

## PRIOR AUTHORIZATION CRITERIA

This list is current as of 12/01/2021 and pertains to the following formularies:

2021 Independent Health's Medicare Advantage Individual Part D Formulary	Version 26
2021 Independent Health's Medicare Advantage Employer Group's Part D Formulary	Version 26

Independent Health requires you (or your physician) to get prior authorization for certain drugs. 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/Limits column on the formularies. This document contains the Prior Authorization requirements that are associated with our Medicare Advantage Part D formularies.

If you have any questions, please contact our Medicare Member Services Department at 1-800-665-1502 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., April 1<sup>st</sup> – September 30<sup>th</sup>: Monday through Friday from 8 a.m. to 8 p.m.

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

# ABILIFY MYCITE (aripiprazole with sensor)

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use, documentation of previous aripiprazole use (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval, the patient must have documentation of at least a one-month trial of generic aripiprazole solution, tablets, or orally-disintegrating tablets.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ACTHAR (corticotropin)

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## Products Affected

- ACTHAR

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. 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>	

# 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	

# ADEMPAS (riociguat)

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## Products Affected

- ADEMPAS

<b>PA Criteria</b>	<b>Criteria Details</b>
<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, submission of negative pregnancy test result for female patients of childbearing age, submission of patient weight and serum creatinine (to calculate estimated creatinine clearance).
<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>	

# ADENOSINE DEAMINASE DEFICIENCY

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## Products Affected

- REVCOVI

PA Criteria	Criteria Details
Exclusion Criteria	Severe thrombocytopenia
Required Medical Information	Diagnosis of covered use, submission of plasma ADA activity and platelet count.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. 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	

# AKYNZEO (netupitant/palonosetron)

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## Products Affected

- AKYNZEO ORAL

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

# ALECENSA (alectinib)

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## Products Affected

- ALECENSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved test confirming presence of ALK-positive tumor.
<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>	



# ALPHA-1-PROTEINASE INHIBITORS

## Products Affected

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

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, 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 new starts only. Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ALUNBRIG (brigatinib)

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## Products Affected

- ALUNBRIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of FDA-approved test confirming presence of ALK-positive tumor.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

## AMANTADINE EXTENDED-RELEASE PRODUCTS

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### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	End stage renal disease (creatinine clearance below 15 mL/min)
<b>Required Medical Information</b>	Diagnosis of covered use, documentation patient tried and failed immediate-release amantadine.
<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>	

# AMBISOME (amphotericin B liposomal injection)

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## Products Affected

- ABELCET
- AMBISOME
- *amphotericin b intravenous*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to infectious diseases
<b>Coverage Duration</b>	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 Medically-accepted Indications.
<b>Off Label Uses</b>	

# ANADROL-50 (oxymetholone)

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## Products Affected

- ANADROL-50

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Carcinoma of the prostate or breast in male patients, carcinoma of the breast in females with hypercalcemia, women who are or may become pregnant, nephrosis or the nephrotic phase of nephritis, severe hepatic dysfunction
<b>Required Medical Information</b>	Diagnosis of covered use, submission of CBC and liver function tests.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ARCALYST (rilonacept)

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## Products Affected

- ARCALYST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Active or chronic infection
<b>Required Medical Information</b>	Diagnosis of covered use, TB skin test result obtained within the past 12 months.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	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 Medically-accepted Indications.
<b>Off Label Uses</b>	

# ARIKAYCE (amikacin inhalation)

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## Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	Non-refractory Mycobacterium avium complex (MAC) lung disease
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	This medication is covered as a Part B benefit except for enrollees residing in a long-term care facility. PA applies to all when covered as a Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	

## AURYXIA (ferric citrate)

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### Products Affected

- AURYXIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Iron overload syndrome
<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>	1 year
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# 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 inhibitors or inducers. For advanced systemic mastocytosis indication only, platelet count below $50 \times 10^9/L$ .
<b>Required Medical Information</b>	Diagnosis of covered use. For gastrointestinal stromal tumor indication only, submission of test result confirming presence of PDGFRA exon 18 mutation. For advanced systemic mastocytosis indication only, submission of platelet count.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to allergy, hematology, 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>	

# BAFIERTAM (monomethyl fumarate)

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## Products Affected

- BAFIERTAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Hypersensitivity to dimethyl fumarate or diroximel fumarate, co-administration with dimethyl fumarate or diroximel fumarate
<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
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. For approval of Bafiertam, the patient must have tried and failed to have an adequate response to or had an intolerance to dimethyl fumarate.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# BALVERSA (erdafitinib)

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## Products Affected

- BALVERSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coadministration with strong CYP2C9 or CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved companion test showing susceptible FGFR2 or FGFR3 genetic alterations, prior chemotherapy regimen(s) 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# BEMPEDOIC ACID

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## 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.
<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 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## 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: corticosteroids, NSAIDs, antimalarials, or immunosuppressants.
<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>	

# BENZNIDAZOLE

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## Products Affected

- *benznidazole*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	2 years of age through 12 years of age
Prescriber Restrictions	Restricted to infectious diseases
Coverage Duration	60 days
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

# BIOLOGIC RESPONSE MODIFIERS

## Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS
- CIMZIA PREFILLED
- CIMZIA STARTER KIT
- CIMZIA SUBCUTANEOUS KIT 2 X 200 MG
- OTEZLA
- SIMPONI SUBCUTANEOUS SOLUTION AUTO-
- INJECTOR
- SIMPONI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- TREMFYA
- ZEPOSIA
- ZEPOSIA 7-DAY STARTER PACK
- ZEPOSIA STARTER KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For Zeposia for the treatment of multiple sclerosis, only diagnosis of covered use is required. For all other drugs managed by this policy and for Zeposia for indications other than multiple sclerosis, diagnosis of covered use, submission of previous therapies. For all drugs managed by this policy except Otezla and Zeposia, submission of baseline latent tuberculosis screening test (Mantoux tuberculin skin test [a.k.a. PPD test] or interferon-gamma release assay [IGRA]).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. With the exception of Zeposia for the treatment of multiple sclerosis only, for approval of a drug managed by this policy, the patient must have tried and failed to have an adequate response to or had an intolerance to at least two preferred agents (Cosentyx, Enbrel, Humira, Rinvoq, Skyrizi, Stelara, and Xeljanz/Xeljanz XR) for the indication submitted, where possible. For all drugs managed by this policy except Otezla and Zeposia, if TB screening test returns a positive result, coverage will be delayed until latent TB is treated. For re-authorization, yearly TB screening test or chest X-ray required for patients who live in, work in, or travel to areas where TB exposure is likely while on treatment or for those who have previously had a positive TB screening test.
<b>Indications</b>	All Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	



# BOSULIF (bosutinib)

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## Products Affected

- BOSULIF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of renal function testing. For accelerated or blast phase Ph+ CML, documentation of resistance or intolerance to at least one of the following prior therapies: imatinib, dasatinib, or nilotinib.
<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>	

## BRAFTOVI/MEKTOVI (encorafenib/binimetinib)

### Products Affected

- BRAFTOVI
- MEKTOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation, serum potassium, and serum magnesium. For metastatic melanoma, confirmation that encorafenib and binimetinib will be co-administered. For metastatic colorectal cancer, confirmation that encorafenib and cetuximab will be co-administered.
<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>	

# BRIVIACT (brivaracetam)

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## Products Affected

- BRIVIACT ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	4 years of age or older
Prescriber Restrictions	PA not required for neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# BRONCHITOL (mannitol powder for inhalation)

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## Products Affected

- BRONCHITOL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Documented Bronchitol Tolerance Test failure
<b>Required Medical Information</b>	Diagnosis of covered use, documentation patient has passed the Bronchitol Tolerance Test, attestation patient will not be using in combination with hypertonic (7%) sodium chloride nebulized solution.
<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 new starts only. For approval, the patient must have tried and failed to have an adequate response to or had an intolerance to hypertonic (7%) sodium chloride nebulized solution.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## BRUKINSA (zanubrutinib)

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### Products Affected

- BRUKINSA

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 prior chemotherapy regimen(s) 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# BUTALBITAL-CONTAINING PRODUCTS IN OLDER PATIENTS

## Products Affected

- ASCOMP-CODEINE
- *butalbital-acetaminophen oral tablet 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*
- PHRENILIN FORTE ORAL CAPSULE 50-300-40 MG
- TENCON ORAL TABLET 50-325 MG
- VANATOL LQ
- VTOL LQ
- ZEBUTAL ORAL CAPSULE 50-325-40 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	All 4 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, (3) documentation that the benefits of the drug outweigh the potential risks to the patient, and (4) documentation patient has tried and failed or have a contraindication to a preferred alternative such as ibuprofen or rizatriptan.
<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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## BYLVAY (odevixibat)

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### Products Affected

- BYLVAY
- BYLVAY (PELLETS)

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, attestation drug-induced pruritus has been ruled out.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to gastroenterology and hepatology
<b>Coverage Duration</b>	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 subsequent reauthorizations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## C1 ESTERASE INHIBITORS (for hereditary angioedema)

### Products Affected

- BERINERT
- HAEGARDA
- RUCONEST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of documentation that epinephrine will be immediately available in the event of an acute severe hypersensitivity reaction.
<b>Age Restrictions</b>	
<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>	



## CABLIVI (caplacizumab-yhdp)

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### Products Affected

- CABLIVI

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

# CABOMETYX (cabozantinib)

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## Products Affected

- CABOMETYX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Severe 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 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>	

# CALQUENCE (acalabrutinib)

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## Products Affected

- CALQUENCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients on proton pump inhibitors
<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 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>	

# CAPLYTA (lumateperone)

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## Products Affected

- CAPLYTA

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use, submission of previous therapies used for indication and liver function testing or Child-Pugh score.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to psychiatry
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval, the patient must have tried and failed to have an adequate response to or had an intolerance to aripiprazole and at least one other generic second-generation atypical antipsychotic (e.g., paliperidone, quetiapine, risperidone, etc.) or Latuda.
Indications	All Medically-accepted Indications.
Off Label Uses	

# CAPRELSA (vandetanib)

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## Products Affected

- CAPRELSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Congenital long QT syndrome, moderate or severe hepatic impairment, QTcF interval greater than 450 msec
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline serum potassium, calcium, magnesium, ALT, AST, bilirubin, TSH, creatinine clearance (or serum creatinine plus current patient weight), and ECG.
<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>	

## CARBAGLU (carglumic acid)

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### Products Affected

- CARBAGLU

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of plasma ammonia level.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

# CERDELGA (eliglustat)

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## Products Affected

- CERDELGA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients who are extensive or intermediate CYP2D6 metabolizers taking a strong CYP2D6 inhibitor with a strong or moderate CYP3A inhibitor, intermediate and poor CYP2D6 metabolizers taking a strong CYP3A inhibitor
<b>Required Medical Information</b>	Diagnosis of covered use, submission of CYP2D6 metabolizer status as detected by an FDA-cleared test for determining CYP2D6 genotype.
<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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# CESAMET (nabilone)

