALP.
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

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

UZEDY (risperidone)

Products Affected

- UZEDY

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	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must have had a documented trial of or had an intolerance/contraindication to generic intramuscular risperidone. 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. This policy applies to new starts only.
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

VANFLYTA (quizartinib)

Products Affected

- VANFLYTA

PA Criteria	Criteria Details
Exclusion Criteria	Requests for maintenance monotherapy after allogeneic hematopoietic stem cell transplant, uncorrected hypokalemia or hypomagnesemia, QTcF interval greater than 450 msec at treatment initiation
Required Medical Information	Diagnosis of covered use including submission of test confirming presence of FLT3 internal tandem duplication-positive mutation, submission of QTcF interval, serum potassium and magnesium levels from within previous 6 months.
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

VANRAFIA (atrasentan)

Products Affected

- VANRAFIA

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, severe hepatic impairment (Child-Pugh class C)
Required Medical Information	Diagnosis of primary IgA nephropathy confirmed by biopsy, submission of 24-hour urine protein of at least 0.5 g/day or 24-hour urine protein-to-creatinine ratio (UPCR) of at least 0.8 g/g, liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to immunology and nephrology
Coverage Duration	1 year
Other Criteria	For initial authorization, the patient must be currently using (or have a contraindication or intolerance to the use of) a maximally-tolerated dose of an ACE inhibitor or ARB. For each annual reauthorization, documentation of clinically relevant response to therapy, including either stabilization or improvement of UPCR or a reduction in 24-hour urine protein from baseline, is required.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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

VERQUVO (vericiguat)

Products Affected

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

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

VERZENIO (abemaciclib)

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	
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

VIBERZI (eluxadoline)

Products Affected

- VIBERZI

PA Criteria	Criteria Details
Exclusion Criteria	Prior cholecystectomy, known or suspected biliary duct obstruction, known or suspected sphincter of Oddi disease or dysfunction, alcoholism, alcohol abuse, alcohol addiction, or patients who drink more than 3 alcoholic beverages/day, history of pancreatitis, structural diseases of pancreas including known or suspected pancreatic duct obstruction, severe hepatic impairment (Child-Pugh class C), severe constipation or sequelae from constipation, known or suspected mechanical gastrointestinal obstruction
Required Medical Information	Diagnosis of covered use, submission of liver function testing or Child-Pugh score.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to gastroenterology
Coverage Duration	1 year
Other Criteria	For each annual reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

VIJOICE (alpelisib)

Products Affected

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

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

VITRAKVI (larotrectinib)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of evidence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, attestation tumor is metastatic or surgical resection and other systemic therapies are unsatisfactory treatment options.
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

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

VONJO (pacritinib)

Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	Estimated glomerular filtration rate (eGFR) less than 30 mL/min, QTc interval greater than 480 msec at baseline
Required Medical Information	Diagnosis of covered use, submission of platelet count with the requirement it is below 50 x 10^9/L, eGFR, and QTc interval, documentation from a physical exam patient has splenomegaly.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology 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

VOQUEZNA (vonoprazan)

Products Affected

- VOQUEZNA ORAL TABLET 10 MG, 20 MG

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

VORANIGO (vorasidenib)

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of IDH1 or IDH2 mutation, attestation patient has had at least one prior surgery (biopsy, sub-total resection, or gross total resection).
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	6 months
Other Criteria	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

VOWST (fecal microbiota spores, live-brpk) EGWP

Products Affected

- VOWST

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

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

WELIREG (belzutifan)

Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	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

WINREVAIR (sotatercept-csrk)

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Platelet count below 50 x 10^9/L
Required Medical Information	Diagnosis of covered use confirmed by right heart catheterization including a mean pulmonary arterial pressure greater than 20 mm Hg at rest, pulmonary arterial wedge pressure less than or equal to 15 mm Hg, pulmonary vascular resistance greater than 2 Woods units, attestation patient is WHO Group 1, New York Heart Association functional class with the requirement the patient falls into Class II, III, or IV, submission of baseline platelet count, current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	For initial authorization, the patient's drug regimen must be submitted and must include at minimum (1) a nitric oxide pathway mediator and (2) an endothelin receptor antagonist, with or without a prostacyclin pathway agonist. If dual or triple therapy is not currently being used, prescriber is required to submit documentation as to why (e.g., intolerances, physiologic parameters, contraindications, etc.). For each reauthorization, confirmation of a symptomatic or clinical improvement (or maintenance of an improvement previously achieved) is required.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	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

XIFAXAN (rifaximin)

Products Affected

- XIFAXAN ORAL TABLET 550 MG

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

XOSPATA (gilteritinib)

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of FLT3 mutation.
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

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

ZEJULA (niraparib)

Products Affected

- ZEJULA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation of response to platinum-based chemotherapy. For germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, submission of test confirming presence of deleterious BRCA mutation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

ZELBORAF (vemurafenib)

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including verification of BRAF V600 mutation as needed for diagnosis, submission of QTc interval with a requirement it is less than or equal to 500 msec.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	This policy applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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
- ZEPBOUND KWIKPEN

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

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

ZORYVE (roflumilast) 0.3% CREAM

Products Affected

- ZORYVE EXTERNAL CREAM 0.3 %

PA Criteria	Criteria Details
Exclusion Criteria	Requests for atopic dermatitis
Required Medical Information	Diagnosis of plaque psoriasis, submission of current or previous therapies used to treat the condition (see Other Criteria).
Age Restrictions	6 years of age or older
Prescriber Restrictions	PA not required for dermatology
Coverage Duration	1 year
Other Criteria	For initial authorization, 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

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

ZURZUVAE (zuranolone)

Products Affected

- ZURZUVAE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of postpartum depression documented using results from a validated screening instrument recommended by the American College of Obstetricians and Gynecologists (Patient Health Questionnaire-9 or Edinburgh Postnatal Depression Scale) or the Hamilton Depression Rating Scale-17, attestation patient is within 12 months postpartum.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to gynecology, obstetrics, and psychiatry
Coverage Duration	14 days
Other Criteria	As there are no safety or efficacy data beyond one 14-day course for postpartum depression, only one 14-day course will be allowed per plan year. 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

ZYMFENTRA (infliximab-dyyb)

Products Affected

- ZYMFENTRA (2 PEN)
- ZYMFENTRA (2 SYRINGE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline latent tuberculosis (TB) screening test or, if patient has been previously positive for TB (or if at high-risk for or had known exposure to TB), either baseline TB screening test or chest X-ray (CXR) from within the past year, 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. If TB screening test returns a positive result, coverage will be delayed until latent TB is treated and follow-up CXR confirms a negative result. For each annual reauthorization, yearly TB screening test or CXR required only for patients who live in, work in, or travel to areas where TB exposure is likely while on treatment or for those who have previously had a positive TB screening test.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

Index

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

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

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

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

VONJO 257
VOQUEZNA ORAL TABLET 10 MG, 20 MG 258
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
XDEMVY 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
zaleplon 276
ZEJULA ORAL TABLET 277
ZELBORAF 278
ZELVYSIA 196
ZENBEXUS 279
ZEPBOUND 280
ZEPBOUND KWIKPEN 280
ZILRETTA 281
zolpidem tartrate er 282
zolpidem tartrate oral tablet 282
ZORYVE EXTERNAL CREAM 0.3 % 283
ZTALMY 284
ZURZUVAE 285
ZYDELIG 286
ZYKADIA ORAL TABLET 287
ZYMFENTRA (2 PEN) 288
ZYMFENTRA (2 SYRINGE) 288