

## **PRIOR AUTHORIZATION CRITERIA**

This list is current as of November 18, 2024, and pertains to the following formularies:

2025 Pharmacy Benefit Dimensions PDP provided by Labor-Management Healthcare Fund Formulary
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Pharmacy Benefit Dimensions requires you (or your physician) to get prior authorization for certain drugs listed on the formularies above. This means that you will need to get approval from us before you fill your prescriptions. If you do not get approval, we may not cover the drug. These drugs are listed with a “PA” in the Requirements/Notes column on the formularies. This document contains the Prior Authorization requirements that are associated with the formularies listed above.

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

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

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

# ABILIFY MYCITE (aripiprazole with sensor)

## Products Affected

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

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

# ABRYSVO (respiratory syncytial virus vaccine)

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## Products Affected

- ABRYSVO

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

# ACTIMMUNE (interferon gamma-1b)

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## Products Affected

- ACTIMMUNE

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

# ADEMPAS (riociguat)

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## Products Affected

- ADEMPAS

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

# ALECENSA (alectinib)

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## Products Affected

- ALECENSA

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

# ALPHA-1-PROTEINASE INHIBITORS

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Individuals with immunoglobulin A (IgA) deficiency who have known antibodies against IgA
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to pulmonology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ALUNBRIG (brigatinib)

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## Products Affected

- ALUNBRIG

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



# AMANTADINE EXTENDED-RELEASE PRODUCTS

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## Products Affected

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

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

# ARANESP (darbepoetin alfa)

**Products Affected**

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	For non-ESRD-related conditions: 90 days. For ESRD-related conditions: 1 year.
<b>Other Criteria</b>	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ARCALYST (rilonacept)

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## Products Affected

- ARCALYST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Active or chronic infection, coadministration with TNF-blocking agents
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline latent tuberculosis screening test (Mantoux tuberculin skin test [a.k.a. PPD test] or interferon-gamma release assay [IGRA]).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. If TB screening test returns a positive result, coverage will be delayed until latent TB is treated. For re-authorization, yearly TB screening test or chest X-ray required for patients who live in, work in, or travel to areas where TB exposure is likely while on treatment or for those who have previously had a positive TB screening test. 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ARIKAYCE (amikacin inhalation)

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## Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Non-refractory Mycobacterium avium complex (MAC) lung disease
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to infectious diseases and pulmonology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	This medication is covered as a Part B benefit except for enrollees residing in a long-term care facility. PA applies to all when covered as a Part D benefit.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AUGTYRO (repotrectinib)

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## Products Affected

- AUGTYRO ORAL CAPSULE 40 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with moderate or strong CYP3A4 inhibitors or inducers, coadministration with P-glycoprotein inhibitors
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test confirming tumor is ROS1-positive for non-small cell lung cancer only, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	12 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AUVELITY (dextromethorphan/bupropion)

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## Products Affected

- AUVELITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Seizure disorder, current or prior diagnosis of bulimia or anorexia nervosa, administration of monoamine oxidase inhibitors within 14 days of initiation
<b>Required Medical Information</b>	Diagnosis of covered use, attestation patient has been screened for and does not have bipolar disorder, prescription claims or documentation from physician showing patient has tried and failed or had an intolerance to at least two different antidepressant medications that are indicated for the diagnosis.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to psychiatry
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AYVAKIT (avapritinib)

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## Products Affected

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

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

# BALVERSA (erdafitinib)

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## Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of susceptible FGFR3 genetic alterations, prior systemic regimen(s) used (see Other Criteria) to match the indication, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. This drug is not recommended for the treatment of patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy. Balversa will not be approved in PD-1/PD-L1 inhibitor-eligible patients who have not received this therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# BEMPEDOIC ACID

## Products Affected

- NEXLETOL
- NEXLIZET

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

# BENLYSTA (belimumab)

## Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe active central nervous system lupus, patients using other biologic medications or intravenous cyclophosphamide
<b>Required Medical Information</b>	Diagnosis of covered use, confirmation that the patient is taking standard therapy defined as at least one of the following: systemic corticosteroids (e.g., prednisone), antimalarials (e.g., hydroxychloroquine), or immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate mofetil). For systemic lupus erythematosus, submission of autoantibody-positive test result for anti-nuclear antibodies (ANA) and/or anti-double-stranded DNA (anti-dsDNA).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to immunology, nephrology, and rheumatology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

## BESREMI (ropeginterferon alfa-2b-njft)

### Products Affected

- BESREMI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	History or presence of severe psychiatric disorders (including severe depression or suicidal ideation), history of presence of active serious or untreated autoimmune disease, moderate or severe hepatic impairment (Child-Pugh class B or C), immunosuppressed transplant recipients, severe or unstable cardiovascular disease (e.g., uncontrolled hypertension, NYHA class 2-4 congestive heart failure, serious cardiac arrhythmia, significant coronary artery stenosis, unstable angina), stroke or myocardial infarction within previous 6 months, severe renal impairment (eGFR less than 30 mL/min)
<b>Required Medical Information</b>	Diagnosis of covered use, submission of eGFR, documentation patient has tried and failed, has a contraindication to, or could not tolerate hydroxyurea (HU), pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	If patient is taking HU, initially 12 weeks, then 1 year. If patient is not taking HU, 1 year.
<b>Other Criteria</b>	PA applies to new starts only in patients not using HU. Reauthorization will be required after 12 weeks in patients using HU at the start of therapy. Attestation patient has tapered completely off HU by the end of week 12 will be necessary for reauthorization.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BEXAROTENE GEL

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

# BIOLOGIC RESPONSE MODIFIERS

## Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS
- CIMZIA (2 SYRINGE)
- CIMZIA SUBCUTANEOUS KIT 2 X 200 MG
- OTEZLA ORAL TABLET 30 MG
- OTEZLA ORAL TABLET THERAPY PACK 10 & 20 & 30 MG
- SOTYKTU
- TYENNE SUBCUTANEOUS
- VELSIPITY

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

# BOSULIF (bosutinib)

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with moderate or strong CYP3A inhibitors or strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For accelerated or blast phase Ph+ CML, documentation of resistance or intolerance to at least one of the following prior therapies: imatinib, dasatinib, or nilotinib.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BRAFTOVI/MEKTOVI (encorafenib/binimetinib)

## Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG
- MEKTOVI

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

# BRONCHITOL (mannitol powder for inhalation)

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## Products Affected

- BRONCHITOL

PA Criteria	Criteria Details
Exclusion Criteria	Documented Bronchitol Tolerance Test failure
Required Medical Information	Diagnosis of covered use, documentation patient has passed the Bronchitol Tolerance Test.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# BRUKINSA (zanubrutinib)

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## Products Affected

- BRUKINSA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For follicular lymphoma, submission of at least two prior systemic regimens tried and failed. 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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BUTALBITAL-CONTAINING PRODUCTS IN OLDER PATIENTS

## Products Affected

- ASCOMP-CODEINE
- BUPAP ORAL TABLET 50-300 MG
- *butalbital-acetaminophen oral tablet 50-300 mg, 50-325 mg*
- *butalbital-apap-caff-cod*
- *butalbital-apap-caffeine oral capsule*
- *butalbital-apap-caffeine oral tablet 50-325-40 mg*
- *butalbital-asa-caff-codeine*
- *butalbital-aspirin-caffeine oral capsule*
- TENCON ORAL TABLET 50-325 MG

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

# CABLIVI (caplacizumab-yhdp)

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## Products Affected

- CABLIVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to cardiology, hematology, and immunology
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	PA applies to all. If the coverage determination request is not for the patient's first use of caplacizumab, coverage will not be authorized if the patient has had more than 2 recurrences of aTTP while on therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CABOMETYX (cabozantinib)

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## Products Affected

- CABOMETYX

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

# CALQUENCE (acalabrutinib)

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## Products Affected

- CALQUENCE

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, coadministration with strong CYP3A inhibitors
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For mantle cell lymphoma, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# CAMZYOS (mavacamten)

## Products Affected

- CAMZYOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Left ventricular ejection fraction (LVEF) less than 55%, coadministration with moderate or strong CYP2C19 inhibitors or inducers, strong CYP3A4 inhibitors, moderate or strong CYP3A4 inducers, a non-dihydropyridine (DHP) calcium channel blocker (CCB) plus a beta-blocker, disopyramide, or ranolazine
<b>Required Medical Information</b>	Diagnosis of covered use including all three of the following: (1) attestation patient has exertional symptoms consistent with the definition of NYHA class II or III disease, (2) confirmation of left ventricular (LV) outflow tract obstruction gradient of at least 50 mmHg either at rest, during Valsalva maneuver testing, or after exercise, and (3) confirmation of LV wall thickness of at least 15 mm or at least 13 mm if condition is familial, submission of current LVEF, any previous or current therapies tried for the condition (see Other Criteria), pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to cardiology
<b>Coverage Duration</b>	Initially 6 months, then 1 year
<b>Other Criteria</b>	PA applies to all. For approval, the patient must have tried and failed to have an adequate response to or had an intolerance/contraindication to both a beta-blocker and a non-DHP CCB. Documentation of a positive response to therapy will be required for initial reauthorization after the first 6 months. Maintenance of a clinical benefit and attestation that prescriber believes benefits of continuing therapy outweigh the potential risks to the patient will be required for subsequent annual reauthorizations.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CAPRELSA (vandetanib)

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## Products Affected

- CAPRELSA

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

# CARGLUMIC ACID

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## Products Affected

- *carglumic acid oral tablet soluble*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of elevated plasma ammonia level.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated plasma ammonia level since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# CERDELGA (eliglustat)

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## Products Affected

- CERDELGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pre-existing cardiac disease, moderate or severe hepatic impairment, long QT syndrome, coadministration with Class Ia or Class III antiarrhythmics. In patients who are extensive CYP2D6 metabolizers only, any degree of hepatic impairment.
<b>Required Medical Information</b>	Diagnosis of covered use, submission of CYP2D6 metabolizer status as detected by a test for determining CYP2D6 genotype (see Other Criteria), liver function testing or Child-Pugh score.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Patients who are ultra-rapid CYP2D6 metabolizers may not reach a therapeutic effect. This drug will not be covered in patients who are ultra-rapid CYP2D6 metabolizers. Updated liver function testing or Child-Pugh score since the previous authorization will be required for subsequent reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CFTR MODULATOR THERAPIES

## Products Affected

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

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

# CGRP INHIBITORS

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use. For migraine headache prevention, submission of baseline headache days per month from medical chart, documentation patient (a) has tried and failed at least two non-CGRP inhibitor FDA-approved (propranolol, timolol, topiramate, valproic acid) or compendial alternatives (e.g., amitriptyline, atenolol) for migraine prophylaxis, or (b) has tried and failed at least one alternative from (a) if they have contraindications to all other alternatives, or (c) has contraindications to all alternatives from (a). For acute migraine treatment, documentation of prior use of at least one triptan.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	For migraine headache prevention, initially 3 months, then 1 year. For acute migraine, 1 year.
<b>Other Criteria</b>	PA applies to all. For episodic migraine prevention, the patient must have documentation of fewer than 15 headache days per month. For approval of Emgality for migraine headache prevention, the patient must have tried and failed to have an adequate response to or had an intolerance to Aimovig and Ajoyv. For migraine headache prevention reauthorization after the first 3 months, submission of on-treatment headache days per month demonstrating improvement from baseline will be required. Documentation of maintenance of a clinical benefit will be required for subsequent reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CHENODAL (chenodiol)