## Products Affected

- CESAMET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of documentation that patient has tried and failed to adequately respond to at least two conventional antiemetic therapies from different classes (5-HT3 receptor antagonists, substance P neurokinin 1 receptor antagonists).
<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 the medication is being administered related to cancer treatment and is a full replacement for intravenous administration of antiemetic therapy within 48 hours of cancer treatment, it is covered as a Part B benefit. To be eligible for Part B coverage, the prescribing physician must indicate this on the prescription. Otherwise it may be covered as a Part D benefit.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# CGRP INHIBITORS

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use. For treatment of migraine headache prevention, submission of migraine days per month from medical chart, documentation patient has tried and failed or has a contraindication to at least two preferred FDA-approved alternatives for migraine prophylaxis (propranolol, timolol, topiramate, valproic acid). For Nurtec for the treatment of acute migraine, 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>	Initially 3 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Continuation requires documentation of clinically relevant response to therapy. For approval of Nurtec for migraine headache prevention, the patient must have a diagnosis of episodic migraine, defined as fewer than 15 migraine days per month, and the patient must have tried and failed to have an adequate response to or had an intolerance to Aimovig and Ajovy. For approval of Emgality for migraine headache prevention, the patient must have tried and failed to have an adequate response to or had an intolerance to Aimovig and Ajovy. For Ajovy, a description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# 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>	
<b>Coverage Duration</b>	24 months
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## CHOLBAM (cholic acid)

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### Products Affected

- CHOLBAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	Restricted to hepatology, gastroenterology, and pediatric gastroenterology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

# COMETRIQ (cabozantinib)

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh class C)
Required Medical Information	Diagnosis of covered use.
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	

# COPIKTRA (duvelisib)

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## Products Affected

- COPIKTRA ORAL CAPSULE 15 MG, 25 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coadministration with strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of at least two prior therapies 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 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>	

# CORLANOR (ivabradine)

## Products Affected

- CORLANOR

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	PA applies to all. Continuation requires documentation of clinically relevant response to therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# COTELLIC (cobimetinib)

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## Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation, submission of left ventricular ejection fraction.
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	

# CRESEMBA (isavuconazonium)

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## Products Affected

- CRESEMBA ORAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Familial short QT syndrome, coadministration with strong CYP3A inhibitors or inducers
<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 hematology, infectious disease, and oncology.
<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>	

# CYSTADROPS (cysteamine)

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## Products Affected

- CYSTADROPS

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

# CYSTARAN (cysteamine)

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## Products Affected

- CYSTARAN

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

# DALFAMPRIDINE

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## Products Affected

- *dalfampridine er*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 serum creatinine, patient weight, and objective measurement of walking speed, 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>	Initially 3 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Re-authorization contingent upon documentation the patient has demonstrated an improvement in walking speed from baseline measure (or maintenance of improvement if patient has been on long-term therapy) since starting medication.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# DAURISMO (glasdegib)

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## Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<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>	

# DAYVIGO (lemborexant)

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## Products Affected

- DAYVIGO ORAL TABLET 10 MG, 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Narcolepsy
Required Medical Information	Diagnosis of covered use. Patient must have tried and failed to tolerate or had an inadequate response to two covered alternative therapies recommended by the American Academy of Sleep Medicine (doxepin, ramelteon, suvorexant, temazepam, triazolam, zolpidem) including one non-suvorexant therapy for sleep maintenance (doxepin, temazepam) if that is the diagnosis of covered use.
Age Restrictions	PA applies to patients 65 years of age or older. PA does not apply to patients 64 years of age or younger.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# DEFERASIROX

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Creatinine clearance less than 40 mL per min or serum creatinine more than 2 times the age-adjusted upper limit of normal, platelet count below $50 \times 10^9/L$
<b>Required Medical Information</b>	Diagnosis of covered use, submission of CBC, LFTs, serum creatinine, ferritin, and urine protein values, submission of patient weight, documentation that member has had yearly ophthalmic and auditory testing.
<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. For continuation, documentation of ferritin level within last 3 months and CBC, LFT, serum creatinine, urine protein value, patient weight, and ophthalmic and auditory testing have been performed within the last year.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# DIACOMIT (stiripentol)

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## Products Affected

- DIACOMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Moderate or severe renal impairment, moderate or severe hepatic impairment
<b>Required Medical Information</b>	Diagnosis of covered use, confirmation patient is also receiving clobazam.
<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. Monotherapy requests for Dravet syndrome will not be approved as there are no clinical data to support using stiripentol in this manner.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# DICLOFENAC 1% GEL

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## Products Affected

- *diclofenac sodium external gel*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery
<b>Required Medical Information</b>	Diagnosis of covered use, including the relief of pain of osteoarthritis of joints amenable to topical treatment, such as the knees and hands.
<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. Not evaluated for use on joints of the spine, hip, or shoulder and therefore requests for use on these areas will not be approved.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# DICLOFENAC 1.5% TOPICAL SOLUTION

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## Products Affected

- *diclofenac sodium external solution*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery
<b>Required Medical Information</b>	Diagnosis of covered use, including the relief of pain of osteoarthritis of the knees.
<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. Not FDA-approved for use on joints of the hands, spine, hip, or shoulder and therefore requests for use on these areas will not be approved.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

## DICLOFENAC 3% GEL

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### Products Affected

- *diclofenac sodium external gel*

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

# DICLOFENAC PATCH

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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>	

## DIFICID (fidaxomicin)

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### Products Affected

- DIFICID

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

## DIGOXIN IN OLDER PATIENTS

### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Current diagnosis of atrial fibrillation or congestive heart failure, submission of patient's current CrCl (mL/min) or current weight and serum creatinine level for the purposes of calculating CrCl with result greater than or equal to 30 mL/min. Patient must have tried and failed to respond adequately to 0.125 mg of digoxin.
<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. PA not required for doses less than or equal to 0.125 mg per day.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# DRONABINOL

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## Products Affected

- *dronabinol*
- SYNDROS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. If authorization is requested for treatment of nausea and vomiting associated with cancer therapy, documentation of previous conventional antiemetic therapies utilized is required.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. If the medication is being administered related to cancer treatment and is a full replacement for intravenous administration of antiemetic therapy within 48 hours of cancer treatment, it is covered as a Part B benefit. To be eligible for Part B coverage, the prescribing physician must indicate this on the prescription. If the medication is being requested for the use of anorexia associated with weight loss in patients with AIDS, approval may be covered under Part D.
Indications	All Medically-accepted Indications.
Off Label Uses	



# DUOBRII (halobetasol/tazarotene)

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## Products Affected

- DUOBRII

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	Diagnosis of covered use, submission of negative pregnancy test result for female patients of childbearing age, documentation patient tried and failed augmented betamethasone dipropionate, clobetasol, fluocinonide 0.1%, halobetasol, or another Class I ultra-high potency topical steroid.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to dermatology
<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>	

## DUOPA (carbidopa/levodopa enteral suspension)

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### Products Affected

- DUOPA ENTERAL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients taking non-selective monoamine oxidase inhibitors
<b>Required Medical Information</b>	Diagnosis of covered use, confirmation patient has a naso-jejunal tube for short-term administration or a PEG-J for long-term administration.
<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>	

# DUPIXENT (dupilumab)

## Products Affected

- DUPIXENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use. For atopic dermatitis, documentation of treatment with at least a moderate strength topical corticosteroid for at four weeks or have a contraindication to their use or therapy is not otherwise advisable. For moderate-to-severe asthma, either (1) documentation of eosinophilic subtype via serum or sputum eosinophil count or lung biopsy or (2) documentation asthma is moderate or severe and requires daily oral corticosteroid for control.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to allergy, dermatology, immunology, otorhinolaryngology, and pulmonology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Continuation requires documentation of a positive response to therapy. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# EGRIFTA (tesamorelin)

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## Products Affected

- EGRIFTA SUBCUTANEOUS SOLUTION RECONSTITUTED 1 MG
- EGRIFTA SV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, active malignancy, disruption of HPA axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation, or head trauma, use for weight loss
<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>	1 year
<b>Other Criteria</b>	PA applies to all. Continuation of therapy requests require confirmation that the patient has demonstrated a clinical improvement (or maintenance of improvement once achieved) from baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## EMFLAZA (deflazacort)

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### Products Affected

- EMFLAZA

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

# EMPAVELI (pegcetacoplan)

## Products Affected

- EMPAVELI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use confirmed by high-sensitivity flow cytometry, proof of vaccination against Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B or 2 weeks of antibacterial drug prophylaxis if the vaccines were administered within the last 2 weeks and therapy is required immediately, submission of lactate dehydrogenase level.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology, immunology, and nephrology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Because this medication is delivered subcutaneously through an infusion pump, it covered as a Part B benefit except for enrollees residing in a long-term care facility. PA applies to all when covered as a Part D benefit.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## EMSAM (selegiline transdermal)

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### Products Affected

- EMSAM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pheochromocytoma
<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>	1 year
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## ENDOTHELIN RECEPTOR ANTAGONISTS

### Products Affected

- *ambrisentan*
- *bosentan*
- OPSUMIT
- TRACLEER ORAL TABLET SOLUBLE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy. For ambrisentan, idiopathic pulmonary fibrosis and moderate or severe hepatic impairment.
<b>Required Medical Information</b>	Diagnosis of covered use, pregnancy status for female patients of childbearing potential, submission of baseline AST, ALT, and bilirubin. For ambrisentan and Opsumit, submission of baseline hemoglobin level.
<b>Age Restrictions</b>	For ambrisentan and Opsumit, 18 years of age or older. For bosentan, 3 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>	



# ENSPRYNG (satralizumab-mwge)

## Products Affected

- ENSPRYNG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Active hepatitis B infection, active or untreated latent tuberculosis (TB)
<b>Required Medical Information</b>	Diagnosis of covered use, submission of confirmation patient has anti-aquaporin-4 (AQP4) antibody-positive NMOSD, submission of baseline latent TB screening test (Mantoux tuberculin skin test [a.k.a. PPD test] or interferon-gamma release assay [IGRA]), attestation patient does not have any active infection.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to neurology and ophthalmology
<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>	

## EPCLUSA (sofosbuvir/velpatasvir)

### Products Affected

- EPCLUSA ORAL TABLET 200-50 MG, 400-100 MG
- *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>	

# EPIDIOLEX (cannabidiol)

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## Products Affected

- EPIDIOLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	1 year 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>	

## ERIVEDGE (vismodegib)

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### Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ERLOTINIB

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## Products Affected

- *erlotinib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For non-small cell lung cancer, submission of FDA-approved test confirming presence of EGFR exon 19 deletion or exon 21 L858R substitution mutation and prior treatments used.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ERYTHROPOIETINS

## Products Affected

- ARANESP (ALBUMIN FREE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 300 MCG/ML, 40 MCG/ML, 60 MCG/ML
- ARANESP (ALBUMIN FREE) INJECTION SOLUTION PREFILLED SYRINGE
- EPOGEN INJECTION SOLUTION 10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML
- PROCIT
- 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 or hematocrit level, serum iron, total iron-binding capacity (TIBC), and transferrin within 30 days of request date, documentation that the patient does not have uncontrolled hypertension.
<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. For approval of Epogen or Procrit, the patient must have tried and failed to have an adequate response to or had an intolerance to Retacrit. 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>	

