



## 2023 Priority Health Medicare Prior Authorization Criteria

An alphabetical index by drug name appears after the drug criteria listings.

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# abiraterone acetate

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## Products Affected

- *abiraterone acetate oral tablet 250 mg, 500 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ACTEMRA

## Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. For systemic sclerosis- related interstitial lung disease (SSc-ILD) , must also have documentation of High Resolution Computed Tomography (HRCT) confirming diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Actemra concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician. For systemic sclerosis- related interstitial lung disease (SSc-ILD): Lung fibrosis must be at least 10% - and - patient must try and fail (defined as an intolerance or inability to improve the condition) mycophenolate or cyclophosphamide at maximally tolerated doses - and - provider must attest that the patient is being adequately treated for any complications of SSc (e.g., pulmonary hypertension) and comorbid disease (e.g., chronic obstructive pulmonary disease) - and - for reauthorization, must have documentation of improvement in condition.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# ACTHAR

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## Products Affected

- ACTHAR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acthar Gel is only covered for the treatment of infantile spasms.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 weeks
<b>Other Criteria</b>	Covered for infantile spasms after trial and failure (defined as an intolerance or inability to improve the condition) with Cortrophin.
<b>Indications</b>	Some FDA-approved Indications Only.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ACTIMMUNE

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## Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient's body surface area (BSA)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ADALIMUMAB-ADAZ

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## Products Affected

- *adalimumab-adaz*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. For shortened-interval dosing in IBD, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotectin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	Two years. Dosing must follow the FDA-approved labeling.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For Crohn's disease: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For uveitis: Must try and fail (defined above) one other drug for the condition (e.g., intraocular or systemic steroids, immunomodulator drugs). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# ADEMPAS

## Products Affected

- ADEMPAS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For pulmonary arterial hypertension (PAH), confirmed diagnosis of World Health Organization (WHO) Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For PAH, trial and failure (defined as an inability to improve the condition) with sildenafil or tadalafil. For chronic thromboembolic pulmonary hypertension (CTEPH), must be in WHO Group 4 - and - must be classified as inoperable or as persistent/recurrent after pulmonary endarterectomy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AIMOVIG

## Products Affected

- AIMOVIG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other CGRP antagonist therapy.
<b>Required Medical Information</b>	Patient has been evaluated for and does not have medication overuse headache (MOH).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist, pain specialist, or other headache specialist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For migraine prevention: Must have a documented trial and failure to two of the following drugs, each from a different group (a, b, c): (a) topiramate, divalproex, valproic acid, (b) propranolol, metoprolol, and (c) amitriptyline or venlafaxine (drugs must be tried for at least 28 days each, with failure defined as an intolerance or an inability to improve the condition). For continuation of all previously approved conditions: Must provide evidence of clinical improvement (e.g., decrease in migraine days per month).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AJOVY

## Products Affected

- AJOVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other CGRP antagonist therapy
<b>Required Medical Information</b>	Patient has been evaluated for and does not have medication overuse headache (MOH).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist, pain specialist, or other headache specialist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For migraine prevention: Must have a documented trial and failure to two of the following drugs, each from a different group (a, b, c): (a) topiramate, divalproex, valproic acid, (b) propranolol, metoprolol, and (c) amitriptyline or venlafaxine (drugs must be tried for at least 28 days each, with failure defined as an intolerance or an inability to improve the condition). For continuation of all previously approved conditions: Must provide evidence of clinical improvement (e.g., decrease in migraine days per month).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AKEEGA

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## Products Affected

- AKEEGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ALECENSA

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## Products Affected

- ALECENSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ALUNBRIG

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## Products Affected

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ambrisentan

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## Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AMJEVITA

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## Products Affected

- AMJEVITA SUBCUTANEOUS SOLUTION AUTO-INJECTOR MG/0.4ML, 40 MG/0.8ML
- AMJEVITA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 10 MG/0.2ML, 20

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. For shortened-interval dosing in IBD, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotectin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	2 years. Dosing must follow the FDA-approved labeling.



PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For Crohn's disease: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For uveitis: Must try and fail (defined above) one other drug for the condition (e.g., intraocular or systemic steroids, immunomodulator drugs). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AMVUTTRA

## Products Affected

- AMVUTTRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., Tegsedi, Onpatro).
<b>Required Medical Information</b>	Medical records supporting the request must be provided - AND - must have documentation of a transthyretin (TTR) mutation (e.g., V30M) - AND - must have documentation of a baseline polyneuropathy disability (PND) score less than or equal to IIIb and/or baseline FAP Stage 1 or 2.
<b>Age Restrictions</b>	Must be at least 18 years of age.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year initial and reauthorization. Dose must align with the FDA-approved labeling.
<b>Other Criteria</b>	Must have documentation of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.) - AND - Patient has not had a liver transplant - AND - For reauthorization, must have a positive clinical response to Amvuttra compared to baseline (e.g., improved neuropathy symptoms, motor function, quality of life, slowing of disease progression).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ARALAST

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## Products Affected

- ARALAST NP INTRAVENOUS SOLUTION  
RECONSTITUTED 1000 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry)
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ARCALYST

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## Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ARIKAYCE

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## Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initial review, sputum culture supporting the diagnosis of Mycobacterium avium complex (MAC) lung disease must be submitted. For continuation, documentation of negative sputum culture obtained within the last 30 days must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an infectious disease specialist.
<b>Coverage Duration</b>	Initial approval for 6 months. Continuation for 12 months.
<b>Other Criteria</b>	For initial review, documentation of failure to obtain a negative sputum cultures after a minimum of 6 months of a multidrug background regimen therapy for MAC lung disease must be provided. Criteria will be applied consistent with current ATS/IDSA guidelines.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# armodafinil

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## Products Affected

- *armodafinil*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# Auryxia

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## Products Affected

- AURYXIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of prior therapies and responses to treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For a diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis, must first try and fail (defined as an intolerance or inability to improve the condition) sevelamer carbonate or calcium acetate.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# AUSTEDO

## Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR PATIENT TITRATION
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HOUR 12 MG, 24 MG, 6 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with tetrabenazine, Ingrezza, a monoamine oxidase inhibitor (MAOI), or reserpine.
<b>Required Medical Information</b>	For diagnosis of tardive dyskinesia (TD), baseline documentation of Abnormal Involuntary Movement Scale (AIMS) score must be provided.
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 1 year. Limit to 48 mg per day.
<b>Other Criteria</b>	For diagnosis of tardive dyskinesia (TD), must have moderate or severe TD, indicated by minimum AIMS score of 3 on item 8 (severity of abnormal movements). For continuation, documentation of improvement in chorea symptoms for Huntington's disease or improvement in AIMS score compared to baseline for TD.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# AUVELITY

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## Products Affected

- AUVELITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Two years. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	Must try and fail (defined as an inability to improve depressive symptoms after at least 4 weeks of treatment) with an SSRI or SNRI and 1 atypical antidepressant (e.g., bupropion, mirtazapine).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AVEED

## Products Affected

- AVEED

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must have two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Approved if the following are met: 1) Patient is male AND 2) has pre-treatment clinical signs or symptoms of low testosterone other than erectile dysfunction or decreased libido (e.g., depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis), AND 3) has been screened for prostate cancer according to current guidelines, AND 4) has a documented trial and failure (defined as an inability to improve symptoms or condition) with a generic injectable - AND - generic topical testosterone therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# AVONEX

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## Products Affected

- AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT
- AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try glatiramer, Glatopa, or dimethyl fumarate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# AYVAKIT

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## Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# BALVERSA

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## Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# BENLYSTA

## Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used with another biologic drug or Lupkynis.
<b>Required Medical Information</b>	For SLE, must have a SELENA-SLEDAI score of 6 or more before starting Benlysta AND either an anti-dsDNA antibody greater than 30 IU/ml or ANA greater than 1:80. For LN, must have a confirmed diagnosis of SLE - AND - a kidney biopsy confirming class 3, 4, and/or 5 disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber must be a specialist in treating the condition or have consulted with a specialist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	FOR SLE: Must be taking two of the following drugs together for at least 12 weeks each: a steroid, immunosuppressant, and/or hydroxychloroquine. FOR LUPUS NEPHRITIS: Must be receiving standard therapy for LN (e.g., mycophenolate or azathioprine plus a steroid). FOR CONTINUATION OF PREVIOUSLY APPROVED SLE REQUESTS: Must have evidence of clinical improvement since starting Benlysta. FOR CONTINUATION OF PREVIOUSLY APPROVED LUPUS NEPHRITIS REQUESTS: Must have evidence of clinical improvement including improved or stable eGFR.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BESREMI

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## Products Affected

- BESREMI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Baseline Complete blood count (CBC).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must trial and fail hydroxyurea (defined as an intolerance and/or persistence or recurrence of disease) - AND - Prescriber must follow dose recommendations per FDA-approved labeling. Once hematologic stability has been achieved with Besremi for one year, dosing interval should be expanded to every 4 weeks.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# BETASERON

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## Products Affected

- BETASERON SUBCUTANEOUS KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try glatiramer, Glatopa, or dimethyl fumarate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# bexarotene

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## Products Affected

- *bexarotene*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# BEXAROTENE GEL

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## Products Affected

- *bexarotene*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try tazarotene.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# bosentan

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## Products Affected

- *bosentan*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# BOSULIF

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## Products Affected

- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# BRAFTOVI

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## Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have documentation of BRAF V600 mutation status.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# BRUKINSA

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## Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# CABOMETYX

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## Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# CALQUENCE

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## Products Affected

- CALQUENCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# CAPLYTA

## Products Affected

- CAPLYTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For schizophrenia: Patient must have tried and failed (defined as taking the medication as prescribed without an adequate response or with intolerance) two of the following generic atypical antipsychotics: aripiprazole, ziprasidone, olanzapine, risperidone, quetiapine. For depressive episodes associated with bipolar disorder: Patient must have tried and failed (defined above) quetiapine or olanzapine with fluoxetine.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CAPRELSA

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## Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# CARGLUMIC ACID

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## Products Affected

- *carglumic acid*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# CAYSTON

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## Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# CHOLBAM

## Products Affected

- CHOLBAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For continuation, must provide documentation showing the patient has met 2 of the following laboratory criteria or 1 laboratory criterion plus a body weight increase by 10% (or stability at greater than the 50th percentile): (1) AST or ALT less than 50 U/L (or baseline levels reduced by 80%) (2) total bilirubin less than 1 mg/dL, and (3) no evidence of cholestasis on liver biopsy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# clobazam

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## Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must first try one generic anticonvulsant. Clobazam suspension may only be used in patients where tablets are contraindicated (e.g., dysphagia).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# clomiphene citrate

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## Products Affected

- *clomiphene citrate oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# COMETRIQ

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# COPIKTRA

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## Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# CORTROPHIN

## Products Affected

- CORTROPHIN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial-in accordance with FDA label or max of 3 mos. if unspecified in label. Continuation-1 year.
<b>Other Criteria</b>	Not covered for FDA-approved indications of acute gouty arthritis, severe psoriasis, and atopic dermatitis. For all covered FDA-approved indications except infantile spasms, must have a therapeutic trial of parenteral glucocorticoid. Supporting documentation for all drug trials is required demonstrating inadequate response, intolerance, or FDA labeled contraindication to therapy. For acute exacerbations of multiple sclerosis: one month trial of oral glucocorticoid. For nephrotic syndrome associated with lupus erythematosus, systemic lupus erythematosus, and inflammatory ocular disorders: one month trial of an immunosuppressant (e.g. cyclophosphamide, tacrolimus, mycophenolate mofetil, methotrexate, azathioprine). For adjunctive therapy for short-term administration rheumatic disease: 12-week trial of one biologic drug. For systemic dermatomyositis (polymyositis): one 12-week trial with rituximab. Continuation of previously authorized therapy requires demonstrated clinical benefit. Quantity limited to dosage as supported by the FDA-approved label. Trial of a Part B drug prior to a Part D drug applies only to beneficiaries enrolled in an MA-PD plan.
<b>Indications</b>	Some FDA-approved Indications Only.
<b>Off Label Uses</b>	