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## Products Affected

- CHENODAL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, known hepatocyte dysfunction, bile duct abnormalities such as intrahepatic cholestasis, primary biliary cirrhosis, or sclerosing cholangitis, radiopaque stones, nonvisualizing gallbladder confirmed as nonvisualizing after 2 consecutive single doses of dye, compelling reasons for gallbladder surgery
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to gastroenterology and hepatology
<b>Coverage Duration</b>	24 months
<b>Other Criteria</b>	PA applies to all. Safety beyond 24 months is not established and will not be authorized.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CHOLBAM (cholic acid)

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## Products Affected

- CHOLBAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of liver function testing.
Age Restrictions	
Prescriber Restrictions	Restricted to gastroenterology, hepatology, and pediatric gastroenterology
Coverage Duration	Initially 3 months, then 1 year
Other Criteria	PA applies to all. Documentation of liver function improvement without complete biliary obstruction or persistent clinical or laboratory indications of worsening liver function or cholestasis will be required for initial reauthorization after the first 3 months. Updated liver function testing since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# CHOLESTATIC PRURITUS

## Products Affected

- BYLVAY
- BYLVAY (PELLETS)
- LIVMARLI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	History of liver transplant, clinical evidence of decompensated cirrhosis
<b>Required Medical Information</b>	Diagnosis of covered use confirmed by molecular genetic testing, documentation of cholestasis, defined as one of the following: (1) total serum bile acid greater than the age-adjusted upper limit of normal (ULN), (2) increased conjugated bilirubin levels, (3) gamma-glutamyl transferase greater than the age-adjusted ULN, or (4) fat-soluble vitamin deficiency or intractable pruritus explainable only by liver disease, attestation drug-induced pruritus has been ruled out, attestation patient has tried and failed at least two of the following medications for pruritus: ursodiol, cholestyramine, naltrexone, rifampin.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to gastroenterology and hepatology
<b>Coverage Duration</b>	Initially 6 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Attestation of improvement in pruritus symptoms and submission of liver function testing, including serum bilirubin, since the previous authorization will be required for initial reauthorization after the first 6 months. For subsequent annual reauthorizations, attestation of stability of or improvement in pruritus symptoms and submission of liver function testing, including serum bilirubin, will be required.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# COMETRIQ (cabozantinib)

## Products Affected

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

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

# COPIKTRA (duvelisib)

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## Products Affected

- COPIKTRA ORAL CAPSULE 15 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of at least two prior therapies tried and failed, submission of pregnancy status for female patients of childbearing potential, attestation patient will receive prophylaxis for <i>Pneumocystis jirovecii</i> pneumonia (PJP) and, if necessary, cytomegalovirus.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology or oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# CORTROPHIN (corticotropin)

## Products Affected

- CORTROPHIN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Request for IV administration, treatment of patients under 2 years of age in whom congenital infections are suspected, patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, a history of or presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin
<b>Required Medical Information</b>	Diagnosis of covered use, submission of blood pressure reading and baseline serum sodium and potassium levels.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Updated blood pressure, sodium, and potassium levels since the previous authorization will be required for subsequent reauthorizations. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# COTELLIC/ZELBORAF (cobimetinib/vemurafenib)

## Products Affected

- COTELLIC
- ZELBORAF

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

# CYSTEAMINE EYE DROPS

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## Products Affected

- CYSTADROPS
- CYSTARAN

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

# DALFAMPRIDINE

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## Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	History of seizure, moderate or severe renal impairment (CrCl less than or equal to 50 mL/min)
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to neurology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Updated creatinine clearance since the previous authorization and confirmation patient is able to walk will be required for subsequent annual reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DAURISMO (glasdegib)

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## Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, confirmation patient will also be receiving cytarabine as part of chemotherapeutic regimen. If patient is under 75 years of age, documentation of comorbidities that preclude use of intensive induction chemotherapy, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# DEFERASIROX

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## Products Affected

- *deferasirox oral tablet soluble*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment, estimated glomerular filtration rate less than 40 mL/min, platelet count below $50 \times 10^9/L$ , high-risk myelodysplastic syndromes, advanced malignancies
<b>Required Medical Information</b>	Diagnosis of covered use, submission of CBC, LFTs, ferritin, and estimated glomerular filtration rate from the previous 3 months.
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	PA applies to all. Updated ferritin level within last 3 months and updated CBC, LFT, and estimated glomerular filtration rate within the previous 6 months will be required for subsequent reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DEFERIPRONE

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## Products Affected

- *deferiprone*
- FERRIPROX ORAL SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Absolute neutrophil count (ANC) below $1.5 \times 10^9/L$
Required Medical Information	Diagnosis of covered use, submission of serum ferritin levels, ANC, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Updated ferritin level and ANC within last 3 months will be required for subsequent reauthorizations. Safety and effectiveness have not been established for transfusional iron overload in patients with myelodysplastic syndrome or Diamond Blackfan anemia and will not be approved for these indications.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# DIACOMIT (stiripentol)

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## Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe renal impairment, moderate or severe hepatic impairment
Required Medical Information	Diagnosis of covered use, confirmation patient is also receiving clobazam.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. Monotherapy requests for Dravet syndrome will not be approved as there are no clinical data to support using stiripentol in this manner.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# DICHLORPHENAMIDE

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## Products Affected

- *dichlorphenamide*
- ORMALVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use of high dose aspirin, severe pulmonary disease limiting compensation to metabolic acidosis, hepatic insufficiency
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initially 2 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Documentation of a positive response to therapy will be required for initial reauthorization after the first 2 months. Maintenance of a clinical benefit will be required for subsequent annual reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DICLOFENAC PATCH

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## Products Affected

- *diclofenac epolamine external*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	PA applies to all. Product is approved for acute pain, defined as short-term pain not lasting longer than a 3-month period.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DIGOXIN IN OLDER PATIENTS

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## 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 applies to all except cardiology. PA not required for doses less than or equal to 0.125 mg per day. Updated creatinine clearance since the previous authorization will be required for subsequent annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# DOPTELET (avatrombopag)

## Products Affected

- DOPTELET ORAL TABLET 20 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 $50 \times 10^9/L$ . For immune thrombocytopenia (ITP), submission of platelet count with a requirement it is less than $30 \times 10^9/L$ or less than $50 \times 10^9/L$ with symptomatic bleeding, documentation patient has undergone splenectomy and/or tried and failed two different ITP therapies including systemic corticosteroids, immunoglobulins, danazol, fostamatinib, or cytotoxics/immunosuppressants such as rituximab.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to gastroenterology, hematology, hepatology, and surgery
<b>Coverage Duration</b>	For patients undergoing a procedure, 5 days. For ITP, initially 6 months, then 1 year.
<b>Other Criteria</b>	PA applies to all. For ITP, documentation of an improvement in platelet count greater than or equal to $50 \times 10^9/L$ after at least 4 weeks on the maximum tolerated dose will be required for initial reauthorization after the first 6 months. Maintenance of this clinical benefit will be required for subsequent annual reauthorizations. This medication should not be administered to patients with chronic liver disease not scheduled to undergo a procedure in an attempt to normalize platelet counts and will not be approved for this indication.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DRONABINOL

## Products Affected

- *dronabinol*
- SYNDROS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use. If authorization is requested for treatment of nausea and vomiting associated with cancer therapy, documentation of previous conventional antiemetic therapies utilized is required (see Other Criteria).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. If authorization is requested for treatment of nausea and vomiting associated with cancer therapy, the patient must have tried and failed to have an adequate response to at least one 5-HT <sub>3</sub> 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DUOBRII (halobetasol/tazarotene)

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## Products Affected

- DUOBRII

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

# DUPIXENT (dupilumab)

## Products Affected

- DUPIXENT SUBCUTANEOUS SOLUTION PEN-INJECTOR
- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Diagnosis of covered use. For atopic dermatitis, (1) documentation of at least 10% body surface area involvement, and (2) documentation of treatment with at least a moderate strength topical corticosteroid for at least four weeks, a contraindication to the use of topical corticosteroids, or documentation why this therapy is not otherwise advisable. For asthma, (1) documentation patient has a pre-bronchodilator FEV1 less than 80% predicted, (2) submission of either blood eosinophil count of at least 150 cells/mcL obtained within 6 weeks of therapy initiation or documentation asthma requires daily oral corticosteroid for control, and (3) attestation dupilumab will be used in addition to other chronic therapies. For chronic rhinosinusitis with nasal polyps (CRSwNP), (1) documentation of evidence of nasal polyps, (2) attestation that patient has symptomatic nasal congestion, (3) documentation of treatment with an intranasal corticosteroid for at least two months, a contraindication to the use of intranasal corticosteroids, or why therapy is not otherwise advisable, and (4) if the patient does not have an intolerance or contraindication to intranasal corticosteroids, attestation dupilumab will be used in addition to this therapy. For eosinophilic esophagitis, (1) documentation diagnosis is confirmed with upper endoscopy with biopsy showing at least 15 eosinophils per high-power field or 60 eosinophils/mm<sup>2</sup>, (2) documentation of patient's signs/symptoms, including but not limited to trouble swallowing, food sticking in esophagus, acid reflux, abdominal or chest pain, or nausea and vomiting. For prurigo nodularis, (1) documentation of pruritis lasting at least 6 weeks, (2) documentation of treatment with at least a moderate strength topical corticosteroid for at least four weeks, a contraindication to the use of topical corticosteroids, or documentation why this therapy is not otherwise advisable, and (3) documentation of presence of pruriginous firm, nodular lesions.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to allergy, dermatology, gastroenterology, immunology, otolaryngology/otorhinolaryngology, and pulmonology
<b>Coverage Duration</b>	Initially 6 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Continuation of therapy requests require objective documentation of a positive response to therapy. For CRSwNP, confirmation patient is still using a maintenance intranasal corticosteroid will be required for all reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Part B Prerequisite</b>	No



# ENDARI (L-glutamine)

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## Products Affected

- *L-glutamine oral packet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of sickle cell disease, documentation patient failed therapy with, had an intolerance, or has a contraindication to hydroxyurea.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# EOHILIA (budesonide oral suspension)