## ESTROGENS IN OLDER PATIENTS

### Products Affected

- *amabelz*
- ANGELIQ
- CLIMARA PRO
- COMBIPATCH
- DIVIGEL
- *dotti*
- DUAVEE
- ELESTRIN
- *estradiol oral*
- *estradiol transdermal*
- *estradiol-norethindrone acet*
- EVAMIST
- *fyavolv*
- *jinteli*
- *lopreeza*
- *lyllana*
- MENEST ORAL TABLET 0.3 MG, 0.625 MG, 1.25 MG
- MENOSTAR
- *mimvey*
- *mimvey lo*
- *norethindrone-eth estradiol*
- PREFEST
- PREMARIN ORAL
- PREMPHASE
- PREMPRO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	All 5 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation the provider is aware of the associated risks including breast and endometrial cancer and an increased risk of clot formation, (3) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, (4) documentation that the benefits of the drug outweigh the potential risks to the patient, and (5) for all indications except treatment of vasomotor symptoms of menopause, documentation of a trial and failure or contraindication to two preferred alternatives is required (for vulvar/vaginal atrophy, topical estradiol and conjugated estrogens, for osteoporosis, alendronate, ibandronate, and raloxifene).
<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>	PA not required for gynecology
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<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 Medically-accepted Indications.
<b>Off Label Uses</b>	



# EVEROLIMUS

## Products Affected

- AFINITOR DISPERZ
- AFINITOR ORAL TABLET 10 MG
- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *everolimus oral tablet soluble*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use. For renal cell carcinoma, documented prior use of sunitinib or sorafenib. For postmenopausal women with advanced hormone receptor-positive, HER-2 negative breast cancer, documentation of treatment failure with letrozole or anastrozole and confirmation drug is being used in combination with exemestane.
<b>Age Restrictions</b>	1 year of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology, 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>	

# EVRYSDI (risdiplam)

## Products Affected

- EVRYSDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Hepatic impairment
<b>Required Medical Information</b>	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, attestation patient does not have hepatic impairment, submission of pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	
<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. Maintenance of or improvement in any motor score or function compared to baseline will be required for reauthorization.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## FARYDAK (panobinostat)

### Products Affected

- FARYDAK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment, recent myocardial infarction or unstable angina
<b>Required Medical Information</b>	Diagnosis of covered use, documentation that the patient has received at least 2 prior regimens including bortezomib and an immunomodulatory agent, submission of baseline ECG documenting QTcF is less than 450 msec prior to initiation, submission of baseline serum electrolytes including potassium and magnesium, submission of baseline CBC documenting platelet count is at least $100 \times 10^9/L$ and absolute neutrophil count is at least $1.5 \times 10^9/L$ , submission of baseline liver function tests including AST, ALT, and total bilirubin. For multiple myeloma, confirmation drug will be given with dexamethasone and bortezomib.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	Initially 8 cycles. An additional 8 cycles if clinical benefit seen.
<b>Other Criteria</b>	PA applies to new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# 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, verified claim or documentation of patient's morphine-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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# FERRIPROX (deferiprone)

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## Products Affected

- *deferiprone*
- FERRIPROX ORAL SOLUTION
- FERRIPROX ORAL TABLET 1000 MG

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

# FILGRASTIM

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use.
<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 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 both Nivestym and 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# FINTEPLA (fenfluramine)

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## Products Affected

- FINTEPLA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Hepatic impairment, moderate or severe renal impairment, administration of monoamine oxidase inhibitors within 14 days of initiation
<b>Required Medical Information</b>	Diagnosis of covered use, submission of patient weight and serum creatinine (to calculate estimated creatinine clearance) and 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>	

## FIRDAPSE (amifampridine)

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### Products Affected

- FIRDAPSE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	History of seizure
<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
<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>	



# 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 previous systemic therapies used to treat renal cell carcinoma including the failure of at least one prior VEGFR inhibitor, pregnancy status for female patients of childbearing potential, confirmation patient has not had episodes of symptomatic heart failure or unstable angina, a myocardial infarction, an arterial thrombotic event, or a significant bleeding event in the 6 months preceding the prior authorization request.
<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>	

## 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
<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 package insert 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>	
<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>	

# GATTEX (teduglutide)

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## Products Affected

- GATTEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline laboratory values including bilirubin, alkaline phosphatase, lipase, and amylase obtained within 6 months prior to starting therapy. For adults 18 years of age or older only, submission of documentation that a colonoscopy (or alternate imaging) of the entire colon with polyp removal was performed within 6 months prior to starting treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Continuation of therapy requires a colonoscopy result within 6 months of PA expiration.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# GAVRETO (pralsetinib)

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## Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of FDA-approved test confirming presence of RET gene fusion or mutation, attestation patient does not have uncontrolled hypertension, pregnancy status for female patients of childbearing potential.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

## GILOTRIF (afatinib)

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### Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. For non-small cell lung cancer, submission of positive FDA-approved test for non-resistant epidermal growth factor receptor mutations. For metastatic, squamous NSCLC, documentation of progression after platinum-based chemotherapy.
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	

## GnRH ANTAGONISTS

### Products Affected

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

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

# GROWTH HORMONE

## Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- NORDITROPIN FLEXPRO
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20
- NUTROPIN AQ NUSPIN 5
- OMNITROPE
- SAIZEN
- ZOMACTON

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. Requests for continuation of therapy require annual submission of updated IGF-1 level, bone age if applicable based on patient age and diagnosis, height, weight, creatinine clearance (or serum creatinine), and fasting glucose.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# HARVONI (ledipasvir/sofosbuvir)

## Products Affected

- HARVONI ORAL PACKET
- HARVONI ORAL TABLET 45-200 MG, 90-400 MG

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, submission of eGFR, 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>	



# HEMANGEOL (propranolol oral solution)

## Products Affected

- HEMANGEOL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Premature infant with corrected age less than 5 weeks, body weight less than 2 kg, asthma or history of bronchospasm, bradycardia (less than 80 beats per minute), greater than first degree heart block, decompensated heart failure, blood pressure less than 50/30 mmHg, pheochromocytoma
<b>Required Medical Information</b>	Diagnosis of covered use, submission of current weight.
<b>Age Restrictions</b>	5 weeks of age up to 1 year of age
<b>Prescriber Restrictions</b>	Restricted to otolaryngology, pediatric otolaryngology, and pediatric ophthalmology
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	PA applies to all. Treatment must be initiated between the ages of 5 weeks and 5 months.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# HETLIOZ (tasimelteon)

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## Products Affected

- HETLIOZ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to neurology and sleep specialty
<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>	

# HIGH-RISK DRUGS IN OLDER PATIENTS

## Products Affected

- *benztropine mesylate oral*
- *dipyridamole oral*
- *disopyramide phosphate oral*
- *guanfacine hcl er*
- *guanfacine hcl oral*
- *indomethacin er*
- *indomethacin oral capsule 25 mg, 50 mg*
- *ketorolac tromethamine oral*
- *methyldopa oral*
- *methyldopa-hydrochlorothiazide*
- *nifedipine oral*
- NORPACE CR
- *phenobarbital oral elixir*
- *phenobarbital oral tablet*
- *thioridazine hcl oral*
- *trihexyphenidyl hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	All 3 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, and (3) documentation that the benefits of the drug outweigh the potential risks to the patient.
<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>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# HYDROXYZINE IN OLDER PATIENTS

## Products Affected

- *hydroxyzine hcl oral tablet*
- *hydroxyzine pamoate oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	All 3 of the following criteria must be met: (1) diagnosis of anxiety or pruritus, (2) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, and (3) documentation that the benefits of the drug outweigh the potential risks to the patient. For pruritus, documentation patient has tried and had an inadequate response to a second-generation antihistamine. For anxiety, documentation patient has tried and failed or 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## IBRANCE (palbociclib)

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### Products Affected

- IBRANCE

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

# ICATIBANT

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## Products Affected

- *icatibant acetate*

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 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	

# ICLUSIG (ponatinib)

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## Products Affected

- ICLUSIG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Newly diagnosed chronic phase CML
<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 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>	

## IDHIFA (enasidenib)

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### Products Affected

- IDHIFA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved test confirming presence of IDH2 mutation.
<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>	



# IDIOPATHIC PULMONARY FIBROSIS TREATMENTS

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## Products Affected

- ESBRIET
- OFEV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	For Esbriet, patients with end stage renal disease on dialysis
<b>Required Medical Information</b>	Diagnosis of covered use. Submission of baseline AST, ALT, and bilirubin. For Esbriet, submission of patient's current weight and serum creatinine level for the purposes of calculating creatinine clearance.
<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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ILARIS

## Products Affected

- ILARIS SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Positive TB test
<b>Required Medical Information</b>	Diagnosis of covered use, submission of TB skin test result obtained within past 12 months, documentation that patient has received all recommended vaccinations as appropriate including pneumococcal vaccine and inactivated influenza vaccine prior to initiation of therapy. For CAPS, confirmed diagnosis including genetic testing for variant FCAS or MWS and documentation patient is not receiving concomitant TNF inhibitor therapy. For SJIA, submission of CBC including platelet count and confirmed diagnosis defined by prominence of systemic and inflammatory features including spiking fevers, rash, swelling and inflammation of lymph nodes, liver, and spleen, and high white blood cell and platelet counts.
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	For SJIA, restricted to rheumatology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. Continuation of therapy requires submission of updated TB skin test result obtained within the past 12 months and objective documentation of positive patient response or maintenance of response. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	

# IMBRUVICA (ibrutinib)

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## Products Affected

- IMBRUVICA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Severe hepatic impairment (Child-Pugh class C)
<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 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>	

# IMCIVREE (setmelanotide)

## Products Affected

- IMCIVREE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, including submission of genetic testing showing homozygous or compound heterozygous gene variants in POMC, PCSK1, or LEPR genes interpreted as pathogenic, likely pathogenic, or of uncertain clinical significance and body mass index (BMI) greater than 30 kg/m <sup>2</sup> in adults or greater than the 97th percentile in children.
<b>Age Restrictions</b>	6 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initially 16 weeks, then 1 year
<b>Other Criteria</b>	PA applies to all. For re-authorization at the 16-week point, submission of clinical documentation attesting to at least 5% weight loss from baseline (or at least 5% BMI from baseline in patients with continued growth potential) is required. Not FDA-approved for other types or causes of obesity, and therefore requests for these uses will not be approved.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# IMMUNE GLOBULIN

## Products Affected

- BIVIGAM INTRAVENOUS SOLUTION 5 GM/50ML
- CARIMUNE NF INTRAVENOUS SOLUTION RECONSTITUTED 12 GM, 6 GM
- CUVITRU SUBCUTANEOUS SOLUTION 1 GM/5ML, 2 GM/10ML, 4 GM/20ML, 8 GM/40ML
- FLEBOGAMMA DIF
- GAMASTAN S/D
- GAMMAGARD
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML, 10 GM/100ML, 20 GM/200ML, 5 GM/50ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 20 GM/400ML, 5 GM/100ML, 5 GM/50ML
- GAMUNEX-C
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 10 GM/100ML, 10 GM/200ML, 2 GM/20ML, 2.5 GM/50ML, 20 GM/200ML, 25 GM/500ML, 5 GM/100ML, 5 GM/50ML
- PRIVIGEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	IgA-deficient patients with antibodies against IgA and a history of hypersensitivity. For IM forms, severe thrombocytopenia or coagulation disorder that would contraindicate an IM injection.
<b>Required Medical Information</b>	Diagnosis of covered use. For ITP, submission of platelet count. For CLL, IgG level less than 600 mg/dL and recent history of serious bacterial infection requiring either oral or IV antibiotic therapy. For CIDP, unequivocal diagnosis and documentation patient is refractory or intolerant to prednisone or azathioprine given in therapeutic doses over at least 3 months. For passive immunization against varicella, confirmation that the patient is immunosuppressed and cannot receive varicella-zoster immune globulin.
<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.