PA Criteria	Criteria Details
Part B Prerequisite	Yes

# COSENTYX

## Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX UNOREADY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For ankylosing spondylitis and non-radiographic axial spondyloarthritis (NRAS): Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For ERA: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - have aggressive disease that necessitates initial biologic therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# COSENTYX 75MG/0.5ML

## Products Affected

- COSENTYX SUBCUTANEOUS SOLUTION  
 PREFILLED SYRINGE 75 MG/0.5ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For ankylosing spondylitis and non-radiographic axial spondyloarthritis (NRAS): Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For ERA: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - have aggressive disease that necessitates initial biologic therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# COTELLIC

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## Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# CRESEMBA

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## Products Affected

- CRESEMBA ORAL CAPSULE 186 MG
- *cresemba oral capsule 74.5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For invasive aspergillosis, must try and fail (defined as an intolerance or inability to improve the condition) voriconazole.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# CRINONE

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## Products Affected

- CRINONE VAGINAL GEL 8 %

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# CYSTADROPS

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## Products Affected

- CYSTADROPS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# CYSTARAN

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## Products Affected

- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# DALFAMPRIDINE ER

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## Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient must not have history of seizure and creatinine clearance must be greater than 50 ml per min.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval for 12 weeks, recertification required every 12 months thereafter
<b>Other Criteria</b>	Baseline timed 25-foot walk (T25FW), patient must be currently ambulatory. Continuation stability and/or improvement in walking speed.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DAURISMO

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**Products Affected**

- DAURISMO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# DAYBUE

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## Products Affected

- DAYBUE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient does not have atypical or variant Rett syndrome.
<b>Required Medical Information</b>	Must have documentation of the following: (1) Patient's current weight, (2) diagnosis of classic/typical Rett Syndrome (RTT), AND (3) a documented mutation in the MECP2 gene.
<b>Age Restrictions</b>	Must be at least 2 years old.
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	One year initial and reauthorization.
<b>Other Criteria</b>	Initial: Must provide documentation of current Rett Syndrome Behavior Questionnaire (RSBQ) score -AND- current Clinical Global Impression-Severity score. For reauthorization: Must provide documentation confirming a positive response to therapy based on the patient's baseline RSBQ and CGIS scores.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DIACOMIT

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## Products Affected

- DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# DICHLORPHENAMIDE

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## Products Affected

- *dichlorphenamide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# diclofenac epolamine patch

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## Products Affected

- *diclofenac epolamine external*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No



# dimethyl fumarate

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## Products Affected

- *dimethyl fumarate oral*
- *dimethyl fumarate starter pack*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# DOJOLVI

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## Products Affected

- DOJOLVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must provide documentation supporting the diagnosis (e.g., medical records).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Patient must not have pancreatic insufficiency. For continuation, patient must have clinically significant benefit compared to baseline (e.g., reduced hospitalizations, myopathy, cardiac symptoms, muscle weakness, etc.).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# droxidopa

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## Products Affected

- *droxidopa*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval: 3 months. Continuation: 1 year.
<b>Other Criteria</b>	Patient must first try midodrine. For continuation: Must have documentation of a positive clinical response (e.g., sustained decrease in dizziness).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# DUPIXENT

## Products Affected

- DUPIXENT SUBCUTANEOUS SOLUTION      PREFILLED SYRINGE 100 MG/0.67ML, 200  
PEN-INJECTOR 200 MG/1.14ML, 300      MG/1.14ML, 300 MG/2ML  
MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biologic drugs.
<b>Required Medical Information</b>	For initial coverage of severe eosinophilic asthma: elevated eosinophil level of greater than or equal to 150 cells/L at therapy start, OR greater than or equal to 300 cells/L in the previous 12 months. For eosinophilic esophagitis: (1) diagnosis confirmed by esophageal biopsy defined by at least 15 eosinophils per high power field (HPF), and (2) patient's current weight is at least 40 kg. For prurigo nodularis: Must have moderate to severe prurigo nodularis defined as a score of at least 7 on the Worst Itching Intensity Numerical Rating Scale (WI-NRS) and at least 20 nodular lesions. Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year initial and continuation. Dosing must follow the FDA-approved labeling.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For asthma: Must try and fail with 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks) - and - for reauthorization, must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). For chronic rhinosinusitis with nasal polyp: Must try and fail (defined as an inability to improve symptoms for least 8 weeks) with intranasal steroids - AND - Must be used in combination with an intranasal steroid - and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). For atopic dermatitis: Must try and fail (defined as an intolerance or inadequate response) to one medium or higher potency topical steroid (e.g., clobetasol) - or - one topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) - AND - must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine) - AND - for reauthorization, must have documented clinical benefit (e.g. less exacerbations, improved symptoms, less steroid use). For eosinophilic esophagitis: (1) Patient must have symptoms of esophageal dysfunction - AND - (2) must try and fail (defined as an intolerance or inability to achieve and maintain remission of low or mild disease activity) with one proton pump inhibitor for at least 2 months - AND - (3) must try and fail (defined above) to one topical steroid (e.g., fluticasone, budesonide) for at least 2 months. For prurigo nodularis: (1) Must try an fail (defined as inability to improve the condition) to one oral antihistamine and, (3) must try and fail (defined above) a medium or higher potency topical steroid or a topical calcineurin inhibitor.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# EMGALITY

## Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other CGRP antagonist therapy.
<b>Required Medical Information</b>	Patient has been evaluated for and does not have medication overuse headache (MOH).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist, pain specialist, or other headache specialist.
<b>Coverage Duration</b>	One year initial and continuation. All dosing must align with FDA-approved labeling.
<b>Other Criteria</b>	For migraine prevention: Must have a documented trial and failure to two of the following drugs, each from a different group (a, b, c): (a) topiramate, divalproex, valproic acid, (b) propranolol, metoprolol, and (c) amitriptyline or venlafaxine (drugs must be tried for at least 28 days each, with failure defined as an intolerance or an inability to improve the condition). For episodic cluster headache: Must have a documented trial and failure (defined as an intolerance or an inability to improve the condition) to verapamil, corticosteroids, or lithium. For continuation of all previously approved conditions: Must provide evidence of clinical improvement (e.g., decrease in migraine days per month).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ENBREL

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## Products Affected

- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 25 MG/0.5ML, 50
- ENBREL SURECLICK SUBCUTANEOUS

SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Enbrel concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# ENBREL MINI

## Products Affected

- ENBREL MINI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Enbrel concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ENSPRYNG

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## Products Affected

- ENSPRYNG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For NMOSD, must provide documentation of anti-aquaporin-4 (AQP4) antibody positive status in chart notes or medical records.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	One year - 3 syringes in month one, 1 syringe per month thereafter
<b>Other Criteria</b>	Patient must have had at least one attack requiring rescue therapy in the last year or two attacks requiring rescue therapy in the last 2 years.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ENTADFI

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## Products Affected

- ENTADFI

PA Criteria	Criteria Details
Exclusion Criteria	use of concomitant generic tadalafil
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	26 weeks
Other Criteria	Patient must have tried and failed either 6 months of finasteride or 3 months of dutasteride and must have tried and failed 28 days of alfuzosin, doxazosin, tamsulosin, or terazosin.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# EPCLUSA

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## Products Affected

- EPCLUSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist.
Coverage Duration	12 weeks
Other Criteria	Criteria will be applied consistent with current AASLD-IDSA guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# EPIDIOLEX

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## Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# ERIVEDGE

**Products Affected**

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ERLEADA

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## Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# erlotinib

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## Products Affected

- *erlotinib hcl oral tablet 100 mg, 150 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# EVENITY

## Products Affected

- EVENITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Cumulative use of Evenity of more than 12 months is not covered.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. Patient's T-score must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by endocrinologist.
<b>Coverage Duration</b>	12 months total therapy
<b>Other Criteria</b>	Must try and fail alendronate, risedronate, or ibandronate - AND - either zoledronic acid or Prolia. Failure is defined as intolerance, decrease in BMD in comparison to previous DEXA scan, new fracture while on therapy OR a contraindication to therapy (e.g., creatinine clearance less than 35 mL/min, inability to sit upright for 30 minutes, esophageal stricture).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# everolimus

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# EVRYSDI

## Products Affected

- EVRYSDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For spinal muscular atrophy (SMA), documentation of the genetic test confirming the diagnosis must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by a neurologist or in consultation with a neurologist with experience treating SMA.
<b>Coverage Duration</b>	Initial - 12 months, continuation - 12 months
<b>Other Criteria</b>	Patient must not be receiving concurrent Spinraza or have previously received or be planning to receive gene therapy for SMA (Zolgensma). For continuation, must provide documentation showing a clinically significant improvement in SMA symptoms (e.g., progression, stabilization, decreased decline in motor function) compared to the predicted and natural trajectory of the disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# EXKIVITY

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## Products Affected

- EXKIVITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# FASENRA

## Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biologic drugs.
<b>Required Medical Information</b>	For initial coverage of severe eosinophilic asthma: elevated eosinophil level of greater than or equal to 150 cells/ $\mu$ L at therapy start, OR greater than or equal to 300 cells/ $\mu$ L in the previous 12 months. Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year initial and continuation. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For asthma: Must try and fail with 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks) - and - for reauthorization, must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# fentanyl citrate transmucosal

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## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Patient must be age 16 or over
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must first try two short-acting oral opioids (e.g., oxycodone, morphine sulfate, hydromorphone).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# FILSPARI

## Products Affected

- FILSPARI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For all requests: Medical records supporting the request must be provided, including documentation of a covered diagnosis, prior therapies, and responses to treatment. For IgAN initial requests: Must also provide (1) documentation confirming biopsy-verified primary immunoglobulin A nephropathy (IgAN) - AND - (2) documentation of a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g - AND - (3) documentation of an eGFR greater than or equal to 30 mL/min/1.73 m2.
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a nephrologist.
<b>Coverage Duration</b>	One year initial and reauthorization.
<b>Other Criteria</b>	For IgAN initial requests: (1) Patient must try and fail (defined as an intolerance or an inadequate response after a minimum of 3 months) with a maximally tolerated dose of an ACE inhibitor or ARB - AND - (2) Patient must try and fail (defined above) one other drug for the condition (e.g., mycophenolate, steroids, SGLT2 inhibitor, etc.) - AND (3) Patient must not be currently receiving dialysis - AND - (4) Patient has not undergone kidney transplant. For IgAN reauthorization requests: (1) Must have documentation of a reduced proteinuria - AND - no decline in eGFR compared to baseline.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FINGOLIMOD

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## Products Affected

- *fingolimod hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# FINTEPLA

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## Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# Firdapse

## Products Affected

- FIRDAPSE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have clinical symptoms of LEMS (i.e., proximal extremity weakness) that interfere with daily activities. Must provide a baseline disease severity score using the Quantitative Myasthenia Gravis (QMG) or the Triple-Timed Up-And-Go (3TUG) test.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval for 4 weeks. Subsequent approvals will be for 12 months.
<b>Other Criteria</b>	The following criteria must be met for initial coverage: (1) If the patient has cancer associated with LEMS, cancer must have been appropriately treated - AND - (2) patient must not have history of seizures, or an increased risk of seizures due to a condition (e.g., brain metastases) and/or medication (e.g., bupropion) - AND - (3) patient must be ambulatory - AND - (4) - for adults only, patient must have documented trial and failure (defined as an intolerance or inability to improve symptoms) to pyridostigmine. For continuation of previously approved requests: Must have documentation showing improvement or stabilization in condition using the QMG or 3TUG test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# FOTIVDA