**Products Affected**

- EOHILIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, documentation of upper endoscopy with biopsy showing at least 15 eosinophils per high-power field or 60 eosinophils/mm <sup>2</sup> , documentation of positive symptomatology, including but not limited to trouble swallowing, food sticking in esophagus, acid reflux, abdominal or chest pain, or nausea and vomiting, documentation patient has tried and failed at least an 8-week course of proton pump inhibitor therapy (i.e., patient has EoE unrelated to gastroesophageal reflux).
<b>Age Restrictions</b>	11 years of age or older
<b>Prescriber Restrictions</b>	Restricted to allergy, gastroenterology, immunology, and otolaryngology/otorhinolaryngology
<b>Coverage Duration</b>	12 weeks
<b>Other Criteria</b>	PA applies to all. A maximum of one 12-week course will be allowed every 365 days.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# EPIDIOLEX (cannabidiol)

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## Products Affected

- EPIDIOLEX

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

# ERIVEDGE (vismodegib)

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## Products Affected

- ERIVEDGE

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

# EVEROLIMUS

## Products Affected

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

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

# EVRYSDI (risdiplam)

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## Products Affected

- EVRYSDI

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

# EXKIVITY (mobocertinib)

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## Products Affected

- EXKIVITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with moderate or strong CYP3A4 inducers, coadministration with strong CYP3A4 inhibitors
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test confirming presence of EGFR exon 20 insertion mutation and previous therapies used, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. For approval, the patient must have documentation of failure of or contraindication to platinum-based chemotherapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FENTANYL TRANSMUCOSAL

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## Products Affected

- *fentanyl citrate buccal*

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



# FILGRASTIM

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## Products Affected

- NEUPOGEN INJECTION SOLUTION 300 MCG/ML, 480 MCG/1.6ML
- NEUPOGEN INJECTION SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For approval of Neupogen for any indication other than Hematopoietic Syndrome of Acute Radiation Syndrome, the patient must have tried and failed to have an adequate response to or had an intolerance to Zarxio. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# FILSPARI (sparsentan)

## Products Affected

- FILSPARI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, hepatic impairment, coadministration with renin-angiotensin system antagonists, endothelin receptor antagonists, proton pump inhibitors, or H2-receptor blockers
<b>Required Medical Information</b>	Diagnosis of primary IgA nephropathy confirmed by biopsy, submission of 24-hour urine protein of at least 1 g/day or 24-hour urine protein-to-creatinine ratio (UPCR) of at least 0.8 g/g, eGFR (with a requirement it is at least 30 mL/min/1.73 m <sup>2</sup> ), liver function testing or Child-Pugh class, pregnancy status for female patients of childbearing potential, attestation patient is stable on a maximally-tolerated ACE inhibitor or ARB and will discontinue this drug upon receiving sparsentan, documentation patient has progressed on at least one immunosuppressant (e.g., azathioprine, mycophenolate, etc.).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to immunology and nephrology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Reauthorization requires eGFR greater than or equal to 30 mL/min/1.73 m <sup>2</sup> and documentation of clinically relevant response to therapy, including either stabilization or improvement of UPCR or a reduction in total urine protein from baseline.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FINTEPLA (fenfluramine)

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## Products Affected

- FINTEPLA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Administration of monoamine oxidase inhibitors within 14 days of initiation, moderate or severe hepatic impairment (Child-Pugh class B or C)
<b>Required Medical Information</b>	Diagnosis of covered use, submission of liver function testing or Child-Pugh score.
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	Restricted to neurology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FIRDAPSE (amifampridine)

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## Products Affected

- FIRDAPSE

PA Criteria	Criteria Details
Exclusion Criteria	History of seizure
Required Medical Information	Diagnosis of covered use confirmed by either electromyography or calcium channel antibody testing.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# FIRST-GENERATION ANTIHISTAMINES IN OLDER PATIENTS

## Products Affected

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

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

# FOTIVDA (tivozanib)

## Products Affected

- FOTIVDA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Uncontrolled hypertension, severe hepatic impairment, coadministration with strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline blood pressure reading, a minimum of two previous systemic therapies used to treat renal cell carcinoma including the failure of at least one prior VEGFR inhibitor, liver function testing or Child-Pugh score, pregnancy status for female patients of childbearing potential, confirmation patient has not had episodes of symptomatic heart failure or unstable angina, a myocardial infarction, an arterial thrombotic event, or a significant bleeding event in the 6 months preceding the prior authorization request.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FRUZAQLA (fruquintinib)

## Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment, uncontrolled hypertension, coadministration with strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use. 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. Baseline blood pressure reading, liver function testing or Child-Pugh score, and pregnancy status for female patients of childbearing potential, documentation of any clinically significant cardiovascular disease or thromboembolic events, and, if there is a positive history, prescriber attestation benefit to patient outweighs potential risk of thromboembolic event.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# GALAFOLD (migalastat)

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## Products Affected

- GALAFOLD

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



# GATTEX (teduglutide)

## Products Affected

- GATTEX

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

# GAVRETO (pralsetinib)

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## Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inhibitors, uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of RET gene fusion or mutation, baseline blood pressure reading, pregnancy status for female patients of childbearing potential.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# GEFITINIB

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## Products Affected

- *gefitinib*

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

# GILOTRIF (afatinib)

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## Products Affected

- GILOTRIF

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

# GLP-1 AGONISTS EGWP

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Off-label use for weight management (see Other Criteria)
<b>Required Medical Information</b>	Attestation of diagnosis of type 2 diabetes, attestation patient is not receiving another GLP-1 agonist for the treatment of any condition.
<b>Age Restrictions</b>	Age must be consistent with the prescribing information of the drug and condition being treated
<b>Prescriber Restrictions</b>	Restricted to endocrinology and primary care/family medicine/internal medicine
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. These products will not be approved for weight management as this off-label use is currently excluded from coverage under Medicare Part D.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# GROWTH HORMONE

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to endocrinology and nephrology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Updated IGF-1 level, bone age (if applicable based on patient age and diagnosis) height, weight, creatinine clearance (or serum creatinine), and fasting glucose since the previous authorization will be required for subsequent annual reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HEREDITARY ANGIOEDEMA THERAPIES, ACUTE EGWP

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**Products Affected**

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Requests for prophylactic hereditary angioedema therapy. For Ruconest, acute laryngeal attacks.
<b>Required Medical Information</b>	Diagnosis of covered use. For Ruconest, documentation of the patient's typical attack presentation/symptoms.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to allergy, dermatology, hematology, or immunology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HEREDITARY ANGIOEDEMA THERAPIES, MAINTENANCE

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Requests for acute hereditary angioedema (HAE) therapy (attacks)
<b>Required Medical Information</b>	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. For Haegarda for patients 12 years of age and older, submission of previous prophylactic therapies for HAE (see Other Criteria).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to allergy, dermatology, hematology, or immunology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. For approval of Haegarda for patients 12 years of age and older, the patient must have tried and failed to have an adequate response to or had an intolerance or contraindication to Takhzyro. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# IBRANCE (palbociclib)

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## Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of genetic tumor testing confirming primary tumor type is HR-positive, HER2-negative, confirmation that the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ICLUSIG (ponatinib)

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## Products Affected

- ICLUSIG

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

# IDHIFA (enasidenib)

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## Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of IDH2 mutation, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# IMBRUVICA (ibrutinib)

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## Products Affected

- IMBRUVICA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment (Child-Pugh class C), coadministration with strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For chronic graft-versus-host disease, documentation of treatment failure with any other systemic immunosuppressive agent.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to hematology, oncology, and transplant specialty
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# IMMUNE GLOBULIN

## Products Affected

- BIVIGAM INTRAVENOUS SOLUTION 5 GM/50ML GM/100ML, 10 GM/200ML, 20 GM/200ML, 20 GM/400ML, 5 GM/100ML, 5 GM/50ML
- FLEBOGAMMA DIF INTRAVENOUS SOLUTION 10 GM/200ML, 20 GM/400ML, 5 GM/100ML
- GAMMAGARD
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML, 10 GM/100ML, 20 GM/200ML, 5 GM/50ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 2 GM/20ML, 2.5 GM/50ML, 20 GM/200ML, 5 GM/100ML, 5 GM/50ML
- GAMUNEX-C
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 10 GM/100ML, 10 GM/200ML, 2 GM/20ML, 2.5 GM/50ML, 20 GM/200ML, 5 GM/100ML, 5 GM/50ML
- PRIVIGEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	IgA-deficient patients with antibodies against IgA and a history of hypersensitivity.
<b>Required Medical Information</b>	Diagnosis of covered use. For ITP, submission of platelet count. For CLL, documentation of IgG level less than 600 mg/dL and recent history of serious bacterial infection requiring either oral or IV antibiotic therapy. For CIDP, unequivocal diagnosis and documentation patient is refractory, intolerant, or has a contraindication to systemic corticosteroids at therapeutic doses over at least 3 months. For passive immunization against varicella, confirmation that the patient is immunosuppressed and cannot receive varicella-zoster immune globulin.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	For acute conditions/new starts, 3 months. For renewal of chronic conditions, 1 year.
<b>Other Criteria</b>	PA applies to all. For continuation of any diagnosis, documentation of the clinical response to therapy must be submitted. For IV formulations, covered as a Part B benefit if administered in the home for the treatment of primary immune deficiency. For any other combination of treatment site and indication, additional information may need to be submitted to determine if the immune globulin will be covered as a Part B or Part D benefit.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# INJECTABLE RISPERIDONE

## Products Affected

- PERSERIS
- RYKINDO
- UZEDY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Dementia-related psychosis
<b>Required Medical Information</b>	Diagnosis of covered use, submission of previous injectable risperidone therapies used (see Other Criteria).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. For approval, the patient must have documentation of failure of or 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. 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# INLYTA (axitinib)

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## Products Affected

- INLYTA

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

# INQOVI (decitabine/cedazuridine)

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## Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# INREBIC (fedratinib)

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## Products Affected

- INREBIC

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

# INVEGA INJECTABLE (paliperidone injectable suspension)

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Dementia-related psychosis
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ISTURISA (osilodrostat)

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## Products Affected

- ISTURISA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Uncorrected hypokalemia or hypomagnesemia
<b>Required Medical Information</b>	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) on two separate occasions, attestation pituitary gland surgery is not an option for the patient or has not been curative, attestation patient is having symptoms of Cushing's disease, submission of baseline serum potassium and magnesium levels.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to endocrinology
<b>Coverage Duration</b>	Dose increases, 6 months. Reauthorization of a previously approved dose, 1 year (see Other Criteria)
<b>Other Criteria</b>	PA applies to all. Dose increase requests require documentation of 24-hour UFC level above the upper limit of normal and attestation patient is still having symptoms of Cushing's disease and will be approved for 6 months. Continuation of the current dose requires documentation of 24-hour UFC level below the upper limit of normal and attestation of improvement in symptoms of Cushing's disease and will be approved for 1 year.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# IWILFIN (eflornithine)

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## Products Affected

- IWILFIN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient demonstrated at least a partial response to prior multiagent, multimodal therapy including an anti-GD2 immunotherapy, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# JAKAFI (ruxolitinib)