PA Criteria	Criteria Details
<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>	

## INBRIJA (levodopa inhalation)

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### Products Affected

- INBRIJA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Currently on nonselective monoamine oxidase inhibitor or has taken one within last 2 weeks, asthma, COPD, or other chronic underlying lung disease
<b>Required Medical Information</b>	Diagnosis of covered use, prescription claim or documentation from physician showing patient is currently taking carbidopa/levodopa, documentation of at least one other medication used for "off" episodes (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 have documentation of a trial of at least one other medication for the treatment of "off" episodes including a dopamine agonist (e.g., pramipexole, ropinirole), a COMT inhibitor (e.g., entacapone), or a monoamine oxidase B inhibitor (e.g., rasagiline, selegiline).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# INJECTABLE TESTOSTERONE

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of serum testosterone level, documentation that patient has been evaluated for the presence of breast and prostate cancer prior to initiation of therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	PA not required for urology or endocrinology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all except when prescribed by urology or endocrinology. 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>	

# INLYTA (axitinib)

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## Products Affected

- INLYTA

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 laboratory values including baseline ALT, AST, bilirubin, submission of baseline blood pressure reading.
<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>	

## 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 complete blood count, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to new starts only. Continuation of initial therapy beyond 6 months requires (a) confirmation of no disease progression and (b) attestation the patient is having no serious adverse events from treatment.
Indications	All Medically-accepted Indications.
Off Label Uses	

## INREBIC (fedratinib)

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### Products Affected

- INREBIC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment, unavoidable concomitant use of moderate or strong CYP3A4 inducers or dual CYP3A4/CYP2C19 inhibitors
<b>Required Medical Information</b>	Diagnosis of covered use, submission of thiamine level and platelet count.
<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. 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>	

# INTERLEUKIN-5 ANTAGONISTS (severe eosinophilic asthma)

## Products Affected

- FASENRA
- FASENRA PEN
- NUCALA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use. For eosinophilic asthma, documentation that patient's symptoms are poorly controlled with inhaled corticosteroids, submission of pulmonary function test results including FEV1, frequency of inhaled short-acting beta2-agonist therapy, frequency of daily and nighttime symptoms and exacerbations, and effect of exacerbations on activity. For Nucala (eosinophilic asthma diagnosis only), submission of blood eosinophil count documenting 150 cells/mcL obtained within 6 weeks of therapy initiation or 300 cells/mcL within 12 months of therapy initiation. For Fasentra, submission of laboratory confirmation of eosinophilic asthma diagnosis (serum eosinophil count, sputum eosinophil count, or lung biopsy).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to allergy, pulmonology, rheumatology, and immunology
<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>PA Criteria</b>	<b>Criteria Details</b>
<b>Off Label Uses</b>	

# INTRANASAL SEIZURE MEDICATIONS

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute narrow-angle glaucoma
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	
<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>	

## INTRON A (interferon alfa-2b)

### Products Affected

- INTRON A

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Autoimmune hepatitis, decompensated liver disease
<b>Required Medical Information</b>	Diagnosis of covered use, submission of triglyceride levels, hemoglobin, complete and differential white blood cell counts, platelet count, serum electrolytes, ALT, serum bilirubin level, serum albumin level, and TSH. For malignant melanoma, submission of the date of surgical treatment. For AIDS-related Kaposi's sarcoma, submission of total CD4 count. For chronic hepatitis C, submission of HCV RNA, prothrombin time, baseline serum creatinine level, and laboratory confirmation of hepatitis C virus, and documentation of previous response to therapy if applicable. For chronic hepatitis B, submission of prothrombin time and documentation patient has been serum HBsAG positive for at least 6 months with evidence of HBV replication.
<b>Age Restrictions</b>	For hairy cell leukemia, malignant melanoma, follicular lymphoma, condylomata acuminata, or AIDS-related Kaposi's sarcoma, 18 years of age or older. For chronic hepatitis C, 3 years of age or older. For chronic hepatitis B, 1 year of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Depends on covered use. See "Other Criteria" section.



PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>PA applies to new starts only. For hairy cell leukemia, the coverage duration is 6 months. For condylomata acuminata, 3 weeks per course, and at least 12 weeks must pass in between multiple courses in order to be reauthorized. For Kaposi's sarcoma, 16 weeks. For hepatitis B infection, 24 weeks. For all other indications/uses, 1 year. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# INVEGA HAFYERA (paliperidone 6-month injectable suspension)

## Products Affected

- INVEGA HAFYERA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Dementia-related psychosis
<b>Required Medical Information</b>	Diagnosis of covered use, documentation of at least 4 months' treatment with 1-month paliperidone palmitate extended-release injectable suspension or at least one 3-month injection of 3-month paliperidone palmitate extended-release injectable suspension.
<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>	

# INVEGA TRINZA (paliperidone 3-month injectable suspension)

## Products Affected

- INVEGA TRINZA INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Dementia-related psychosis
<b>Required Medical Information</b>	Diagnosis of covered use, documentation of at least 4 months' treatment with 1-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>	

## IRESSA (gefitinib)

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### Products Affected

- IRESSA

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

## ISTURISA (osilodrostat)

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### Products Affected

- ISTURISA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, attestation pituitary gland surgery is not an option for the patient or has not been curative, submission of baseline serum potassium and magnesium levels.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Continuation requires documentation of clinically relevant response to therapy, including, but not limited to urine free cortisol level.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ITRACONAZOLE

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## Products Affected

- *itraconazole oral*
- TOLSURA

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

# JAKAFI (ruxolitinib)

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## Products Affected

- JAKAFI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For myelofibrosis, a platelet count less than $50 \times 10^9/L$ with either concomitant estimated creatinine clearance between 15 and 59 mL/min, end stage renal disease not on dialysis, or any degree of hepatic impairment
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline platelet count, ALT, AST, and bilirubin, submission of creatinine clearance or current body weight with serum creatinine for calculation of estimated creatinine clearance. For polycythemia vera, documented intolerance or inadequate response to hydroxyurea.
<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>	

## JUXTAPID (lomitapide)

### Products Affected

- JUXTAPID

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, moderate or severe hepatic impairment (Child-Pugh class B or C), active liver disease
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline lab values including ALT, AST, alkaline phosphatase, total bilirubin, baseline LDL-C, total cholesterol (TC), apoB, and non-HDL-C, pregnancy status for female patients of childbearing potential, submission of renal indices, documentation of contraindication to or treatment failure with evolocumab.
<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 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# JYNARQUE (tolvaptan)

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## Products Affected

- JYNARQUE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	History of signs or symptoms of significant liver impairment or injury (not including uncomplicated polycystic liver disease), uncorrected abnormal blood sodium concentrations, inability to sense or respond to thirst, hypovolemia, uncorrected urinary outflow obstruction, anuria
<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 nephrology
<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>	

## KALYDECO (ivacaftor)

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### Products Affected

- KALYDECO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of cystic fibrosis mutation test result and baseline ALT and AST.
<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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

## KESIMPTA (ofatumumab)

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### Products Affected

- KESIMPTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Active HBV infection
<b>Required Medical Information</b>	Diagnosis of covered use, attestation patient has undergone screening for hepatitis B virus and quantitative serum immunoglobulins and there is no active infection, 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 neurology
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to all. For approval of Kesimpta, the patient must have tried and failed to have an adequate response to or had an intolerance to Ocrevus (ocrelizumab).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# 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>	

## KEVEYIS (dichlorphenamide)

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### Products Affected

- KEVEYIS

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of high dose aspirin, severe pulmonary disease limiting compensation to metabolic acidosis, hepatic insufficiency
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initially 2 months, then 1 year
Other Criteria	PA applies to all. Documentation of patient's response at 2 months is required for continuation of approval.
Indications	All Medically-accepted Indications.
Off Label Uses	

## KISQALI (ribociclib)

### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Congenital long QT syndrome, moderate or severe hepatic impairment, QTcF interval greater than 450 msec, uncorrected hypokalemia or hypomagnesemia, patients on rifampin, phenytoin, or carbamazepine
<b>Required Medical Information</b>	Diagnosis of covered use, submission of genetic tumor testing showing that the primary tumor type is HR-positive, HER2-negative, confirmation that the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant, submission of baseline liver function tests, ECG, serum electrolytes, and CBC.
<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>	

# KORLYM (mifepristone)

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## Products Affected

- KORLYM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, female patient with a history of unexplained vaginal bleeding, endometrial hyperplasia with atypia, or endometrial carcinoma, patients on concurrent long-term corticosteroid therapy, simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline serum potassium, serum creatinine, patient weight, 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 Medically-accepted Indications.
<b>Off Label Uses</b>	



## KOSELUGO (selumetinib)

### Products Affected

- KOSELUGO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of left ventricular ejection fraction, Child-Pugh score or liver function testing results, and pregnancy status for female patients of childbearing potential.
<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>	Initially 6 months, then 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. Continuation of initial therapy beyond 6 months requires (a) documentation of any positive clinical response and (b) attestation the patient is having no serious adverse events to treatment.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## KUVAN (sapropterin)

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### Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of blood phenylalanine level.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Submission of blood phenylalanine level required for reauthorization.
Indications	All Medically-accepted Indications.
Off Label Uses	

## KYNMOBI (apomorphine film)

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### Products Affected

- KYNMOBI
- KYNMOBI TITRATION KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, attestation patient is experiencing "off" episodes despite carbidopa/levodopa therapy.
Age Restrictions	
Prescriber Restrictions	PA not required for neurology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

## LAMPIT (nifurtimox)

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### Products Affected

- LAMPIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	17 years of age or younger
Prescriber Restrictions	Restricted to infectious diseases
Coverage Duration	60 days
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

# LENVIMA (lenvatinib)

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline blood pressure showing blood pressure is controlled.
<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>	

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

# LIDOCAINE TRANSDERMAL PATCHES

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## Products Affected

- *lidocaine external patch 5 %*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. FDA-approved only for postherpetic neuralgia. Requests for other indications will not be approved.
Indications	All FDA-approved Indications.
Off Label Uses	