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## Products Affected

- FOTIVDA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# GALAFOLD

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## Products Affected

- GALAFOLD

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have a confirmed diagnosis of Fabry disease and documentation of an amenable galactosidase alpha gene variant based on in vitro assay data.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Patient must not be taking Galafold in combination with enzyme replacement therapy (ERT), such as Fabrazyme.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# GATTEX

## Products Affected

- GATTEX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval is 6 months. Subsequent approval for one year.
<b>Other Criteria</b>	Patient must be dependent on parenteral support for 12 months or greater. Continuation requires documentation of clinical benefit from Gattex (e.g., reduction in parenteral support, sustained response after reduction, etc.).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# GAVRETO

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## Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# GEFITINIB

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## Products Affected

- *gefitinib*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# GILOTRIF

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## Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# glatiramer

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## Products Affected

- *glatiramer acetate subcutaneous solution  
prefilled syringe 20 mg/ml, 40 mg/ml*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# GLATOPA

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## Products Affected

- GLATOPA SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE 20 MG/ML, 40  
MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# GROWTH HORMONE

## Products Affected

- GENOTROPIN INJECTOR
- GENOTROPIN MINIQUICK
- NORDITROPIN FLEXPRO  
SUBCUTANEOUS SOLUTION PEN-

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	FOR CHILDREN: must submit an untreated growth velocity curve with a minimum of 1 year of growth data showing a growth velocity of less than 10th % for bone age and gender, growth plates must be open, bone age must be a minimum of 1 year behind chronological age (unless GHD is related to pituitary surgery, radiation therapy, or with precocious puberty), must have a documented GH deficiency via 2 growth hormone stimulation tests below 10ng/ml or GH stimulation test level less than 15 ng/ml + IGF-1 and IGF-PB3 levels below normal for bone age and sex, decreased muscle tone by exam. FOR ADULTS with a diagnosis of GHD: Must have confirmation of GHD by meeting one of the following: (1) A suboptimal response using an appropriate GH-stimulation test, (2) Child-onset GHD with confirmed persistent GHD, or (3) patient has all the following: (a) documented pituitary or hypothalamic disease (e.g., brain tumor with previous brain irradiation), (b) greater than or equal to 3 pituitary hormone deficiencies (thyroid-stimulating hormone (TSH), corticotropin (ACTH), and gonadotropins), and (c) low insulin-like growth factor-1 (IGF-1). If IGF-1 value is indeterminate, a suboptimal response on an appropriate GH-stimulation test required.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by an endocrinologist, gastroenterologist, or nephrologist.
<b>Coverage Duration</b>	One year

PA Criteria	Criteria Details
<b>Other Criteria</b>	FOR CHILDREN: Diagnosis of Growth Hormone Deficiency-height must be less than the 5th% fir age/sex. Diagnosis of Turner's syndrome-height must be less than 10th%. Diagnosis of Pre-transplant chronic renal insufficiency-height must be less than 5th% for age/sex and patient must be receiving weekly dialysis or SCR less than 2 mg/dL. FOR CHILDREN: must not have constitutional growth delay, or acute or chronic catabolic illness. FOR ADULTS, the following conditions are not covered: treatment of reduced growth hormone related to aging, Turner's syndrome or cystinosis. For continuation in adults and children: Above normal IGF-1 level requires provider attestation that dose will be decreased and therapy will be managed to obtain a level within normal range.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HADLIMA

## Products Affected

- HADLIMA PUSHTOUCH SUBCUTANEOUS SOLUTION AUTO-INJECTOR 40 MG/0.4ML, 40 MG/0.8ML, 40 MG/0.8ML
- HADLIMA SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. For shortened-interval dosing in IBD, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotectin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	Two years. Dosing must follow the FDA-approved labeling.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For Crohn's disease: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For uveitis: Must try and fail (defined above) one other drug for the condition (e.g., intraocular or systemic steroids, immunomodulator drugs). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HEMADY

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## Products Affected

- HEMADY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must try and fail dexamethasone oral tablet (generic Decadron) for current multiple myeloma treatment. Fail is defined as having an intolerance to an inability to improve the condition.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# HUMIRA

## Products Affected

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS PREFILLED SYRINGE KIT 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.4ML, 40 MG/0.8ML, 80 MG/0.8ML
- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PEDIATRIC UC START
- HUMIRA PEN-PS/UV//ADOL HS START SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML
- HUMIRA PEN-PSOR/UEIT STARTER
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. For shortened-interval dosing in IBD, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotectin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.



PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For Crohn's disease: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For uveitis: Must try and fail (defined above) one other drug for the condition (e.g., intraocular or systemic steroids, immunomodulator drugs). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# HYFTOR

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## Products Affected

- HYFTOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be receiving systemic mTOR inhibitor therapy (e.g., everolimus).
<b>Required Medical Information</b>	Medical records supporting the request must be provided. Must have 3 or more facial angiofibromas.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a dermatologist, neurologist, or geneticist.
<b>Coverage Duration</b>	Initial coverage: 3 months. Reauthorization: 1 year.
<b>Other Criteria</b>	Must not be a candidate for laser therapy or surgery. Reauthorization: Must have evidence of improvement in facial angiofibromas compared to baseline.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# IBRANCE

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## Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# icatibant acetate

## Products Affected

- *icatibant acetate*
- *sajazir*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of an angiotensin-converting enzyme inhibitor (ACEI) is not covered.
<b>Required Medical Information</b>	Documentation of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis.
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE.
<b>Coverage Duration</b>	6 months, initial and continuation. Limited to 3 syringes (9mls) every 15 days.
<b>Other Criteria</b>	For continuation: Must have documentation showing use of previously approved syringes AND a favorable clinical response (decrease in the duration of attacks, quick onset of symptom relief, resolution of symptoms, decrease in attack frequency or severity).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ICLUSIG