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## Products Affected

- JAKAFI

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

# JAYPIRCA (pirtobrutinib)

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## Products Affected

- JAYPIRCA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient has tried and failed at least two previous lines of systemic therapy (see Other Criteria), pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For mantle cell lymphoma, one of two previous lines of therapy must have included a Bruton's tyrosine kinase (BTK) inhibitor. For chronic lymphocytic leukemia or small lymphocytic lymphoma, previous lines of therapy must have included a Bruton's tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# JOENJA (leniolisib)

## Products Affected

- JOENJA

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

# JUXTAPID (lomitapide)

## Products Affected

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

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



# KERENDIA (finerenone)

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## Products Affected

- KERENDIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Adrenal insufficiency, estimated glomerular filtration rate (eGFR) less than 25 mL/min/1.73 m <sup>2</sup> , serum potassium above 5.0 mEq/L, severe (Child-Pugh class C) hepatic impairment, coadministration with strong CYP3A4 inhibitors or moderate or strong CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of estimated glomerular filtration rate (eGFR) and baseline serum potassium level.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. For approval, the patient must have documentation of a trial of Farxiga or Jardiance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# KETOCONAZOLE ORAL

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## Products Affected

- *ketoconazole oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute or chronic liver disease, treatment of fungal meningitis or fungal infections of the skin or nails
<b>Required Medical Information</b>	Ketoconazole is being requested for the treatment of culture-proven systemic blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis, submission of baseline ALT, AST, total bilirubin, alkaline phosphatase, prothrombin time and INR, confirmation from the prescriber that the potential benefits of therapy outweigh the risks.
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# KISQALI (ribociclib)

## Products Affected

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

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

# KOSELUGO (selumetinib)

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## Products Affected

- KOSELUGO

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

# KRAZATI (adagrasib)

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## Products Affected

- KRAZATI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Congenital long QT syndrome, coadministration with strong CYP3A4 inducers or drugs that prolong the QT interval
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test confirming presence of KRAS G12C mutation. For NSCLC, documentation of at least one previous therapy that was tried and failed. For CRC, documentation of previous therapy with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LAPATINIB

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## Products Affected

- *lapatinib ditosylate*

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

# LEDIPASVIR/SOFOSBUVIR

## Products Affected

- *ledipasvir-sofosbuvir*

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

# LENALIDOMIDE

## Products Affected

- *lenalidomide*
- REVLIMID

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



# LENVIMA (lenvatinib)

## Products Affected

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Uncorrected electrolyte abnormalities, uncontrolled hypertension
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline blood pressure, pregnancy status for female patients of childbearing potential. For renal cell carcinoma, attestation drug will be coadministered with pembrolizumab or everolimus. If being coadministered with everolimus, submission of anti-angiogenic therapy tried and failed. For endometrial carcinoma, attestation drug will be coadministered with pembrolizumab.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LEUKINE (sargramostim, GM-CSF)

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## Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# LIDOCAINE TRANSDERMAL PATCHES

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. FDA-approved only for postherpetic neuralgia. Requests for other indications will not be approved.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# LIVTENCITY (maribavir)

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## Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including a documented history of hematopoietic stem cell or solid organ transplant, submission of previous anti-CMV medication(s) patient has tried and failed (at least one of cidofovir, foscarnet, ganciclovir, valganciclovir).
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to hematology, infectious diseases, oncology, and transplant specialty
Coverage Duration	8 weeks
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# LODOCO (colchicine)

## Products Affected

- LODOCO

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

# LONSURF (trifluridine/tipiracil)

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## Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment
Required Medical Information	Diagnosis of covered use, submission of prior therapies used for indication, pregnancy status for female patients of childbearing potential. For metastatic colorectal cancer, documentation of KRAS status.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# LORBRENA (lorlatinib)

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## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

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

# LUMAKRAS (sotorasib)

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## Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 320 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with strong CYP3A inducers, coadministration with proton pump inhibitors or H2 receptor antagonists
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test confirming presence of KRAS G12C mutation, documentation of at least one previous therapy that was tried and failed.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



## LYBALVI (olanzapine/samidorphan)

### Products Affected

- LYBALVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Dementia-related psychosis, coadministration with opioids, levodopa, dopamine agonists, or strong CYP3A inducers, acute opioid withdrawal, end-stage renal disease
<b>Required Medical Information</b>	Diagnosis of covered use, confirmation patient has previously tried and failed, had an intolerance to, or had a contraindication to at least one generic second-generation antipsychotic with low incidence of metabolic side effects (e.g., aripiprazole, ziprasidone), attestation patient has had a trial of generic olanzapine with documentation showing a positive therapeutic benefit but unacceptable weight gain while using olanzapine.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to neurology and psychiatry
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. Reduction in or stabilization of body weight since the previous authorization will be required for subsequent reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LYNPARZA (olaparib)

## Products Affected

- LYNPARZA ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with moderate or strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test confirming presence of applicable mutations, pregnancy status for female patients of childbearing potential. For pancreatic cancer, documentation that disease has not progressed on at least 16 weeks of platinum-based chemotherapy. For prostate cancer in patients with deleterious or suspected deleterious germline or somatic homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer, documentation disease has progressed following priortreatment with enzalutamide or abiraterone. For breast cancer with deleterious or suspected deleterious gBRCAm HER2-negative high risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy. For breast cancer with deleterious or suspected deleterious gBRCAm, HER2-negative metastatic breast cancer previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with HR-positive breast cancer should have been treated with a prior endocrine therapy if not inappropriate. For ovarian cancer, maintenance treatment for deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy. For ovarian cancer with bevacizumab for the maintenance treatment of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer with complete or partial response to first-line platinum-based chemotherapy and the cancer is associated with HRD-positive status defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability. For ovarian cancer, maintenance treatment of deleterious or suspected deleterious germline or somatic BRCA-mutated recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, with in complete or partial response to platinum-based chemotherapy.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology and urology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LYTGOBI (futibatinib)

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## Products Affected

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

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

# MAVYRET (glecaprevir/pibrentasvir)

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## Products Affected

- MAVYRET

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

# MECASERMIN

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## Products Affected

- INCRELEX

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

# MEGESTROL IN OLDER PATIENTS

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## Products Affected

- *megestrol acetate oral suspension 40 mg/ml, 400 mg/10ml, 625 mg/5ml*

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

# MEKINIST/TAFINLAR (trametinib/dabrafenib)

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## Products Affected

- MEKINIST
- TAFINLAR

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

# METHOTREXATE INJECTABLE (SUBCUTANEOUS)

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## Products Affected

- OTREXUP SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.4ML, 12.5 MG/0.4ML, 15 MG/0.4ML, 17.5 MG/0.4ML, 20 MG/0.4ML, 22.5 MG/0.4ML, 25 MG/0.4ML

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, documentation of intolerance or inadequate response to oral or non-subcutaneous injectable forms of methotrexate.
Age Restrictions	
Prescriber Restrictions	Restricted to rheumatology and dermatology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# MIFEPRISTONE (CUSHING'S SYNDROME)

## Products Affected

- *mifepristone oral tablet 300 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, severe hepatic impairment, uncorrected hypokalemia, female patients with a history of unexplained vaginal bleeding or endometrial hyperplasia with atypia or endometrial carcinoma, patients using systemic corticosteroids for life-saving purposes, coadministration with strong CYP3A4 inducers, simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges
<b>Required Medical Information</b>	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 baseline serum potassium, AST, ALT, and alkaline phosphatase, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to endocrinology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# MIGLUSTAT

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## Products Affected

- *miglustat*
- YARGESA

PA Criteria	Criteria Details
Exclusion Criteria	Severe renal impairment (CrCl less than 30 mL/min)
Required Medical Information	Diagnosis of covered use, documentation that enzyme replacement is not a therapeutic option (e.g., allergy, poor central venous access, hypersensitivity).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# MYALEPT (metreleptin)

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## Products Affected

- MYALEPT

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

## MYCAPSSA (octreotide)

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### Products Affected

- MYCAPSSA

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

# MYTESI (crofelemer)

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## Products Affected

- MYTESI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, attestation infectious causes of diarrhea have been ruled out.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# NAMZARIC (memantine and donepezil)

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## Products Affected

- NAMZARIC

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

# NERLYNX (neratinib)

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## Products Affected

- NERLYNX

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

# NEXAVAR (sorafenib)

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## Products Affected

- *sorafenib tosylate*

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



# NINLARO (ixazomib)

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## Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, documentation that medication will be administered concomitantly with lenalidomide and dexamethasone, documentation of prior therapy regimen for multiple myeloma, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# NITISINONE

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## Products Affected

- *nitisinone*
- ORFADIN ORAL SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of succinylacetone in urine or plasma.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Updated liver function tests, urine succinylacetone levels, alpha-fetoprotein level, serum tyrosine level, and serum phenylalanine level since the previous authorization will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# NUCALA (mepolizumab)

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Regular (non-eosinophilic) granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)
<b>Required Medical Information</b>	Diagnosis of covered use. For asthma, 1) documentation of a pre-bronchodilator FEV1 less than 80% predicted in adults, less than 90% in adolescents, or less than 110% in patients 6 to 11 years old, 2) submission of blood eosinophil count of at least 150 cells/mcL obtained within 6 weeks of therapy initiation or at least 300 cells/mcL within 12 months of therapy initiation, 3) documentation symptoms are poorly controlled with at least a 30-day trial of inhaled corticosteroids plus at least one of: a long-acting beta-agonist, long-acting muscarinic antagonist, leukotriene inhibitor, or theophylline, and 4) attestation mepolizumab will be used in addition to other chronic therapies. For chronic rhinosinusitis with nasal polyps, 1) documentation of evidence of nasal polyps, 2) attestation that patient has symptomatic nasal congestion, 3) documentation of treatment with an intranasal corticosteroid for at least 2 months, a contraindication to their use, or why therapy is not advisable, and 3) if the patient does not have an intolerance or contraindication to intranasal corticosteroids, attestation mepolizumab will be used in addition to this therapy. For eosinophilic granulomatosis with polyangiitis, documentation of 1) a history of asthma, 2) an eosinophil percentage greater than or equal to 10% or an absolute eosinophil count greater than 1000 cells/cubic millimeter from the previous 6 weeks, and 3) disease lasting at least 6 months that is relapsed or refractory to oral corticosteroids and/or immunosuppressive therapies. For hypereosinophilic syndrome, documentation of 1) uncontrolled disease defined as a history of at least 2 flares requiring systemic therapy within the past 12 months and a blood eosinophil count of at least 1000 cells/mcL from the previous 6 weeks, 2) disease that does not have an identifiable non-hematologic secondary cause, and 3) receipt of oral corticosteroids cytotoxic therapy, or immunosuppressive therapy for the previous 4 weeks.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to allergy, hematology, immunology, otorhinolaryngology, pulmonology, and rheumatology
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	PA applies to all. Continuation of therapy requests require objective documentation of a positive response to therapy. For CRSwNP, confirmation patient is still using a maintenance intranasal corticosteroid will be required for all reauthorizations. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NUEDEXTA (dextromethorphan and quinidine)