## LONG-ACTING SOMATOSTATIN ANALOGS

### Products Affected

- SOMATULINE DEPOT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, documentation of baseline serum GH, IGF-1, TSH, and blood glucose levels. For acromegaly, degree of control of clinical acromegaly symptoms.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to endocrinology and oncology
<b>Coverage Duration</b>	Initially 3 months, then up to 1 year
<b>Other Criteria</b>	PA applies to new starts only. Continuation of therapy requires documentation of a positive clinical response. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# LONSURF (trifluridine/tipiracil)

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## Products Affected

- LONSURF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Moderate or severe hepatic impairment
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline CBC, absolute neutrophil count, ALT, AST, and bilirubin, documentation of KRAS status.
<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>	

# LORBRENA (lorlatinib)

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## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved test confirming presence of ALK-positive tumor, 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>	

# LUCEMYRA (lofexidine)

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## Products Affected

- LUCEMYRA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Congenital long QT syndrome, severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure
<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>	14 days
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## LUMAKRAS (sotorasib)

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### Products Affected

- LUMAKRAS

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 result confirming presence of KRAS G12C mutations, submission of previous systemic treatment(s) tried.
<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>	

# LUPKYNIS (voclosporin)

## Products Affected

- LUPKYNIS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment, unavoidable concomitant use of strong CYP3A4 inhibitors, concomitant use of cyclophosphamide
<b>Required Medical Information</b>	Diagnosis of covered use, attestation patient will be taking concurrently with mycophenolate mofetil and corticosteroids, submission of estimated glomerular filtration rate (eGFR), pregnancy status for female patients of childbearing potential. If the patients eGFR is less than or equal to 45 mL/min/1.73 m <sup>2</sup> , attestation that prescriber believes benefits of therapy outweigh the potential risks to the patient.
<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 tried and failed to have an adequate response to or had an intolerance/contraindication to Benlysta (belimumab). Continuation at the 1-year mark requires documentation of clinically relevant response to therapy and attestation that prescriber believes benefits of continuing therapy outweigh the potential risks to the patient.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# LYBALVI (olanzapine/samidorphan)

## Products Affected

- LYBALVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Dementia-related psychosis, coadministration with opioids 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 (greater than or equal to a 7% gain from baseline body weight) while using olanzapine.
<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. 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>	

# LYNPARZA (olaparib)

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## Products Affected

- LYNPARZA ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved test confirming presence of applicable mutations depending on cancer type as necessary, submission of baseline CBC.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology, 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>	

## MAVENCLAD (cladribine)

### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Current malignancy, pregnancy, HIV or other active chronic infection (e.g., hepatitis or tuberculosis), lymphocyte count below normal limit before first course or less than 800 cells/microliter before second course, creatinine clearance below 60 mL/min, Child-Pugh score greater than 6
<b>Required Medical Information</b>	Diagnosis of covered use, pregnancy status for female patients of childbearing potential, submission of lymphocyte count, submission of patient weight and serum creatinine (to calculate estimated creatinine clearance).
<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. After the completion of 2 treatment courses (2 years' treatment), additional treatment courses are not recommended over the following 2 years because of malignancy risk. Re-initiating treatment after those 2 years have passed has not been studied. Requests for therapy for a combined total of greater than 2 years will not be approved.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



## MAVYRET (glecaprevir/pibrentasvir)

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### Products Affected

- MAVYRET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Severe hepatic impairment (Child-Pugh class C), patients on 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>	

# MECASERMIN

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## Products Affected

- INCRELEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to endocrinology and nephrology
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	PA applies to all. Requests for continuation of therapy require annual submission of updated IGF-1 and growth hormone levels.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## MEGESTROL IN OLDER PATIENTS

### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	All 4 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation the provider is aware of the associated risks of megestrol including an increased risk of thrombotic events and death, (3) documentation provider is aware medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, (4) documentation that the benefits of the drug outweigh the potential risks to the patient.
<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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## MEKINIST (trametinib)

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### Products Affected

- MEKINIST

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

# METHAMPHETAMINE

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## Products Affected

- *methamphetamine hcl*

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

# METHOTREXATE INJECTABLE (SUBCUTANEOUS)

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, documentation of intolerance or inadequate response to oral or non-subcutaneous injectable forms of methotrexate.
Age Restrictions	
Prescriber Restrictions	Restricted to rheumatology and dermatology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

# METHYLTESTOSTERONE

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## Products Affected

- METHITEST
- *methyltestosterone oral*

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

# MIGLUSTAT

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## Products Affected

- *miglustat*

PA Criteria	Criteria Details
Exclusion Criteria	Severe renal impairment (CrCl less than 30 mL/min)
Required Medical Information	Diagnosis of covered use, documentation that enzyme replacement is not a therapeutic option.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	



# MODANIFIL AND DERIVATIVES

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## Products Affected

- *armodafinil*
- *modafinil*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	17 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

# MYALEPT (metreleptin)

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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. Continuation of approval requires submission of patient weight, updated HbA1c, fasting glucose, and fasting triglyceride levels.
Indications	All Medically-accepted Indications.
Off Label Uses	

## MYCAPSSA (otcreotide)

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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	

## MYFEMBREE (relugolix/estradiol/norethindrone)

### Products Affected

- MYFEMBREE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, known liver impairment or disease, known osteoporosis, undiagnosed abnormal uterine bleeding, women at increased risk of or current/a history of thrombotic or thromboembolic disorders (including women over 35 years of age who smoke and women with uncontrolled hypertension), current/history of breast cancer or other hormone-sensitive cancer
<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>	
<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>	

# MYTESI (crofelemer)

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## Products Affected

- MYTESI

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 new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# 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	

# NATPARA (parathyroid hormone)

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## Products Affected

- NATPARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation that (albumin-corrected) serum calcium is greater than 7.5 mg/dL and confirmation that 25-hydroxyvitamin D stores are sufficient.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

# NERLYNX (neratinib)

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## Products Affected

- NERLYNX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with proton pump inhibitors
<b>Required Medical Information</b>	Diagnosis of covered use, submission of genetic tumor testing showing that the primary tumor type is HR-positive, HER2-positive, confirmation member has completed adjuvant trastuzumab-based therapy or will be using in combination with capecitabine, submission of baseline liver function tests, pregnancy status for female patients of childbearing potential.
<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>	



# NEXAVAR (sorafenib)

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## Products Affected

- NEXAVAR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<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 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>	

# NINLARO (ixazomib)

## Products Affected

- NINLARO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, documentation that medication will be administered concomitantly with lenalidomide and dexamethasone, documentation of prior therapy regimen for multiple myeloma, submission of baseline platelet count and absolute neutrophil count.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	Initially 3 months, then 1 year
<b>Other Criteria</b>	PA applies to new starts only. For continuation, documentation of platelet count greater than 30,000/mm <sup>3</sup> , ANC greater than 500/mm <sup>3</sup> , and Grade 1 or lower non-hematological toxicities (including rash, peripheral neuropathies) required.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# NITISINONE

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initially 6 months, then 1 year
Other Criteria	PA applies to all. Submission of liver function tests, urine succinylacetone levels, alpha-fetoprotein level, serum tyrosine level, serum phenylalanine level required for reauthorization.
Indications	All Medically-accepted Indications.
Off Label Uses	

# NORTHERA (droxidopa)

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## Products Affected

- *droxidopa*

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

# 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
<b>Required Medical Information</b>	Diagnosis of covered use, submission of ECG (specifically QT interval).
<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 as this is considered an off-label use.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## NUPLAZID (pimavanserin)

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### Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis unrelated to Parkinson's disease psychosis
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

## OCALIVA (obeticholic acid)

### Products Affected

- OCALIVA ORAL TABLET 10 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Complete biliary obstruction, decompensated cirrhosis (Child-Pugh B or C) or prior decompensation event, compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
<b>Required Medical Information</b>	Diagnosis of covered use, documentation either (1) drug will be used in combination with ursodeoxycholic acid (UDCA) and UDCA has been used for 1 year or (2) patient had intolerance to UDCA, submission of baseline LFTs including ALP and total bilirubin, attestation patient does not have evidence of portal hypertension and has not had a prior decompensation event.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initially 3 months, then 1 year
<b>Other Criteria</b>	PA applies to all. Submission of ALP obtained within the previous 3 months required for continuation of therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## ODOMZO (sonidegib)

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### Products Affected

- ODOMZO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<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>	



## ONUREG (azacitidine)

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### Products Affected

- ONUREG

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

# ORENITRAM (treprostinil)

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## Products Affected

- ORENITRAM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Moderate or severe (Child-Pugh class B or C) 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 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>	

# ORGOVYX (relugolix)

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## Products Affected

- ORGOVYX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<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 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>	

## ORIAHNN (elagolix/estradiol/norethindrone)

### Products Affected

- ORIAHNN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy, known liver impairment or disease, known osteoporosis, undiagnosed abnormal uterine bleeding, women at increased risk of or current/a history of thrombotic or thromboembolic disorders (including women over 35 years of age who smoke and women with uncontrolled hypertension), current/history of breast cancer or other hormone-sensitive cancer
<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>	
<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>	

# ORILISSA (elagolix)

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## Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy, severe hepatic impairment (Child-Pugh class C), known osteoporosis
<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 endocrinology and gynecology
<b>Coverage Duration</b>	Up to 24 months based on liver function and coexisting dyspareunia. See "Other Criteria" section.
<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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## ORKAMBI (lumacaftor/ivacaftor)

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### Products Affected

- ORKAMBI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, documentation that the patient is homozygous for the F508del mutation in the CFTR gene provided from an FDA-cleared CF mutation test, attestation baseline and follow-up ophthalmologic exams will be performed in pediatric patients starting on therapy.
<b>Age Restrictions</b>	2 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 new starts only.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## ORLADEYO (berotralstat)

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### Products Affected

- ORLADEYO

PA Criteria	Criteria Details
Exclusion Criteria	End-stage renal disease
Required Medical Information	Diagnosis of covered use.
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval, the patient must have tried and failed to have an adequate response to or had an intolerance to Takhzyro.
Indications	All Medically-accepted Indications.
Off Label Uses	

## OXBRYTA (voxelotor)

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### Products Affected

- OXBRYTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Hemoglobin greater than 10.5 g/dL
<b>Required Medical Information</b>	Diagnosis of covered use, submission of hemoglobin level.
<b>Age Restrictions</b>	12 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	PA applies to all. Continuation of therapy requests require objective documentation from the prescriber that the patient's hemoglobin level has increased.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# OXERVATE (cenegermin-bkbj)

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## Products Affected

- OXERVATE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Restricted to optometry and ophthalmology
<b>Coverage Duration</b>	8 weeks
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# PALYNZIQ (pegvaliase-pqpz)

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## Products Affected

- PALYNZIQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of blood phenylalanine concentration.
<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. Continuation of therapy after 1 year requires documentation of blood phenylalanine concentration below 600 micromol/L or at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# PCSK9 INHIBITORS