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## Products Affected

- ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ICOSAPENT ETHYL

## Products Affected

- *icosapent ethyl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For severe hypertriglyceridemia, laboratory confirmation of a baseline triglyceride level of at least 500 mg/dL prior to starting icosapent ethyl. For reducing the risk of myocardial infarction (MI), stroke, coronary revascularization, and unstable angina requiring hospitalization, laboratory confirmation of a baseline triglyceride level of at least 150mg/dL prior to starting icosapent ethyl.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For cardiovascular (CV) risk reduction, must have either established CV disease (e.g., coronary artery disease, heart attack, stroke) OR diabetes mellitus with 2 or more additional risk factors for CV disease (e.g., smoking, hypertension, elevated CRP) - AND - one of the following: (1) Documented trial with ezetimibe AND one high intensity statin (e.g., atorvastatin or rosuvastatin) or, if a high-intensity statin is not tolerated, one statin at the maximally tolerated dose - OR - (2) ezetimibe trial with documented statin intolerance defined as experiencing statin-related muscle symptoms during separate trials of two different statins with symptoms resolving upon discontinuation of the statin during each trial. For hypertriglyceridemia: must have tried fenofibrate for at least 12 weeks with an inability to lower triglycerides below 150mg/dL.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# IDHIFA

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## Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of IDH2 (isocitrate dehydrogenase-2) mutation must be submitted.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# imatinib mesylate

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## Products Affected

- *imatinib mesylate oral tablet 100 mg, 400 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorized for one year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# IMBRUVICA

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	Criteria will be applied consistent with current NCCN guidance. Reauthorization for GVHD: Must have documentation of clinical benefit.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# INGREZZA

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## Products Affected

- INGREZZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with tetrabenazine or Austedo.
<b>Required Medical Information</b>	For diagnosis of tardive dyskinesia (TD), baseline documentation of Abnormal Involuntary Movement Scale (AIMS) score must be provided.
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 6 months. Renewal: 1 year. Limit to 80 mg per day.
<b>Other Criteria</b>	For diagnosis of tardive dyskinesia (TD), must have moderate or severe TD, indicated by minimum AIMS score of 3 on item 8 (severity of abnormal movements). For reauthorization for tardive dyskinesia, documentation of improvement compared to baseline AIMS score. For reauthorization for Huntington's disease, documentation of improvement in chorea symptoms.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# INLYTA

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## Products Affected

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# INQOVI

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## Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must first try IV decitabine. Part B before Part D Step Therapy. Applies only to beneficiaries in an MA-PD plan.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	Yes

# INREBIC

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## Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year initial and continuation.
Other Criteria	Must have tried and failed (defined as an intolerance or inability to improve the condition) Jakafi.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# ISTURISA

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## Products Affected

- ISTURISA ORAL TABLET 1 MG, 10 MG, 5 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have failed pituitary surgery or have a contraindication to pituitary surgery.
<b>Age Restrictions</b>	Must be 18 years of age or older.
<b>Prescriber Restrictions</b>	Must be prescribed by an endocrinologist
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must have tried and failed two of the following: ketoconazole, Lysodren, cabergoline, and/or Signifor/LAR.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# IVIG

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## Products Affected

- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMUNEX-C

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must provide current weight and requested dose.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Dosing must follow FDA-approved labeling or have documentation supporting the dose follows accepted standards of medical practice.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# JAKAFI

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## Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Criteria will be applied consistent with current NCCN guidance. Reauthorization for GVHD: Must have documentation of clinical benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# JAYPIRCA

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## Products Affected

- JAYPIRCA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Two years
<b>Other Criteria</b>	Use of Jaypirca must follow current NCCN recommendations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# JOENJA

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## Products Affected

- JOENJA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not use in combination with immunosuppressive medications.
<b>Required Medical Information</b>	Documentation of activated phosphoinositide 3-kinase delta syndrome (APDS) with PIK3CD or PIK3R1 mutation confirmed by genetic testing.
<b>Age Restrictions</b>	Must be at least 12 years old.
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a provider who specializes in the management of APDS.
<b>Coverage Duration</b>	One year initial and reauthorization.
<b>Other Criteria</b>	Patient must have nodal and/or extranodal lymphoproliferation, history of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g. lung, liver) - AND - for reauthorization, must provide documentation confirming a positive response to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# KALYDECO

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## Products Affected

- KALYDECO ORAL PACKET
- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have laboratory confirmation of ivacaftor-responsive mutation in the CFTR gene.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# KERENDIA

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## Products Affected

- KERENDIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For initial treatment, eGFR greater than or equal to 25ml/min/1.73m <sup>2</sup> .
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Must try and fail (defined as an inability to improve symptoms) or intolerance to a SGLT2i (e.g., Farxiga or Jardiance) AND must be on maximally tolerated ACEI or ARB.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# KEVEYIS

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## Products Affected

- KEVEYIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# KISQALI

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# KISQALI FEMARA

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# KORLYM

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## Products Affected

- KORLYM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Must be prescribed by an endocrinologist.
Coverage Duration	One year
Other Criteria	For continuation of previously approved requests: Must provide documentation of improvement in hyperglycemia control with Korlym.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No



# KOSELUGO

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## Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# KRAZATI

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## Products Affected

- *krazati*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Two years
<b>Other Criteria</b>	Use of Krazati must follow current NCCN recommendations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# lapatinib

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## Products Affected

- *lapatinib ditosylate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ledipasvir-sofosbuvir

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## Products Affected

- *ledipasvir-sofosbuvir*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Must first try Epclusa. Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LENALIDOMIDE

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## Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# LENVIMA