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## Products Affected

- NUEDEXTA

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

# NUPLAZID (pimavanserin)

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## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

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

# ODOMZO (sonidegib)

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## Products Affected

- ODOMZO

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

## OFEV (nintedanib)

### Products Affected

- OFEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Moderate or severe (Child-Pugh class B or C) hepatic impairment, coadministration of a dual P-glycoprotein/CYP3A4 inducer
<b>Required Medical Information</b>	Diagnosis of covered use, submission of liver function tests or Child-Pugh status, pregnancy status for female patients of childbearing potential. For chronic fibrosing interstitial lung diseases with a progressive phenotype and systemic sclerosis-associated interstitial lung disease diagnoses, submission of HRCT scan showing fibrosis of the lungs within the previous 12 months.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to pulmonology or rheumatology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Updated liver function testing or Child-Pugh score since the previous authorization will be required for subsequent reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# OGSIVEO (nirogacestat)

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with moderate or strong CYP3A inhibitors or inducers, proton pump inhibitors, or H2 receptor antagonists
<b>Required Medical Information</b>	Diagnosis of covered use with documentation of tumor progression, submission of pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology and sarcoma specialty
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test confirming presence of BRAF V600 mutation or BRAF gene fusion or rearrangement, documentation of previous systemic therapy/therapies for pediatric low-grade glioma tried and failed with a minimum of one previous therapy necessary for approval, pregnancy status for female patients of childbearing potential. If genetic testing does not reveal a BRAF gene fusion or rearrangement, documentation of previous intolerance to, contraindication to, or other reason why the patient cannot use the combination of trametinib and dabrafenib.
<b>Age Restrictions</b>	Initiation: 21 years of age or younger (see Other Criteria)
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. Tovorafenib is indicated as therapy in children and young adults and will not be approved for adults unless the patient started on the medication prior to 22 years of age.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# OJJAARA (momelotinib)

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Active infection, uncontrolled acute or chronic liver disease
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ONUREG (azacitidine)

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## Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient achieved first complete remission or complete remission with incomplete blood count recovery following intensive induction chemotherapy and cannot complete intensive curative therapy, submission of absolute neutrophil count, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. This dosage form is not intended to be a substitute for or substituted for injectable azacitidine.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# OPFOLDA (miglustat)

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## Products Affected

- OPFOLDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of previous enzyme replacement therapies tried and failed, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Opfolda is indicated only to stabilize and prevent breakdown of cipaglucoisidase alfa and will not be authorized for the treatment of any medical condition.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# OREXIN RECEPTOR ANTAGONISTS

## Products Affected

- DAYVIGO ORAL TABLET 10 MG, 5 MG
- QUVIVIQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Narcolepsy
<b>Required Medical Information</b>	Diagnosis of covered use. Patient must have tried and failed to tolerate or had an inadequate response to two covered alternative therapies recommended by the American Academy of Sleep Medicine (doxepin, eszopiclone, ramelteon, suvorexant, temazepam, zaleplon, zolpidem) including one non-suvorexant therapy for sleep maintenance (doxepin, eszopiclone, temazepam) if that is the diagnosis of covered use.
<b>Age Restrictions</b>	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORILISSA (elagolix)

## Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, severe hepatic impairment (Child-Pugh class C), known osteoporosis, coadministration with OATP1B1 inhibitors
<b>Required Medical Information</b>	Diagnosis of covered use, attestation patient is premenopausal, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to endocrinology and gynecology
<b>Coverage Duration</b>	Up to 24 months based on liver function and coexisting dyspareunia (see Other Criteria)
<b>Other Criteria</b>	PA applies to all. For endometriosis with dyspareunia or in women with moderate hepatic impairment, 6 months. For endometriosis without dyspareunia, 150 mg daily for 24 months. Use of this drug for more than 2 years increases risk of bone loss and requests for therapy for more than 2 years will not be approved.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORSERDU (elacestrant)

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## Products Affected

- ORSERDU

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment (Child-Pugh class C), coadministration with moderate or strong CYP3A inhibitors or inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test confirming the primary tumor type is ER-positive, HER2-negative, and ESR1-mutated, submission of liver function testing or Child-Pugh score, documentation of prior endocrine therapy/therapies patient has tried and failed. For female patients, attestation patient is postmenopausal.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# OXBRYTA (voxelotor)

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## Products Affected

- OXBRYTA

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

# OXERVATE (cenegermin-bkbj)

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## Products Affected

- OXERVATE

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

# OXYBATE SALT MEDICATIONS

## Products Affected

- XYREM
- XYWAV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with sedative hypnotics
<b>Required Medical Information</b>	Diagnosis of covered use confirmed with documentation from a sleep study, submission of previous therapies used for diagnosis (see Other Criteria).
<b>Age Restrictions</b>	7 years of age or older
<b>Prescriber Restrictions</b>	Restricted to neurology, psychiatry, and sleep medicine
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. For adults with excessive daytime sleepiness associated with narcolepsy, drugs in this policy will be authorized only if the patient previously tried and had an inadequate clinical response, intolerance, or contraindication to (1) armodafinil or modafinil and (2) solriamfetol. Medications covered in this policy are not indicated to treat insomnia and will not be approved for this use.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PALYNZIQ (pegvaliase-pqpz)

## Products Affected

- PALYNZIQ

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

# PANRETIN (alitretinoin)

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## Products Affected

- PANRETIN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, requirement for systemic Kaposi's sarcoma therapy (more than 10 new Kaposi's sarcoma lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary Kaposi's sarcoma, or symptomatic visceral involvement)
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to dermatology and oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

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

## Products Affected

- *apomorphine hcl subcutaneous*
- INBRIJA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For Inbrija, administration of non-selective monoamine oxidase inhibitors within 14 days of initiation, asthma, COPD, or other chronic underlying lung disease.
<b>Required Medical Information</b>	Diagnosis of covered use, attestation patient is experiencing "off" episodes despite carbidopa/levodopa therapy, prescription claims or documentation from physician showing patient (a) has tried and failed or had an intolerance to medications from at least two different drug classes that can help to reduce "off" episodes (COMT inhibitors, dopamine agonists, monoamine oxidase B inhibitors), or (b) has tried and failed or had an intolerance to one medication from a drug class that can help to reduce "off" episodes if they have contraindications to two of these drug classes, or (c) has contraindications to all three drug classes that can help to reduce "off" episodes.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to neurology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PCSK9 INHIBITORS

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of current or previous lipid-lowering therapies (see Other Criteria).
<b>Age Restrictions</b>	For Repatha, 10 years of age or older. For Praluent, 8 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. For approval, the patient must currently be using a statin plus ezetimibe or the patient must have tried and failed to have an adequate response to or had an intolerance to at least two statins or one statin and ezetimibe. At least one statin previously tried and failed must be a hydrophilic statin.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PEGFILGRASTIM

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



# PEMAZYRE (pemigatinib)

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A4 inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of either FGFR1 rearrangement or FGFR2 fusion or rearrangement depending on the indication, submission of previous systemic treatment(s) tried, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# PHEBURANE (sodium phenylbutyrate)

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## Products Affected

- PHEBURANE

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

# PIQRAY (alpelisib)

## Products Affected

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

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

# PIRFENIDONE

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## Products Affected

- *pirfenidone oral tablet 267 mg, 801 mg*

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

# POMALYST (pomalidomide)

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## Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For multiple myeloma, documentation patient has previously used lenalidomide and a proteasome inhibitor and patient has demonstrated disease progression 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# PRETOMANID

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## Products Affected

- *pretomanid*

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

# PRIOR AUTHORIZATION TO OVERRIDE SPECIALTY RESTRICTIONS

## Products Affected

- CORLANOR ORAL SOLUTION
- *diclofenac sodium external gel 3 %*
- *ivabradine hcl*
- NAYZILAM
- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- SYMLINPEN 120 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- SYMLINPEN 60 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- *tazarotene external cream 0.1 %*
- *tazarotene external gel*
- TAZORAC EXTERNAL CREAM 0.05 %
- VABOMERE
- VALTOCO 10 MG DOSE
- VALTOCO 15 MG DOSE
- VALTOCO 20 MG DOSE
- VALTOCO 5 MG DOSE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use. Drugs in this policy require prior authorization but are exempted from this requirement if prescribed by certain specialists (see Prescriber Restrictions).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	(a) for Corlanor: cardiology exempt, (b) for diclofenac 3% gel: dermatology or oncology exempt, (c) for Nayzilam and Valtoco: neurology exempt, (d) for Pegasys: gastroenterology, hepatology, or infectious diseases exempt, (e) for Symlin: endocrinology exempt, (f) for tazarotene and Tazorac: dermatology exempt, (g) for Vabomere: infectious diseases or nephrology exempt
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PROLIA (denosumab)

## Products Affected

- PROLIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Hypocalcemia, pregnancy
<b>Required Medical Information</b>	Diagnosis of covered use, confirmation of osteoporosis diagnosis either through densitometry (T-score less than or equal to -2.5 at the total hip, femoral neck, or lumbar spine) or clinically (documented presence of fragility fracture), submission of calcium level, pregnancy status for female patients of childbearing potential. "High risk for fracture" is defined as (1) a history of osteoporotic fracture or (2) multiple risk factors for fracture or (3) patients who have failed or are intolerant of other available osteoporosis therapies.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Updated serum calcium level since the previous authorization will be required for subsequent reauthorizations. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# PROMACTA (eltrombopag)

## Products Affected

- PROMACTA ORAL PACKET
- PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of platelet count. For immune thrombocytopenia (ITP), submission of previous therapies tried and failed (see Other Criteria). For thrombocytopenia in patients with chronic hepatitis C, attestation patient will be receiving interferon therapy to treat HCV. For aplastic anemia (AA), submission of immunosuppressive therapy that will be used concomitantly or, in the case of refractory disease, submission of therapy or therapies tried and failed.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to gastroenterology, hematology, hepatology, and infectious diseases
<b>Coverage Duration</b>	For ITP, initially 12 weeks, then 1 year. For AA, 6 months. For all other indications, 1 year.
<b>Other Criteria</b>	PA applies to all. Initial approval for ITP requires (1) platelet count less than $30 \times 10^9/L$ or less than $50 \times 10^9/L$ with documented increased risk of bleeding and (2) documentation patient has undergone splenectomy and/or tried and failed two different ITP therapies including systemic corticosteroids, immunoglobulins, danazol, fostamatinib, or cytotoxics/immunosuppressants such as rituximab. For ITP, documentation of an improvement in platelet count will be required for initial reauthorization after the first 12 weeks. Maintenance of a clinical benefit will be required for subsequent annual reauthorizations. Initial approval in patients with chronic hepatitis C requires platelet count less than $75 \times 10^9/L$ . Initial approval for aplastic anemia requires platelet count less than $30 \times 10^9/L$ . Updated platelet count since the previous authorization will be required for subsequent reauthorizations. Not indicated for treatment of patients with myelodysplastic syndrome and will not be approved for this use.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PROMETHAZINE IN OLDER PATIENTS