## 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>	For all indications, submission of LDL level obtained within the previous 6 months. For primary hyperlipidemia (including HeFH) and ASCVD indications, documentation that medication is being used as an adjunct to maximally-tolerated statin therapy or documentation of inability to tolerate statin therapy (with at least one hydrophilic statin having been tried and failed). For HeFH, documentation of genetic test result documenting HeFH or diagnosis by clinical criteria using Simon Broom or WHO/Dutch Lipid Network criteria. For ASCVD, documented history of MI, ACS, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or PAD.
<b>Age Restrictions</b>	For Repatha, 13 years of age or older. For Praluent, 18 years of age or older.
<b>Prescriber Restrictions</b>	Restricted to prescribing by/under the documented recommendation of a cardiologist, lipidologist, or endocrinologist 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 documenting clinically significant response to therapy will be required for reauthorization.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## PDE5 INHIBITORS (PAH)

### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For tadalafil, diagnosis of severe (Child-Pugh class C) hepatic impairment, creatinine clearance below 30 mL/min or on hemodialysis
<b>Required Medical Information</b>	Diagnosis of covered use. For tadalafil, submission of patient weight and serum creatinine (to calculate estimated creatinine clearance).
<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>	

# 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	
Required Medical Information	Diagnosis of covered use, submission of test result confirming presence of FGFR2 fusion or rearrangement, submission of previous systemic treatment(s) tried.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# PENICILLAMINE

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## Products Affected

- *penicillamine oral capsule*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy unless being treated for Wilson's disease or certain patients with cystinuria, rheumatoid arthritis patients with a history or other evidence of renal insufficiency
<b>Required Medical Information</b>	Diagnosis of covered use, laboratory analysis applicable to indication for use, documentation that patient has tried and failed or had an intolerance to penicillamine tablets.
<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 Medically-accepted Indications.
<b>Off Label Uses</b>	

## PIQRAY (alpelisib)

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### 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>	Concomitant use with strong CYP3A inducers or BCRP inhibitors
<b>Required Medical Information</b>	Diagnosis of covered use, submission of genetic tumor testing showing that the primary tumor type is HR-positive, HER2-negative, PIK3CA-mutated, attestation that patient has advanced or metastatic disease and will be taking concurrently with fulvestrant, submission of prior therapies tried, pregnancy status for female patients of childbearing potential.
<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>	

## POMALYST (pomalidomide)

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### Products Affected

- POMALYST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline serum bilirubin, AST, ALT, CBC including ANC and platelet count, prior therapies, when prior therapy was completed, pregnancy status for female patients of childbearing potential.
<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>	



# PRETOMANID

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## Products Affected

- PRETOMANID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Inability to use bedaquiline or linezolid
<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>	

# PREVYMIS (letermovir)

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## Products Affected

- PREVYMIS ORAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of day number post-HSCT, documentation of any previous doses of letermovir.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology, oncology, transplant specialist, and infectious diseases
<b>Coverage Duration</b>	100 days
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# PRIOR AUTHORIZATION TO OVERRIDE SPECIALTY RESTRICTIONS

## Products Affected

- APOKYN SUBCUTANEOUS SOLUTION CARTRIDGE
- CRINONE
- FABIOR
- PEGASYS PROCLICK SUBCUTANEOUS SOLUTION 180 MCG/0.5ML
- PEGASYS SUBCUTANEOUS SOLUTION 180 MCG/ML
- PEGASYS SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- *tazarotene external*
- TAZORAC EXTERNAL CREAM 0.05 %
- TAZORAC EXTERNAL GEL
- VABOMERE
- XYREM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	The following physician specialties are exempt from prior authorization (by drug): (a) for Fabior, tazarotene, and Tazorac: dermatology exempt, (b) for Pegasys: gastroenterology, hepatology, or infectious diseases exempt, (c) for Crinone: gynecology, obstetrics, reproductive endocrinology, or women's health exempt, (d) for Vabomere: infectious diseases or nephrology exempt, (e) for Apokyn: neurology exempt, (f) for Xyrem: neurology or pulmonology exempt
<b>Coverage Duration</b>	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 Medically-accepted Indications.
<b>Off Label Uses</b>	

## PRIOR AUTHORIZATION TO OVERRIDE SPECIALTY RESTRICTIONS (PROTECTED CLASS DRUGS)

### Products Affected

- SYLATRON SUBCUTANEOUS KIT 200 MCG, 300 MCG, 600 MCG
- VALCHLOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	PA applies to new starts only. Physicians who specialize in the treatment of medical conditions most commonly treated with this medication are exempt from prior authorization. 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>	

# PROCYSBI (cysteamine)

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## Products Affected

- PROCYSBI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation that patient has tried and failed or had an intolerance to immediate-release cysteamine.
Age Restrictions	1 year of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. For approval, the patient must have tried and failed to have an adequate response to, had an intolerance to, or have a contraindication to therapy with immediate-release cysteamine.
Indications	All Medically-accepted Indications.
Off Label Uses	

# PROLIA (denosumab)

## Products Affected

- PROLIA SUBCUTANEOUS SOLUTION  
 PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Hypocalcemia, pregnancy
<b>Required Medical Information</b>	Diagnosis of covered use. "High risk for fracture" is defined as (1) a history of osteoporotic fracture or (2) multiple risk factors for fracture or (3) patients who have failed or are intolerant of other available osteoporosis therapies, confirmation of osteoporosis diagnosis either through densitometry (T-score less than or equal to -2.5 at the total hip, femoral neck, or lumbar spine) or clinically (documented presence of fragility fracture).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	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 Medically-accepted Indications.
<b>Off Label Uses</b>	

# PROMACTA (eltrombopag)

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## Products Affected

- PROMACTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use (including cause of thrombocytopenia if being used for that indication), documentation of previous therapies tried (corticosteroids, immunoglobulins), submission of platelet count.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	PA applies to all. Not indicated for treatment of patients with myelodysplastic syndrome and will not be approved for this use.
Indications	All Medically-accepted Indications.
Off Label Uses	

## PROMETHAZINE IN OLDER PATIENTS

### Products Affected

- PHENADOZ RECTAL SUPPOSITORY 12.5 MG      25 mg
- *promethazine hcl oral syrup*      • PROMETHEGAN RECTAL SUPPOSITORY 25
- *promethazine hcl oral tablet*      MG, 50 MG
- *promethazine hcl rectal suppository 12.5 mg,*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For all diagnoses of covered use, justification why the benefits of the drug will outweigh the risks for the specific patient must be submitted. 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>	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>	



## PROSTATE CANCER ORAL MEDICATIONS

### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For abiraterone, severe hepatic impairment (Child-Pugh class C)
<b>Required Medical Information</b>	Diagnosis of covered use and documentation of other treatments tried. For Nubeqa, documentation of other treatments tried. For abiraterone, confirmation patient will receive concurrent prednisone, submission of baseline ALT, AST, bilirubin, and serum potassium level.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology, 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>	

## QINLOCK (ripretinib)

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### Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of previous kinase inhibitor therapies, including a trial of imatinib, attestation patient does not have uncontrolled hypertension, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

## RAVICTI (glycerol phenylbutyrate)

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### Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline fasting plasma ammonia level.
Age Restrictions	2 months of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

# RETEVMO (selpercatinib)

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## Products Affected

- RETEVMO ORAL CAPSULE 40 MG, 80 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved test confirming presence of RET gene fusion or mutation, attestation patient does not have uncontrolled hypertension, pregnancy status for female patients of childbearing potential. For patients with RET fusion-positive thyroid cancer, submission of date or year of previous previous radioactive iodine treatment or reason why radioactive iodine therapy is not appropriate.
<b>Age Restrictions</b>	12 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>	

# REVLIMID (lenalidomide)

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## Products Affected

- 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, submission of CBC including ANC and platelet count, pregnancy status for female patients of childbearing potential. For mantle cell lymphoma, documentation of at least two prior therapies tried, one of which included bortezomib (or a documented contraindication to bortezomib).
<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>	

# REZUROCK (belumosudil)

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## Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of at least 2 previous therapies tried and failed for chronic graft-versus-host disease, pregnancy status for female patients of childbearing potential.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to hematology, oncology, and transplant specialty
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	

## ROZLYTREK (entrectinib)

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### Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coadministration with moderate or strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use. For non-small cell lung cancer, submission of results showing tumor is ROS1-positive as detected by an FDA-approved test. For solid tumors, submission of evidence of a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation.
<b>Age Restrictions</b>	12 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>	

# RUBRACA (rucaparib)

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## Products Affected

- RUBRACA

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



## RUZURGI (amifampridine)

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### Products Affected

- RUZURGI

PA Criteria	Criteria Details
Exclusion Criteria	History of seizure
Required Medical Information	Diagnosis of covered use.
Age Restrictions	6 years of age through 16 years of age
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

## **RYDAPT (midostaurin)**

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### **Products Affected**

- RYDAPT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use. For acute myeloid leukemia, submission of FDA-approved test confirming presence of FLT3 mutation.
<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>	

## SAMSCA (tolvaptan)

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### Products Affected

- SAMSCA ORAL TABLET 15 MG
- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	Anuria
Required Medical Information	Diagnosis of covered use, submission of serum sodium.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	30 days
Other Criteria	PA applies to all. Treatment is limited to 30 days to prevent liver injury.
Indications	All Medically-accepted Indications.
Off Label Uses	

## SEDATING 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*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	All 4 of the following criteria must be met: (1) diagnosis of covered use, (2) unless using carbinoxamine or cyproheptadine for dermatographism, documentation patient tried and failed or had an inadequate response to a second-generation antihistamine, (3) documentation provider is aware the medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, and (4) justification is submitted which explains the benefits of the drug and how that benefit outweighs the potential risks to the patient.
<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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# SEROSTIM (somatropin)

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	
<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>	

## SIGNIFOR (pasireotide)

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### Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Severe hepatic impairment (Child-Pugh class C)
<b>Required Medical Information</b>	Diagnosis of covered use, submission of ALT, aspartate aminotransferase, alkaline phosphatase, and total bilirubin.
<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. 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>	

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

# SIRTURO (bedaquiline)

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## Products Affected

- SIRTURO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline ECG, serum potassium, calcium, magnesium, ALT, AST, alkaline phosphatase, and bilirubin, confirmation that Sirturo will be co-administered with pretomanid and linezolid or at least 3 other drugs proven to be or at least 4 other drugs suspected to be effective against the patient's M. tuberculosis isolate and submission of susceptibility testing, if available.
Age Restrictions	5 years of age or older
Prescriber Restrictions	Restricted to infectious diseases and pulmonology
Coverage Duration	26 weeks
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	



# SIVEXTRO (tedizolid)

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## Products Affected

- SIVEXTRO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, documentation of a culture and sensitivity showing that the suspected causative agent is susceptible to this medication.
<b>Age Restrictions</b>	12 years of age or older
<b>Prescriber Restrictions</b>	Restricted to infectious diseases
<b>Coverage Duration</b>	6 days
<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 Medically-accepted Indications.
<b>Off Label Uses</b>	