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# LEQVIO

## Products Affected

- LEQVIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with a PCSK9 inhibitor (e.g., Repatha), Nexletol, or Nexlizet.
<b>Required Medical Information</b>	Must submit most recent LDL-C level. Must submit documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board-certified lipidologist.
<b>Coverage Duration</b>	One year. Limited to 3 syringes year one and 1 syringe every 6 months thereafter.
<b>Other Criteria</b>	Patient must meet the following: (1) Patient has tried a PCSK9 inhibitor (e.g., Repatha) and LDL-C remains greater than or equal to 70mg/dL - and - (2) Patient has tried one high-intensity statin (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than or equal to 20 mg daily) and LDL-C remains greater than or equal to 70mg/dL - or - (3) Patient is statin intolerant demonstrated by experiencing statin-associated rhabdomyolysis to one statin OR failing to achieve LDL-C goal because of skeletal-muscle related symptoms that have continued despite both lowering the statin strength and attempting a different statin. For reauthorization, must also have improved and maintained an improved LDL compared to baseline.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LIDOCAINE PATCH

## Products Affected

- *lidocaine external patch 5 %*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Medically accepted indications for lidocaine 5% patch include relief of pain associated with postherpetic neuralgia (PHN), diabetic neuropathy, and cancer-related neuropathic pain.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# LIVTENCITY

## Products Affected

- LIVTENCITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Baseline CMV DNA level confirming diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	8 weeks
<b>Other Criteria</b>	Must not be used concomitantly with other CMV antivirals (e.g., ganciclovir, valganciclovir). Dosing must follow FDA-approved labeling. Must have documented trial and failure with ganciclovir or valganciclovir. For continuation, documentation of response (e.g., CMV DNA level) must be provided.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LONSURF

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## Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# LORBRENA

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## Products Affected

- LORBRENA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# LUMAKRAS

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## Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 320 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# LUMIZYME

## Products Affected

- LUMIZYME

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation of baseline FVC and/or 6MWT values must be provided. Must provide patient's current weight and requested dose. Documentation of diagnosis confirmation by enzyme assay or genetic testing must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a specialist in inherited metabolic disorders (e.g., genetic and metabolic specialist, neurologist, cardiologist).
<b>Coverage Duration</b>	One year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For continuation requests, must also provide documentation demonstrating improvement or stabilization in condition.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# LYNPARZA

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## Products Affected

- LYNPARZA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# LYTGOBI

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# MATULANE

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## Products Affected

- MATULANE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# MAVYRET

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## Products Affected

- MAVYRET ORAL PACKET
- MAVYRET ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must have chronic hepatitis C infection.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist.
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Must first try Epclusa. Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# MAYZENT

## Products Affected

- MAYZENT ORAL TABLET 0.25 MG, 1 MG, 2 MG
- MAYZENT STARTER PACK ORAL TABLET THERAPY PACK 12 X 0.25 MG, 7 X 0.25 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try glatiramer, Glatopa, or dimethyl fumarate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# MEKINIST

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## Products Affected

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# MEKINIST ORAL SOLUTION

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## Products Affected

- MEKINIST ORAL SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be less than 18 years old.
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# MEKTOVI

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## Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have documentation of BRAF V600 mutation status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# METHYLTESTOSTERONE

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## Products Affected

- *methyltestosterone oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# modafinil

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## Products Affected

- *modafinil*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# MYALEPT

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## Products Affected

- MYALEPT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Laboratory confirmed leptin deficiency. Must have one of the following: triglyceride level more than 200mg/dL or diabetes mellitus.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must not have HIV, infectious liver disease, or acquired lipodystrophy with hematologic abnormalities
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# NATPARA

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## Products Affected

- NATPARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Current calcium levels must be provided to confirm dosing follows FDA-approved labeling.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# NERLYNX

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## Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months total therapy
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# NEXLETOL

## Products Affected

- NEXLETOL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used along with PCSK9 inhibitors (e.g., Repatha), Juxtapid.
<b>Required Medical Information</b>	Must submit most recent LDL-C level. Must submit documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board-certified lipidologist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must meet the following: (1) Patient has tried one high-intensity statin (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than or equal to 20 mg daily) plus ezetimibe concomitantly for a minimum of 8 weeks and LDL-C remains greater than or equal to 70mg/dL or (2) Patient has tried ezetimibe and is statin intolerant demonstrated by experiencing statin-associated rhabdomyolysis to one statin OR failing to achieve LDL-C goal because of skeletal-muscle related symptoms that have continued despite both lowering the statin strength and attempting a different statin.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NEXLIZET

## Products Affected

- NEXLIZET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used along with PCSK9 inhibitors (e.g., Repatha), Juxtapid.
<b>Required Medical Information</b>	Must submit most recent LDL-C level. Must submit documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board-certified lipidologist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must meet the following: (1) Patient has tried one high-intensity statin (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than or equal to 20 mg daily) plus ezetimibe concomitantly for a minimum of 8 weeks and LDL-C remains greater than or equal to 70mg/dL or (2) Patient has tried ezetimibe and is statin intolerant demonstrated by experiencing statin-associated rhabdomyolysis to one statin OR failing to achieve LDL-C goal because of skeletal-muscle related symptoms that have continued despite both lowering the statin strength and attempting a different statin.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NIVESTYM

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## Products Affected

- NIVESTYM INJECTION SOLUTION  
 PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# NUBEQA

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## Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# NUCALA