## Products Affected

- *promethazine hcl oral*
- *promethazine hcl rectal suppository 12.5 mg, 25 mg*
- *promethazine vc plain*
- *promethazine-phenylephrine*
- PROMETHEGAN RECTAL SUPPOSITORY 25 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Promethazine is a potent anticholinergic considered high-risk in older patients due to risks of confusion, dry mouth, constipation, and decreased clearance with advanced age.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PROSTATE CANCER ORAL MEDICATIONS

## Products Affected

- AKEEGA
- ERLEADA
- NUBEQA
- XTANDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For Akeega, severe hepatic impairment (Child-Pugh class C), uncontrolled hypertension, uncontrolled hypokalemia
<b>Required Medical Information</b>	Diagnosis of covered use. For Nubeqa, documentation of other treatments tried (see Other Criteria). For Akeega, submission of test confirming presence of deleterious BRCA mutation, baseline blood pressure reading, and serum potassium level.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology and urology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. Nubeqa will be authorized only if the patient previously tried and had an inadequate clinical response or an intolerance to both Erleada and Xtandi.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PYRUKYND (mitapivat)

## Products Affected

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

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

# QINLOCK (ripretinib)

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## Products Affected

- QINLOCK

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

# RADICAVA ORS (edaravone)

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## Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT

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

# RECORLEV (levoketoconazole)

## Products Affected

- RECORLEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Cirrhosis, acute, poorly-controlled chronic, or extensive metastatic liver disease, baseline AST or ALT greater than 3 times the upper limit of normal, recurrent symptomatic cholelithiasis, a prior history of drug-induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, prolonged QTcF interval greater than 470 msec at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, prolonged QT syndrome, coadministration with drugs that cause QT prolongation associated with ventricular arrhythmias
<b>Required Medical Information</b>	Diagnosis of covered use, submission of 24-hour urine free cortisol (UFC) level demonstrating a baseline value more than 1.5 times the upper limit of normal (50 micrograms or 145 nmol), attestation pituitary gland surgery is not an option for the patient or has not been curative, electrocardiogram (including QTcF), and liver function tests all performed within 3 months of prior authorization request, documentation patient tried and failed at least one other therapy for Cushing's syndrome (e.g., mifepristone, osilodrostat, pasireotide).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to endocrinology
<b>Coverage Duration</b>	Initially 6 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Continuation requires documentation of clinically relevant response to therapy, including, but not limited to 24-hour UFC level. Recorlev is not approved for the treatment of fungal infections and will not be approved for this use.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# RELISTOR (methylnaltrexone)

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## Products Affected

- RELISTOR ORAL
- RELISTOR SUBCUTANEOUS SOLUTION 12 MG/0.6ML, 8 MG/0.4ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Known or suspected mechanical gastrointestinal obstruction and at increased risk of recurrent obstruction
<b>Required Medical Information</b>	Diagnosis of covered use, documentation patient has tried and failed, has a contraindication to, or could not tolerate both lubiprostone and Movantik. For patients with non-cancer pain, documentation of a steady dose of opioid for the previous 8 weeks.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Confirmation patient remains on an opioid will be required for all reauthorizations.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# 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
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	For non-ESRD-related conditions: 90 days. For ESRD-related conditions: 1 year.
<b>Other Criteria</b>	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# RETEVMO (selpercatinib)

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Uncontrolled hypertension, coadministration with moderate or strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test confirming presence of RET gene fusion or mutation, baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For RET fusion-positive thyroid cancer, documentation of previous radioactive iodine treatment or reason why radioactive iodine therapy is not appropriate. For solid tumors with a RET gene fusion, documentation of previous systemic therapy tried or reason why patient has no satisfactory alternative treatment options.
<b>Age Restrictions</b>	2 years of age or older based on indication
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# REZLIDHIA (olutasidenib)

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## Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with moderate or strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of IDH1 mutation, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# REZUROCK (belumosudil)

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## Products Affected

- REZUROCK

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

# RIVFLOZA (nedosiran)

## Products Affected

- RIVFLOZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73 m <sup>2</sup>
<b>Required Medical Information</b>	Diagnosis of covered use, documentation of AGXT mutation confirmed by liver enzyme analysis or genetic testing, submission of 24-hour urinary oxalate (Uox) excretion with a requirement it is greater than or equal to 0.7 mmol (normalized to body surface area if patient is under 18 years of age) and estimated glomerular filtration rate (eGFR), attestation patient has not received a prior kidney or liver transplant, attestation patient will not be using in combination with lumasiran (Oxlumo).
<b>Age Restrictions</b>	9 years of age or older
<b>Prescriber Restrictions</b>	Restricted to nephrology and urology
<b>Coverage Duration</b>	Initially 6 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Reauthorization requires documentation of clinically relevant response to therapy as evidenced by reduced Uox or plasma oxalate levels.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ROZLYTREK (entrectinib)

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## Products Affected

- ROZLYTREK

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

# RUBRACA (rucaparib)

## Products Affected

- RUBRACA

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

# RYDAPT (midostaurin)

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## Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with strong CYP3A inducers
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential. For acute myeloid leukemia, submission of test confirming presence of FLT3 mutation, documentation of chemotherapy that will be coadministered with midostaurin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to allergy, hematology, and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# SAPROPTERIN

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of blood phenylalanine concentration.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Reduction in blood phenylalanine concentration from pre-treatment baseline will be required for initial reauthorization. Documentation of continued phenylalanine level improvement or maintenance of initial phenylalanine level improvement will be required for subsequent reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# SCEMBLIX (asciminib)

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For use in patients with a T315I mutation, documentation patient has first tried and failed or become intolerant to ponatinib. For use in patients without a T315I mutation, documentation of two or more other tyrosine kinase inhibitors tried and failed.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

## SECOND-GENERATION ANTIPSYCHOTICS

### Products Affected

- CAPLYTA ORAL CAPSULE 10.5 MG, 21 MG, 42 MG
- FANAPT ORAL TABLET 1 MG, 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG
- FANAPT TITRATION PACK
- SECUADO TRANSDERMAL PATCH 24 HOUR 3.8 MG/24HR, 5.7 MG/24HR, 7.6 MG/24HR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Dementia-related psychosis
<b>Required Medical Information</b>	Diagnosis of covered use. For schizophrenia or an indication related to bipolar disorder type I, submission of previous therapies used (see Other Criteria).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to psychiatry
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. For approval 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 approval of Caplyta for depressive episodes associated with bipolar I disorder, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two of the following drugs: cariprazine, lurasidone, olanzapine, or quetiapine.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SEDATIVE HYPNOTICS IN OLDER PATIENTS

## Products Affected

- *eszopiclone*
- *zaleplon*
- *zolpidem tartrate oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. Sedative hypnotic medications are high-risk medications in older patients due to increased risks of cognitive impairment, delirium, unsteady gait, syncope, falls, fractures, and motor vehicle accidents.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SIGNIFOR (pasireotide)

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## Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment (Child-Pugh class C), uncorrected hypokalemia or hypomagnesemia
<b>Required Medical Information</b>	Diagnosis of covered use, submission of 24-hour urine free cortisol (UFC) level demonstrating a baseline value more than 1.5 times the upper limit of normal (50 micrograms or 145 nmol), attestation pituitary gland surgery is not an option for the patient or has not been curative, submission of ALT, aspartate aminotransferase, alkaline phosphatase, total bilirubin, and serum potassium and magnesium levels.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to endocrinology
<b>Coverage Duration</b>	Initially 6 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Continuation requires documentation of clinically relevant response to therapy including, but not limited to 24-hour UFC level.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SIMVASTATIN 80 mg per day

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation that patient has been taking simvastatin 80 mg daily for 12 months or longer without adverse effects.
Age Restrictions	10 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. Not recommended as initial therapy nor for patients already taking lower doses of simvastatin whose response is inadequate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# SIRTURO (bedaquiline)

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## Products Affected

- SIRTURO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Drug-sensitive tuberculosis, latent infection, extra-pulmonary tuberculosis
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	5 years of age or older
<b>Prescriber Restrictions</b>	Restricted to infectious diseases and pulmonology
<b>Coverage Duration</b>	26 weeks
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SIVEXTRO (tedizolid)

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## Products Affected

- SIVEXTRO

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



# SKYCLARYS (omaveloxolone)

## Products Affected

- SKYCLARYS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment, coadministration with moderate or strong CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of covered use confirmed by genetic testing, submission of liver function testing or Child-Pugh score.
<b>Age Restrictions</b>	16 years of age or older
<b>Prescriber Restrictions</b>	Restricted to neurology and specialists in genetic diseases
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Documentation of a positive response to therapy will be required for initial reauthorization after the first year. Maintenance of a clinical benefit and attestation that prescriber believes benefits of continuing therapy outweigh the potential risks to the patient will be required for subsequent annual reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SOFOSBUVIR/VELPATASVIR

## Products Affected

- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) infection, submission of baseline HCV RNA level, documentation of whether cirrhosis is present or not and whether it is compensated or decompensated, confirmation that patients with decompensated cirrhosis will receive concomitant ribavirin therapy unless ribavirin therapy is otherwise clinically not indicated, submission of eGFR (safety and efficacy of sofosbuvir/velpatasvir has not been established in patients with eGFR less than 30 mL/min/1.73 m <sup>2</sup> ), confirmation a test for HBV infection (HBsAg and anti-HBc) was completed.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 weeks
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SOHONOS (palovarotene)

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## Products Affected

- SOHONOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, coadministration with strong CYP3A4 inhibitors, coadministration with moderate or strong CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test confirming presence of R206H ACVR1 mutation, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	For female patients, 8 years of age or older. For male patients, 10 years of age or older.
<b>Prescriber Restrictions</b>	Restricted to orthopedics, rheumatology, and specialists in rare connective tissue diseases
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Attestation patient is benefitting from treatment and continues to undergo regular pregnancy testing (as necessary for patients of childbearing potential) will be required for all annual reauthorizations.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SOMAVERT (pegvisomant)

## Products Affected

- SOMAVERT

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

# SPRYCEL (dasatinib)

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## Products Affected

- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Uncorrected hypokalemia, uncorrected hypomagnesemia, coadministration with proton pump inhibitors or H2 receptor antagonists
<b>Required Medical Information</b>	Diagnosis of covered use, submission of serum potassium and magnesium, pregnancy status for female patients of childbearing potential. For adults with resistance or intolerance to prior therapy, documentation of prior therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# STIVARGA (regorafenib)

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## Products Affected

- STIVARGA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe or uncontrolled hypertension, coadministration with strong CYP3A4 inhibitors or inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline blood pressure reading, pregnancy status for female patients of childbearing potential. For metastatic CRC, documentation of previous treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an antiVEGF therapy, and, if RAS wild-type, an anti-EGFR therapy. For GIST, documentation of previous treatment with imatinib and sunitinib. For HCC, documentation of previous treatment with sorafenib.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SUCRAID (sacrosidase)