## SKELETAL MUSCLE RELAXANTS IN OLDER PATIENTS

### Products Affected

- *chlorzoxazone oral tablet 500 mg*
- *cyclobenzaprine hcl oral*
- *metaxalone*
- *methocarbamol oral*
- *orphenadrine citrate er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For diagnosis of fibromyalgia, coverage will be provided for cyclobenzaprine for patients who have tried and failed to tolerate or had an inadequate response to at least 2 of the following: duloxetine, gabapentin, milnacipran, or pregabalin. For treatment of acute, painful musculoskeletal conditions, coverage will be provided when the prescriber attests to understanding the risks of skeletal muscle relaxants in the elderly, which include increased risk of fall and fracture due to sedation and anticholinergic effects.
<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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## SOMAVERT (pegvisomant)

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### Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline IGF-1, ALT, AST, alkaline phosphatase, and serum total bilirubin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology
Coverage Duration	1 year
Other Criteria	PA applies to all. Continuation of therapy requests require submission of updated IGF-1, ALT, AST, alkaline phosphatase, and serum total bilirubin levels.
Indications	All Medically-accepted Indications.
Off Label Uses	

## SOVALDI (sofosbuvir)

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### Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, laboratory confirmation of hepatitis C virus (HCV) genotype 1a, 1b, 2, 3, or 4 infection, documentation of whether cirrhosis is present or not and whether or not it is compensated or decompensated, confirmation a test for HBV infection (HBsAg and anti-HBc) was completed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Criteria for coverage duration will be applied consistent with current AASLD-IDSA guidance.
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

# SPRYCEL (dasatinib)

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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
Exclusion Criteria	Uncorrected hypokalemia, uncorrected hypomagnesemia
Required Medical Information	Diagnosis of covered use, submission of serum potassium and magnesium. For adults with resistance or intolerance to prior therapy, documentation of prior therapy.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

## STIVARGA (regorafenib)

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### Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	Severe or uncontrolled hypertension
Required Medical Information	Diagnosis of covered use, submission of previous therapies, submission of baseline ALT, AST, serum bilirubin, and blood pressure reading.
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	

# 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	

# SUNOSI (solriamfetol)

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## Products Affected

- SUNOSI ORAL TABLET 150 MG, 75 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	End stage renal disease, concurrent treatment with monoamine oxidase inhibitor (MAOI) or use of an MAOI within the past 14 days
<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>	1 year
<b>Other Criteria</b>	PA applies to all. Solriamfetol is not indicated to treat the underlying airway obstruction in obstructive sleep apnea and will not be approved for this use.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



## SUTENT (sunitinib)

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### Products Affected

- *sunitinib malate*

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

## SYMDEKO (tezacaftor/ivacaftor)

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### Products Affected

- SYMDEKO

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

# SYMLIN (pramlintide)

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## Products Affected

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

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

## SYMPROIC (naldemedine)

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### Products Affected

- SYMPROIC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Known or suspected gastrointestinal obstruction or increased risk of recurrent obstruction, severe hepatic impairment (Child-Pugh class C)
<b>Required Medical Information</b>	Diagnosis of covered use, documentation patient has been using opioids at a morphine equivalent dose of at least 30 mg daily for at least 4 weeks prior to initiation, provider must attest that if opioid medication is stopped for any reason, naldemedine will be discontinued.
<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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## SYNAREL (nafarelin)

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### Products Affected

- SYNAREL

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy/breast-feeding, undiagnosed abnormal vaginal bleeding
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	For endometriosis, 6 months. For all other diagnoses, 1 year.
Other Criteria	PA applies to all. Re-treatment for endometriosis is not recommended because safety data are not available.
Indications	All Medically-accepted Indications.
Off Label Uses	

# SYNRIBO (omacetaxine)

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## Products Affected

- SYNRIPO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	

# TABRECTA (capmatinib)

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## Products Affected

- TABRECTA ORAL TABLET 150 MG, 200 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of prior therapies used, submission of FDA-approved test confirming presence of MET exon 14 skipping mutation, 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>	

# TAFAMIDIS

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## Products Affected

- VYNDAMAX
- VYNDAQEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<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 cardiology
<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>	



# TAFINLAR (dabrafenib)

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## Products Affected

- TAFINLAR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coadministration with strong CYP2C8 or CYP3A4 inhibitors
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation. For non-small cell lung cancer or unresectable/metastatic melanoma with a BRAF V600K mutation, attestation that therapy will be used in combination with trametinib.
<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>	

# TAGRISO (osimertinib)

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## Products Affected

- TAGRISO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, confirmation of the presence of required genetic mutations/deletions as detected by an FDA-approved test. For EGFR T790M mutation-positive NSCLC, documentation that the patient has progressed on or after EGFR TKI therapy.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	Initially 3 months, then 1 year
<b>Other Criteria</b>	PA applies to new starts only. Continuation of approval requires affirmation of absence of unacceptable toxicities.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TAKHZYRO (lanadelumab-flyo)

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## Products Affected

- TAKHZYRO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use.
<b>Age Restrictions</b>	12 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>	

# TALZENNA (talazoparib)

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## Products Affected

- TALZENNA ORAL CAPSULE 0.25 MG, 1 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of FDA-approved companion test results showing patient is a candidate for therapy and pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# TARGRETIN (bexarotene) GEL

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## Products Affected

- TARGRETIN EXTERNAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<b>Required Medical Information</b>	Diagnosis of covered use, submission of previous therapies.
<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 FDA-approved Indications.
<b>Off Label Uses</b>	

# TASIGNA (nilotinib)

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## Products Affected

- TASIGNA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Uncorrected hypokalemia, uncorrected hypomagnesemia, long QT syndrome
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline EKG, Philadelphia chromosome (Ph) status, 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>	

# TAVALISSE (fostamatinib)

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## Products Affected

- TAVALISSE ORAL TABLET 100 MG, 150 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of platelet count, documentation patient had an insufficient response to prior treatment (including at least one of the following: corticosteroids, immunoglobulins, splenectomy, and/or a thrombopoietin receptor agonist).
<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. Continuation of therapy requires submission of platelet count.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TAZVERIK (tazemetostat)

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## Products Affected

- TAZVERIK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with strong CYP3A inhibitors or moderate or strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	16 years of age or older
<b>Prescriber Restrictions</b>	Restricted to hematology and oncology
<b>Coverage Duration</b>	Initially 16 weeks, then 1 year
<b>Other Criteria</b>	PA applies to new starts only. Continuation of therapy requires (a) documentation of a positive clinical response and (b) attestation no known secondary malignancies have developed.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



# TEGSEDI (inotersen)

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## Products Affected

- TEGSEDI

PA Criteria	Criteria Details
Exclusion Criteria	Platelet count less than $100 \times 10^9$ L
Required Medical Information	Diagnosis of covered use, submission of platelet count.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all.
Indications	All Medically-accepted Indications.
Off Label Uses	

# TEPMETKO (tepotinib)

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## Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of prior therapies used, submission of FDA-approved test confirming presence of MET exon 14 skipping mutation, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# TERIPARATIDE

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## Products Affected

- FORTEO SUBCUTANEOUS SOLUTION PEN-INJECTOR 620 MCG/2.48ML
- *teriparatide (recombinant)*

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

# TESTOSTERONE REPLACEMENT PRODUCTS

## Products Affected

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

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

# THROMBOPOIETIN RECEPTOR AGONISTS

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## Products Affected

- DOPTLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology, gastroenterology, and surgery
Coverage Duration	Doptelet: 5 days for undergoing a procedure or 1 year for immune thrombocytopenia
Other Criteria	PA applies to all. These medications should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts and will not be approved for this indication.
Indications	All Medically-accepted Indications.
Off Label Uses	

# TIBSOVO (ivosidenib)

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## Products Affected

- TIBSOVO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coadministration with strong CYP3A inducers
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved test confirming presence of IDH1 mutation.
<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>	

# TOBI PODHALER (tobramycin)

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## Products Affected

- TOBI PODHALER

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

# TOPICAL ONYCHOMYCOSIS TREATMENTS

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## Products Affected

- JUBLIA
- *tavaborole*

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



# TRICYCLIC ANTIDEPRESSANTS IN OLDER PATIENTS

## Products Affected

- *amitriptyline hcl oral*
- *chlordiazepoxide-amitriptyline*
- *clomipramine hcl oral*
- *doxepin hcl oral capsule*
- *doxepin hcl oral concentrate*
- *imipramine hcl oral*
- *perphenazine-amitriptyline*
- *trimipramine maleate oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>Diagnosis of covered use. Patient must have tried and failed to tolerate or had an inadequate response to two preferred alternative therapies for labeled indications or off-labeled uses including the following: (1) for depression (applies to amitriptyline, imipramine, doxepin, and trimipramine): paroxetine, sertraline, venlafaxine, duloxetine, citalopram, escitalopram, fluoxetine, or trazodone, (2) for headache treatment and prophylaxis (applies to amitriptyline): propranolol, timolol, topiramate, valproic acid, or divalproex, (3) for anxiety (applies to doxepin): paroxetine, venlafaxine, duloxetine, or buspirone, (4) for postherpetic neuralgia (applies to amitriptyline) or other neuropathic pain: gabapentin or pregabalin, (5) for obsessive-compulsive disorder (applies to clomipramine): paroxetine, sertraline, fluoxetine, or fluvoxamine, (6) for irritable bowel syndrome (applies to amitriptyline): laxatives or loperamide. For covered diagnoses not listed above, must try two FDA-approved alternatives (or one, if there is only one). Documentation must be submitted confirming that the prescriber is aware the medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services and justification is submitted by the prescriber which explains how the benefits outweigh the potential risks for the specific patient.</p>
<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>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# TRIENTINE

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## Products Affected

- *clovique*
- *trientine hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation of intolerance to penicillamine.
Age Restrictions	6 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	

# TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)

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## Products Affected

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

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

# TRUSELTIQ (infigratinib)

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Coadministration with moderate or strong CYP3A inducers or inhibitors, coadministration with proton pump inhibitors
<b>Required Medical Information</b>	Diagnosis of covered use, submission of test result confirming presence of FGFR2 fusion or rearrangement, submission of previous systemic treatment(s) tried.
<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>	

# TUKYSA (tucatinib)

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## Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Pregnancy
<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, confirmation that the treatment regimen will include concomitant use of capecitabine and trastuzumab.
<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>	

# TURALIO (pexidartinib)

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## Products Affected

- TURALIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Active liver or biliary tract disease, pre-existing increased serum transaminases, total or direct bilirubin greater than the upper limit of normal, unavoidable concomitant use of other hepatotoxic medications, strong CYP3A inducers, or proton pump inhibitors
<b>Required Medical Information</b>	Diagnosis of covered use (and surgical intervention is not possible or practical), submission of serum transaminases, total and direct bilirubin, and ALP.
<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>	

# TYKERB (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 LVEF and potassium and magnesium levels.
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	