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## Products Affected

- SUCRAID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of laboratory-confirmed congenital sucrase-isomaltase deficiency via differential urinary disaccharide test or measurement of intestinal disaccharides following small bowel biopsy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# SUNITINIB

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## Products Affected

- *sunitinib malate*

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



# SUNOSI (solriamfetol)

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## Products Affected

- SUNOSI ORAL TABLET 150 MG, 75 MG

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

# TABRECTA (capmatinib)

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## Products Affected

- TABRECTA

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

# TADALAFIL FOR BPH

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## Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Erectile dysfunction indication (see Other Criteria), severe hepatic impairment
Required Medical Information	Diagnosis of benign prostatic hyperplasia (BPH)
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to urology
Coverage Duration	1 year
Other Criteria	PA applies to all. This product will not be approved for erectile dysfunction as this off-label use is currently excluded from coverage under Medicare Part D.
Indications	Some FDA-approved Indications Only.
Off Label Uses	
Part B Prerequisite	No

# TAFAMIDIS

## Products Affected

- VYNDAMAX
- VYNDAQEL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of transthyretin amyloid cardiomyopathy (ATTRwt or ATTRm) confirmed by one of the following: (1) presence of amyloid deposits on cardiac biopsy, (2) presence of transthyretin precursor protein confirmed on immunohistochemical analysis, scintigraphy, or mass spectrometry, or (3) a TTR genetic mutation plus cardiac involvement defined as thickening of the interseptal ventricular wall. In addition, patients should also have documentation of history of heart failure, with at least one prior hospitalization for heart failure or clinical evidence of heart failure with signs or symptoms of volume overload requiring treatment with a diuretic for improvement.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to cardiology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Documentation of a positive response to therapy will be required for annual reauthorization.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TAGRISSO (osimertinib)

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## Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of test confirming presence of required genetic mutations/deletions for indication, pregnancy status for female patients of childbearing potential. For EGFR T790M mutation-positive NSCLC, 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	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TALZENNA (talazoparib)

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## Products Affected

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

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

# TASIGNA (nilotinib)

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## Products Affected

- TASIGNA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Uncorrected hypokalemia, uncorrected hypomagnesemia, long QT syndrome, coadministration with drugs that prolong the QT interval, proton pump inhibitors, or strong CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of Philadelphia chromosome (Ph) status, baseline serum potassium and magnesium levels.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TASIMELTEON

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## Products Affected

- *tasimelteon*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment, coadministration with strong CYP1A2 inhibitors or CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of covered use. For Smith-Magenis Syndrome patients only, documentation of genetic testing results confirming diagnosis is required.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to neurology and sleep medicine
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. For non-24-hour sleep-wake disorder, patients are required to be totally blind to match the population in which tasimelteon was studied.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# TAVALISSE (fostamatinib)

## Products Affected

- TAVALISSE ORAL TABLET 100 MG, 150 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of platelet count with a requirement it is less than $30 \times 10^9/L$ or less than $50 \times 10^9/L$ with documented increased risk of bleeding, documentation patient has undergone splenectomy and/or tried and failed two different ITP therapies including systemic corticosteroids, immunoglobulins, danazol, fostamatinib, or cytotoxics/immunosuppressants such as rituximab.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology
<b>Coverage Duration</b>	Initially 12 weeks, then 1 year
<b>Other Criteria</b>	PA applies to all. Documentation of an improvement in platelet count will be required for initial reauthorization after the first 12 weeks. Maintenance of a clinical benefit will be required for subsequent annual reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TAVNEOS (avacopan)

## Products Affected

- TAVNEOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with moderate or strong CYP3A4 inducers, active serious infection, chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis, cirrhosis
<b>Required Medical Information</b>	Diagnosis of covered use (GPA or MPA variant of ANCA-associated vasculitis) and confirmation patient is using rituximab, cyclophosphamide/azathioprine, or another compendium-supported therapy for the treatment of ANCA-associated vasculitis, along with glucocorticoids.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to immunology, nephrology, pulmonology, and rheumatology
<b>Coverage Duration</b>	Initially 6 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Initial reauthorization requires documentation of clinically relevant response to therapy, including but not limited to disease remission defined using changes in Birmingham Vasculitis Activity Score, a documented reduction in maintenance glucocorticoid dose, or improved or sustained renal function. Maintenance of a clinical benefit will be required for subsequent annual reauthorizations.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TAZVERIK (tazemetostat)

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## Products Affected

- TAZVERIK

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

# TEGSEDI (inotersen)

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## Products Affected

- TEGSEDI

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

# TEPMETKO (tepotinib)

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## Products Affected

- TEPMETKO

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

# TERIPARATIDE

## Products Affected

- *teriparatide subcutaneous solution pen-injector 600 mcg/2.4ml, 620 mcg/2.48ml*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pre-existing hypercalcemia, underlying hypercalcemic disorder (such as primary hyperparathyroidism), patients with an increased risk of osteosarcoma (such as those with Paget's disease)
<b>Required Medical Information</b>	Diagnosis of covered use where "high risk for fracture" is defined as (1) a history of osteoporotic fracture or (2) multiple risk factors for fracture or (3) patients who have failed or are intolerant of other available osteoporosis therapies, submission of baseline serum calcium, postmenopausal status, documentation that at least one bisphosphonate was tried and failed (or all bisphosphonates, including zoledronic acid, are contraindicated), submission of a value, condition, or past medical history that assesses fracture risk (e.g., DEXA scan results or prior fracture), submission of number of total months of all prior use of parathyroid hormone analogs and parathyroid hormone related peptides.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	2 years unless patient is at high risk for fracture after 2 years of therapy (see Other Criteria)
<b>Other Criteria</b>	PA applies to all. Updated serum calcium since the previous authorization will be required for reauthorization. Use of parathyroid hormone analogs and/or parathyroid hormone related peptides for more than 2 years during a patient's lifetime is generally not recommended. Requests for continuation of therapy beyond a total of 2 years must be accompanied by evidence that patient remains at high risk for fracture.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TESTOSTERONE REPLACEMENT PRODUCTS

## Products Affected

- testosterone transdermal gel 1.62 %, 10 mg/act (2%), 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)
- testosterone transdermal solution

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	History of breast cancer
<b>Required Medical Information</b>	Diagnosis of covered use, submission of serum testosterone level, documentation that patient has been evaluated for the presence of prostate cancer prior to initiation of therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Documentation of clinically relevant response to therapy (including, but not limited to submission of updated serum testosterone level) will be required for subsequent reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TIBSOVO (ivosidenib)

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## Products Affected

- TIBSOVO

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



# TOLVAPTAN (HYPONATREMIA)

## Products Affected

- *tolvaptan oral tablet 15 mg, 30 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Underlying liver disease, need to raise serum sodium acutely, inability to sense or respond to thirst, hypovolemia, anuria, coadministration with strong CYP3A inhibitors or inducers or desmopressin
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	PA applies to all. Treatment should be initiated in a setting where serum sodium can be monitored closely. Treatment is limited to 30 days to prevent liver injury. This formulation of tolvaptan will not be approved for autosomal dominant polycystic kidney disease (ADPKD) because the tolvaptan formulation approved for ADPKD has a mandatory REMS program.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TOPICAL PSORIASIS TREATMENTS

## Products Affected

- VTAMA
- ZORYVE EXTERNAL CREAM 0.3 %

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

# TRUQAP (capivasertib)

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## Products Affected

- TRUQAP ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with moderate or strong CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential, genetic tumor testing showing that the primary tumor type is HR-positive, HER2-negative, submission of test confirming presence of PIK3CA, AKT1, and/or PTEN mutation, submission of previous systemic treatment(s) tried to match the indication, and confirmation drug will be given with fulvestrant. In patients with a PIK3CA mutation and no AKT1 and/or PTEN mutation, documentation patient has tried and failed, had an intolerance to, or has a contraindication to alpelisib.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TUKYSA (tucatinib)

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## Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, coadministration with strong CYP3A inducers or moderate CYP2C8 inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of genetic tumor testing showing that the primary tumor type is HER2-positive, submission of previous systemic treatment including prior HER2-directed therapy, pregnancy status for female patients of childbearing potential. For metastatic colon cancer, documentation tumor is RAS wild-type.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TURALIO (pexidartinib)

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## Products Affected

- TURALIO ORAL CAPSULE 125 MG

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

# TYMLOS (abaloparatide)

## Products Affected

- TYMLOS

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

# UTERINE FIBROID ORAL THERAPIES

## Products Affected

- MYFEMBREE
- ORIAHNN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, known liver impairment or disease, known osteoporosis, undiagnosed abnormal uterine bleeding, women who are at increased risk of, have a history of, or currently have thrombotic or thromboembolic disorders (including women over 35 years of age who smoke and women with uncontrolled hypertension), current/history of breast cancer or other hormone-sensitive cancer
<b>Required Medical Information</b>	Diagnosis of covered use, attestation patient is premenopausal, submission of baseline blood pressure, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to endocrinology and gynecology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Use of this drug for more than 2 years increases risk of bone loss and requests for therapy for more than 2 years will not be approved.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VALCHLOR (mechlorethamine)

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## Products Affected

- VALCHLOR

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



# VANFLYTA (quizartinib)

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## Products Affected

- VANFLYTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Uncorrected hypokalemia or hypomagnesemia, long QT syndrome, QTcF interval greater than 450 msec at treatment initiation, coadministration with moderate or strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use including submission of test confirming presence of FLT3 mutation, submission of QTcF interval, baseline serum potassium and magnesium levels, and pregnancy status for female patients of childbearing potential, attestation patient does not have history of ventricular arrhythmias or torsades de pointes.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VENCLEXTA (venetoclax)

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with moderate or strong CYP3A inducers. For CLL/SLL, coadministration with strong CYP3A inhibitors at treatment initiation and initial dosage titration.
<b>Required Medical Information</b>	Diagnosis of covered use, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VEOZAH (fezolinetant)

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## Products Affected

- VEOZAH

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with CYP1A2 inhibitors, severe renal impairment or end-stage renal disease, known cirrhosis
<b>Required Medical Information</b>	Diagnosis of covered use, submission of creatinine clearance (or serum creatinine, actual body weight, and height to calculate estimated creatinine clearance), documentation patient has tried and had an inadequate response to at least 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 at least two different medication classes.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VERQUVO (vericiguat)

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, concomitant use of another soluble guanylate cyclase (sGC) stimulator or a phosphodiesterase-5 (PDE-5) inhibitor
<b>Required Medical Information</b>	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. Prescribers are also required to submit current regimen for the treatment of HFrEF, which must include (1) a renin-angiotensin system (RAS) inhibitor (ACE inhibitor, ARB, or sacubitril/valsartan), (2) a beta-blocker (BB), and (3) a mineralocorticoid receptor antagonist (MRA), each at maximally-tolerated doses. If any of these three therapies are not currently being used, prescriber is required to submit documentation as to why (e.g., contraindications, intolerances, etc.). Using the recommended dose of each therapeutic component to treat HFrEF is required. If the doses of any of these three components have not been optimized to the recommended dose to treat HFrEF, the prescriber is required to submit documentation as to why (e.g., intolerances, physiologic parameters, etc.). If the patient is using a BB not indicated for HFrEF, the patient will be required to switch to one of the three FDA-approved BBs for HFrEF (bisoprolol, carvedilol, or metoprolol succinate).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. An updated HFrEF regimen to follow requirements as outlined in the Required Medical Information criteria is required at each annual reauthorization.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VERZENIO (abemaciclib)

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## Products Affected

- VERZENIO

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

# VIBERZI (eluxadoline)

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## Products Affected

- VIBERZI

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

# VIJOICE (alpelisib)

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## Products Affected

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

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

# VITRAKVI (larotrectinib)

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## Products Affected

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

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



# VIVJOA (oteseconazole)

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## 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, submission of eGFR, attestations patient is either (a) postmenopausal or (b) infertile, and patient does not have severe hepatic impairment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	PA applies to all.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# VIZIMPRO (dacomitinib)

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## Products Affected

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

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

# VMAT2 INHIBITORS

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Congenital long QT syndrome or a history of cardiac arrhythmia associated with a prolonged QT interval, coadministration with monoamine oxidase inhibitors. For Austedo, actively suicidal or untreated/undertreated depression, hepatic impairment.
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to neurology and psychiatry
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VONJO (pacritinib)

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## Products Affected

- VONJO

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

# VOQUEZNA (vonoprazan)

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## Products Affected

- VOQUEZNA ORAL TABLET 10 MG, 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of (1) erosive esophagitis confirmed by endoscopy, (2) non-erosive gastroesophageal reflux disease (GERD), or (3) Helicobacter pylori infection. For erosive esophagitis only, documentation of treatment failure with at least one proton pump inhibitor or a contraindication to the proton pump inhibitor class. For 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	32 weeks
Other Criteria	PA applies to all. For non-erosive GERD, the initial coverage duration will be 4 weeks, then 20 weeks on renewal. 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

# VORANIGO (vorasidenib)

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## Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed diagnosis of grade 2 oligodendroglioma or grade 2 astrocytoma, confirmed isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation, patient has had at least one prior surgery (sub-total resection or gross total resection).
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	6 months
Other Criteria	PA applies to new starts only
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# VOSEVI (sofosbuvir, velpatasvir, voxilaprevir)

## Products Affected

- VOSEVI

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

# VOTRIENT (pazopanib)

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## Products Affected

- *pazopanib hcl*

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



# VOWST (fecal microbiota, live-jslm) EGWP

## Products Affected

- VOWST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 course (3 days)
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VOYDEYA (danicopan)

## Products Affected

- VOYDEYA ORAL TABLET
- VOYDEYA ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient has clinically significant extravascular hemolysis, defined as a hemoglobin level less than or equal to 9.5 g/dL and an absolute reticulocyte count greater than $120 \times 10^9/L$ after having used a complement C5 inhibitor at a stable dose (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. For approval, the patient must have been on a stable regimen of eculizumab or ravulizumab for the previous 6 months. Danicopan has not been shown to be effective as monotherapy and should only be prescribed as an add-on to complement C5 inhibitor therapy. For initial reauthorization after 6 months of therapy, documentation of an increase in hemoglobin at least 2 g/dL over baseline will be required. Annual continuation of therapy requests require confirmation of the maintenance of therapeutic effect without incidence of intolerable toxicity.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	Yes

# WAINUA (eplontersen)

## Products Affected

- WAINUA

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

# WAKIX (pitolisant)

## Products Affected

- WAKIX ORAL TABLET 17.8 MG, 4.45 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment, end-stage renal disease, known QT interval prolongation, symptomatic bradycardia, uncorrected hypokalemia or hypomagnesemia, coadministration with medications that prolong the QT interval
<b>Required Medical Information</b>	Diagnosis of covered use, submission of serum potassium and magnesium and previous therapies used for diagnosis (see Other Criteria).
<b>Age Restrictions</b>	6 years of age or older
<b>Prescriber Restrictions</b>	Restricted to neurology and sleep medicine
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. For excessive daytime sleepiness associated with narcolepsy. For adult patients, pitolisant will be authorized only if the patient previously tried and had an inadequate clinical response, an intolerance, or contraindication to (1) armodafinil or modafinil and (2) solriamfetol. Updated serum potassium and magnesium since the previous authorization will be required for subsequent annual reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# WELIREG (belzutifan)

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## Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of pregnancy status for female patients of childbearing potential. For von Hippel-Lindau (VHL) disease, confirmation of a germline VHL alteration and attestation patient does not require immediate surgery. For advanced renal cell carcinoma, confirmation patient was previously treated with a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# WINREVAIR (sotatercept-csrk)

## Products Affected

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

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

# XALKORI (crizotinib)

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## Products Affected

- XALKORI

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

# XDEMVY (lotilaner)

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## Products Affected

- XDEMVY

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



# XERMELO (telotristat)

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## Products Affected

- XERMELO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation patient has been on at least 12 weeks of prior somatostatin analog therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	PA applies to all. Continuation of therapy requires that patient remains on somatostatin analog therapy (unless contraindicated), symptoms have stabilized or improved and that the patient has not experienced episodes of severe constipation.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# XGEVA (denosumab)

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## Products Affected

- XGEVA

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia
Required Medical Information	Diagnosis of covered use, submission of serum calcium level, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# XOLAIR (omalizumab)

## Products Affected

- XOLAIR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Weight greater than 150 kg
<b>Required Medical Information</b>	<p>Diagnosis of covered use. For asthma, (1) documentation patient has a pre-bronchodilator FEV1 less than 80 percent predicted, (2) submission of pre-treatment serum IgE level between 30 and 700 IU/mL in patients 12 years of age and older, (3) documentation that patient's symptoms are poorly controlled with at least a 30-day trial of inhaled corticosteroids plus at least one of the following: a long-acting beta-agonist, long-acting muscarinic antagonist, leukotriene inhibitor, or theophylline, and (4) positive skin test result or demonstrated in vitro reactivity (RAST test) to a perennial aeroallergen. For chronic spontaneous urticaria, documentation that the patient continues to experience severe itching and hives despite the use of an H1 antihistamine for at least 30 days. For chronic rhinosinusitis with nasal polyps (CRSwNP), (1) documentation of evidence of nasal polyps, (2) attestation that patient has symptomatic nasal congestion, (3) submission of pre-treatment serum IgE level with a requirement it must be at least 30 IU/mL, (4) documentation of treatment with an intranasal corticosteroid for at least 2 months, a contraindication to the use of intranasal corticosteroids, or why therapy is not otherwise advisable, and (5) if the patient does not have an intolerance or contraindication to intranasal corticosteroids, attestation omalizumab will be used in addition to this therapy. For food allergy, documentation of at least one IgE-mediated food allergy proven by skin prick test and positive IgE testing, submission of pre-treatment serum IgE level with a requirement it must be at least 30 IU/mL, attestation patient will continue to follow a food allergen-avoidance diet.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to allergy, dermatology, immunology, otolaryngology/otorhinolaryngology, and pulmonology
<b>Coverage Duration</b>	Initially 6 months, then 1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	PA applies to all. Xolair will not be approved for food allergy if the patient is already using Palforzia. For all indications except food allergy, continuation of therapy requests require objective documentation of a positive response to therapy. For CRSwNP, confirmation patient is still using a maintenance intranasal corticosteroid will be required for all reauthorizations. For food allergy, attestation patient has medical necessity and will continue to derive benefit from Xolair therapy will be required for all reauthorizations. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XOLREMDI (mavorixafor)

## Products Affected

- XOLREMDI

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

# XOSPATA (gilteritinib)

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## Products Affected

- XOSPATA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Uncorrected hypokalemia or hypomagnesemia, coadministration with dual strong CYP3A/P-glycoprotein inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test confirming presence of FLT3 mutation, baseline serum potassium and magnesium levels, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XPOVIO (selinexor)

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, documentation of treatment failure with or intolerance to all prior therapies to match the indication, submission of pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XURIDEN (uridine triacetate)

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## Products Affected

- XURIDEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline CBC including neutrophil count and mean corpuscular volume, baseline urine orotic acid level.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Improvements or stabilization of urine orotic acid level, neutrophil count, and mean corpuscular volume will be required for annual reauthorizations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# ZEJULA (niraparib)

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## Products Affected

- ZEJULA ORAL CAPSULE
- ZEJULA ORAL TABLET

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

# ZILBRYSQ (zilucoplan)

## Products Affected

- ZILBRYSQ

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use including confirmation via a history of abnormal neuromuscular transmission tests or improvement with acetylcholinesterase inhibitors and a positive serological test for AChR-Ab, submission of MGFA classification with a requirement the patient has class II-IV MG and baseline MG-ADL score with a requirement the score is at least 6, attestation patient will not concurrently use rituximab or eculizumab, confirmation patient has failed to respond to at least one drug in two of the following three drug groups: (1) acetylcholinesterase inhibitors (e.g., pyridostigmine), (2) corticosteroids (e.g., prednisone), or (3) non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate), attestation patient has received meningococcal vaccination against subgroups A, B, C, W, and Y and does not have an unresolved N. meningitidis infection.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to neurology
<b>Coverage Duration</b>	Initially 6 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Documentation of any positive response to therapy will be required for initial reauthorization after the first 6 months. Maintenance of a clinical benefit, attestation the patient is up to date on all vaccinations, and attestation that prescriber believes benefits of continuing therapy outweigh the potential risks to the patient will be required for subsequent annual reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZOKINVY (lonafarnib)

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## Products Affected

- ZOKINVY ORAL CAPSULE 50 MG, 75 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Body surface area less than 0.39 m <sup>2</sup> , coadministration with moderate or strong CYP3A inhibitors or inducers, midazolam, atorvastatin, lovastatin, or simvastatin
<b>Required Medical Information</b>	Diagnosis of covered use including results of genetic testing supporting diagnosis, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to specialists in genetic diseases or inborn errors of metabolism
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Attestation patient is benefitting from treatment in the absence of serious adverse effects will be required for all annual reauthorizations.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZONTIVITY (vorapaxar)

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## Products Affected

- ZONTIVITY

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

# ZTALMY (ganaxolone)

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## Products Affected

- ZTALMY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use confirmed by genetic testing including either (a) a CDKL5 gene that is pathogenic or likely to be pathogenic or (b) CDKL5 deficiency, documentation of failure of at least two previous anticonvulsant therapies.
Age Restrictions	
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ZURZUVAE (zuranolone)

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## Products Affected

- ZURZUVAE

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

# ZYDELIG (idelalisib)

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## Products Affected

- ZYDELIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	History of toxic epidermal necrolysis with any drug, coadministration with strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, attestation therapy will be coadministered with rituximab, documentation of at least one previous line of systemic therapy, submission of pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZYKADIA (ceritinib)

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## Products Affected

- ZYKADIA ORAL TABLET

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





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