# TYMLOS (abaloparatide)

## Products Affected

- TYMLOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Males
<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 a bisphosphonate is contraindicated), submission of a value, condition, or past medical history that assesses fracture risk (e.g., DEXA scan results or prior fracture), submission of number of total months of all prior use of parathyroid hormone analogs and parathyroid hormone related peptides.
<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 and requests for therapy with any of these agents for a combined total of greater than 2 years will not be approved.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# UKONIQ (umbralisib)

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## Products Affected

- UKONIQ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, 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. For follicular lymphoma, submission of at least three prior systemic therapies used. For marginal zone lymphoma, submission of at least one prior anti-CD20-based regimen used.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

## UPNEEQ (oxymetazoline)

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### Products Affected

- UPNEEQ

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

## UPTRAVI (selexipag)

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### Products Affected

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

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

## VECAMYL (mecamylamine)

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### Products Affected

- VECAMYL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Mild, moderate, labile hypertension, coronary insufficiency or history of recent myocardial infarction, uremia, glaucoma, organic pyloric stenosis
<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 cardiology and 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>	

# VEMLIDY (tenofovir alafenamide)

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## Products Affected

- VEMLIDY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	End stage renal disease patients not receiving chronic hemodialysis, decompensated (Child-Pugh class B or C) hepatic impairment
<b>Required Medical Information</b>	Diagnosis of covered use, confirmation of HIV test and that drug will not be used by itself in the case of HIV co-infection.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	PA not required for gastroenterology or infectious diseases
<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>	

# VENCLEXTA (venetoclax)

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<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 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>	

# VENTAVIS (iloprost)

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## Products Affected

- VENTAVIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to cardiology and pulmonology
Coverage Duration	1 year
Other Criteria	This medication is covered as a Part B benefit except for enrollees residing in a long-term care facility. PA applies to new starts only when covered as a Part D benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	



## VERQUVO (vericiguat)

### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	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 and pregnancy status for female patients of childbearing potential. Prescribers are also required to submit current regimen for the treatment of HFrEF, which must include (1) a renin-angiotensin system (RAS) inhibitor (ACE inhibitor, ARB, or sacubitril/valsartan), (2) a beta-blocker (BB), and (3) a mineralocorticoid receptor antagonist (MRA), each at maximally-tolerated doses. If any of these three therapies are not currently being used, prescriber is required to submit documentation as to why (e.g., contraindications, intolerances, etc.). Using the recommended dose of each therapeutic component to treat HFrEF is required. If the doses of any of these three components have not been optimized to the recommended dose to treat HFrEF, the prescriber is required to submit documentation as to why (e.g., intolerances, physiologic parameters, etc.). If the patient is using a BB not indicated for HFrEF, the patient will be required to switch to one of the three FDA-approved BBs for HFrEF (bisoprolol, carvedilol, or metoprolol succinate).
<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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	

# VERZENIO (abemaciclib)

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## Products Affected

- VERZENIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of genetic tumor testing showing that the primary tumor type is HR-positive, HER2-negative, submission of baseline liver function tests and CBC, pregnancy status for female patients of childbearing potential.
<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>	

# 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>	

# 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 the solid tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, pregnancy status for female patients of childbearing potential.
Age Restrictions	
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# 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 FDA-approved test confirming presence of EGFR exon 19 deletion or exon 21 L858R substitution mutation, pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

## VMAT2 INHIBITORS

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### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For tetrabenazine and 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>	

## VOSEVI (sofosbuvir, velpatasvir, voxilaprevir)

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### Products Affected

- VOSEVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients on rifampin
<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, 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>	

# VOTRIENT (pazopanib)

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## Products Affected

- VOTRIENT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Severe hepatic impairment
<b>Required Medical Information</b>	Diagnosis of covered use, submission of baseline ALT, AST, and bilirubin.
<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>	



# VRAYLAR (cariprazine)

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## Products Affected

- VRAYLAR

PA Criteria	Criteria Details
Exclusion Criteria	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and psychiatry
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

## VUMERITY (diroximel fumarate)

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### Products Affected

- VUMERITY
- VUMERITY (STARTER)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Moderate or severe renal impairment, hypersensitivity to dimethyl fumarate, co-administration with dimethyl fumarate
<b>Required Medical Information</b>	Diagnosis of covered use, submission of patient weight and serum creatinine (to calculate estimated creatinine clearance).
<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. For approval of Vumerity, the patient must have tried and failed to have an adequate response to or had an intolerance to dimethyl fumarate.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## WAKIX (pitolisant)

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### Products Affected

- WAKIX ORAL TABLET 17.8 MG, 4.45 MG

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment, end stage renal disease
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology and sleep medicine
Coverage Duration	1 year
Other Criteria	PA applies to all. Wakix will be authorized only if the patient previously tried and had an inadequate clinical response or an intolerance to armodafinil or modafinil.
Indications	All Medically-accepted Indications.
Off Label Uses	

# WELIREG (belzutifan)

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## Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use including confirmation patient does not require immediate surgery, submission of pregnancy status for female patients of childbearing potential.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All Medically-accepted Indications.
Off Label Uses	

# WHITE BLOOD CELL STIMULATORS

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## Products Affected

- NEULASTA ONPRO
- NEULASTA SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE
- UDENYCA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of FDA-approved indication.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<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>	

# XALKORI (crizotinib)

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## Products Affected

- XALKORI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Congenital long QT syndrome
<b>Required Medical Information</b>	Diagnosis of covered use, submission of results showing tumor is ALK or ROS1-positive as detected by an FDA-approved test, pregnancy status for female patients of childbearing potential.
<b>Age Restrictions</b>	For ALK-positive systemic anaplastic large cell lymphoma only, 1 year of age to 21 years of age
<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>	

## XATMEP (methotrexate oral solution)

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### Products Affected

- XATMEP

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Pregnancy (for polyarticular juvenile idiopathic arthritis [pJIA] indication only)
<b>Required Medical Information</b>	Diagnosis of covered use. For pJIA, confirmation that member is intolerant to or had an inadequate response to first-line therapy. For acute lymphoblastic leukemia, confirmation that medication is being used as a component of a combination chemotherapy maintenance regimen.
<b>Age Restrictions</b>	2 years of age through 18 years of age
<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>	

## XCOPRI (cenobamate)

### Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Familial short QT syndrome, patients with end-stage renal disease (creatinine clearance less than 15 mL/min) undergoing dialysis, severe 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
<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>	



# 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 symptoms have stabilized or improved and that the patient has not experienced episodes of severe constipation.
Indications	All Medically-accepted Indications.
Off Label Uses	

# XGEVA (denosumab)

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## Products Affected

- XGEVA

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

# XOLAIR (omalizumab)

## Products Affected

- XOLAIR

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

# XOSPATA (gilteritinib)

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## Products Affected

- XOSPATA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved test confirming presence of FLT3 mutation, 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>	

# XPOVIO (selinexor)

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation of treatment failure with or intolerance to all prior therapies to match the indication.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.
Indications	All FDA-approved Indications.
Off Label Uses	

# XURIDEN (uridine triacetate)

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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. Continuation of approval requires submission of CBC including neutrophil count and mean corpuscular volume and urine orotic acid level.
Indications	All Medically-accepted Indications.
Off Label Uses	

## XYWAV (oxybate salts)

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### Products Affected

- XYWAV

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	7 years of age or older
Prescriber Restrictions	Restricted to neurology, psychiatry, and sleep medicine
Coverage Duration	1 year
Other Criteria	PA applies to all. Xywav will be authorized only if the patient has used sodium oxybate (Xyrem) and prescriber submits a clinical reason detailing the need to switch to Xywav.
Indications	All Medically-accepted Indications.
Off Label Uses	



# ZEJULA (niraparib)

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## Products Affected

- ZEJULA

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

# ZELBORAF (vemurafenib)

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## Products Affected

- ZELBORAF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Long QT syndrome, QTc greater than 500 msec, uncorrected electrolyte abnormalities
<b>Required Medical Information</b>	Diagnosis of covered use, submission of results showing BRAF V600 mutation as detected by an FDA-approved test, submission of ECG, serum potassium, magnesium, and calcium levels.
<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. Not indicated in wild-type BRAF melanoma and will not be approved for this use.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

## ZERBAXA (ceftolozane/tazobactam)

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### Products Affected

- ZERBAXA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, confirmation patient will receive concurrent metronidazole therapy when used for the treatment of complicated intra-abdominal infections.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	For UTI including pyelonephritis, 7 days. For all other FDA-approved indications, 14 days.
Other Criteria	PA applies to all. A description of how the drug will be used and/or obtained may be required to determine whether it will be covered under Medicare Part B or Part D. If the medication will be self-administered after proper training or the provider agrees to have the medication filled at a pharmacy and delivered to the office by the patient for provider administration, it may be covered under Part D. If these conditions are not satisfied this medication may be covered under Part B.
Indications	All Medically-accepted Indications.
Off Label Uses	

# ZILEUTON ER

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## Products Affected

- *zileuton er*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Active liver disease or persistent hepatic function elevation enzyme greater than or equal to 3 times the upper limit of normal
<b>Required Medical Information</b>	Diagnosis of covered use, submission of hepatic function enzymes and serum bilirubin.
<b>Age Restrictions</b>	12 years of age or older
<b>Prescriber Restrictions</b>	
<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>	

# ZOKINVY (lonafarnib)

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## Products Affected

- ZOKINVY ORAL CAPSULE 50 MG, 75 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Body surface area less than 0.39 m <sup>2</sup>
<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>	
<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>	

## ZOLPIDEM IN OLDER PATIENTS

### Products Affected

- *zolpidem tartrate oral*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	All 4 of the following criteria must be met: (1) diagnosis of covered use, (2) documentation provider is aware of risks of therapy including cognitive impairment, delirium, unsteady gait, syncope, falls, fractures and motor vehicle accidents and that the medication is considered a high-risk medication for elderly patients according to the Centers for Medicare and Medicaid Services, (3) documentation that the benefits of the drug outweigh the potential risks to the patient, (4) documentation that 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.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

# ZONTIVITY (vorapaxar)

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## Products Affected

- ZONTIVITY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	History of stroke, transient ischemic attack, or intracranial hemorrhage, active pathological bleeding, severe hepatic impairment
<b>Required Medical Information</b>	Diagnosis of covered use, confirmation that patient has not had prior stroke, transient ischemic attack, or intracranial hemorrhage, documentation of concurrent use with aspirin and/or clopidogrel.
<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>	

# ZORBTIVE (somatropin)

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## Products Affected

- ZORBTIVE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<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>	4 weeks
<b>Other Criteria</b>	PA applies to all.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	



## ZYDELIG (idelalisib)

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### Products Affected

- ZYDELIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	History of serious hypersensitivity reactions, including anaphylaxis and toxic epidermal necrolysis
<b>Required Medical Information</b>	Diagnosis of covered use. For relapsed small lymphocytic lymphoma and follicular B-cell non-Hodgkin lymphoma, documentation of at least two prior systemic therapies.
<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>	

# ZYKADIA (ceritinib)

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## Products Affected

- ZYKADIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of covered use, submission of FDA-approved test confirming presence of ALK-positive tumor.
<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>	



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