## Products Affected

- NUCALA SUBCUTANEOUS SOLUTION AUTO-INJECTOR
  - NUCALA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 40
  - NUCALA SUBCUTANEOUS SOLUTION RECONSTITUTED
- MG/0.4ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biologic drugs.
<b>Required Medical Information</b>	For initial coverage of severe eosinophilic asthma: elevated eosinophil level of greater than or equal to 150 cells/ $\mu$ L at therapy start, OR greater than or equal to 300 cells/ $\mu$ L in the previous 12 months. For Hypereosinophilic Syndrome (HES), must have blood eosinophil count at least 1,000 cells/mcL. Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year initial and continuation. Dosing must follow the FDA-approved labeling.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For asthma: Must try and fail with 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks) - and - for reauthorization, must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). For chronic rhinosinusitis with nasal polyp: Must try and fail (defined as an inability to improve symptoms for least 8 weeks) with intranasal steroids - AND - Must be used in combination with an intranasal steroid - and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). For eosinophilic granulomatosis with polyangiitis (EGWP): Must try and fail (defined as an intolerance or inability to improve symptoms) with one traditional, non-biologic immunomodulator (e.g., azathioprine, cyclophosphamide) -- and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). For Hypereosinophilic Syndrome (HES): Must have had at least 2 HES flares in the past year defined as symptoms requiring a steroid or increase in current steroid - and - must try and fail (defined as an inability to improve symptoms) with a generic steroid-sparing drug (e.g., methotrexate, hydroxyurea) - and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).</p>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# NUEDEXTA

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## Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	Must be prescribed by a neurologist
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# NULIBRY

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## Products Affected

- NULIBRY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of MoCD Type A by genetic testing. Documentation of genetic testing results must be submitted.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with a physician who specializes in the treatment of inherited metabolic disorders.
<b>Coverage Duration</b>	12 months for initial and continuation.
<b>Other Criteria</b>	For continuation requests, must also provide documentation demonstrating a beneficial response to therapy compared to pretreatment baseline in one or more of the following: neurological function, gross motor function, and/or developmental milestones.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# NUPLAZID

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## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# OCALIVA

## Products Affected

- OCALIVA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must have one of the following: alkaline phosphatase level greater than or equal to 1.67 times the upper limit of normal, or total bilirubin greater than or equal to 1 times the upper limit of normal but less than 2 times the upper limit of normal.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must have received 12 months of ursodiol therapy and have had an inadequate response or be intolerant to ursodiol.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ODOMZO

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## Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# OFEV

## Products Affected

- OFEV

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For all indications, must have documentation of High Resolution Computed Tomography (HRCT) confirming diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is or has consulted with a pulmonologist.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For idiopathic pulmonary fibrosis (IPF): Prescriber must rule out other known causes of interstitial lung disease - and - must have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy. For chronic fibrosing interstitial lung disease with progressive phenotype: Lung fibrosis must be at least 10% - and - Forced Vital Capacity (FVC) decline must be at least 10% - OR - at least 5% with one of the following: worsening respiratory symptoms OR worsening fibrosis on imaging. For systemic sclerosis- related interstitial lung disease (SSc-ILD): Lung fibrosis must be at least 10% - and - patient must try and fail (defined as an intolerance or inability to improve the condition) mycophenolate or cyclophosphamide at maximally tolerated doses - and - provider must attest that the patient is being adequately treated for any complications of SSc (e.g., pulmonary hypertension) and comorbid disease (e.g., chronic obstructive pulmonary disease). For reauthorization of all indications: must have documentation of improvement in condition.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# OJJAARA

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## Products Affected

- OJJAARA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Criteria will be applied consistent with current NCCN guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ONUREG

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## Products Affected

- ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# OPSUMIT

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## Products Affected

- OPSUMIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Trial and failure (defined as an inability to improve the condition) with ambrisentan or bosentan.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORENCIA

## Products Affected

- ORENCIA SUBCUTANEOUS SOLUTION  
 PREFILLED SYRINGE 125 MG/ML, 50  
 MG/0.4ML, 87.5 MG/0.7ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Orencia concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORENCIA CLICKJECT

## Products Affected

- ORENCIA CLICKJECT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Orencia concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORENITRAM

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Trial and failure (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND an endothelin receptor antagonist (e.g., ambrisentan or bosentan).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORGOVYX

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## Products Affected

- ORGOVYX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ORKAMBI

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## Products Affected

- ORKAMBI ORAL PACKET 100-125 MG, 150-188 MG, 75-94 MG
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have laboratory confirmation of homozygous F508del mutation in the cystic fibrosis transmembrane regulator (CFTR) gene
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# ORLADEYO

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## Products Affected

- ORLADEYO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used along with an angiotensin-converting enzyme inhibitor (ACEI) . Must not be used along with other preventative therapies for HAE (e.g., Takhzyro, Haegarda).
<b>Required Medical Information</b>	Requires submission of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis.
<b>Age Restrictions</b>	Must be age 12 or older.
<b>Prescriber Restrictions</b>	Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For reauthorization: Must also have documentation showing a decrease in the frequency of attacks.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ORSERDU

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## Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	Use of Orserdu must follow current NCCN recommendations.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# OTEZLA

## Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with biological drugs (e.g., adalimumab).
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For PsO: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g. methotrexate, cyclosporine, acitretin). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For oral ulcers associated with Behcet's disease: Must try and fail (defined above) one other systemic therapy (e.g., colchicine, thalidomide, interferon alpha, tumor necrosis factor inhibitors) for the condition.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# OXERVATE

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## Products Affected

- OXERVATE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	More than 8-weeks of treatment per lifetime will not be covered.
<b>Required Medical Information</b>	Documentation confirming diagnosis of Stage 2 (persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis such as through slit lamp examination.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, an ophthalmologist or optometrist who specializes in corneal diseases.
<b>Coverage Duration</b>	8 weeks total treatment. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PANRETIN

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## Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try and fail (defined as an intolerance or inability to improve the condition) with imiquimod 5% cream.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# PAZOPANIB

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## Products Affected

- *pazopanib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# PEMAZYRE

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## Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# penicillamine

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## Products Affected

- *penicillamine oral tablet*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For cystinuria, documentation that treatment with conservative measures (e.g. high fluid intake, sodium and protein restriction, urinary alkalization) were ineffective, not tolerated, or contraindicated. Quantity limited to dosage as supported by the FDA-approved label.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# pentamidine

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## Products Affected

- *pentamidine isethionate inhalation*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	CD4 lymphocyte count. For patients 30 days to 1 year of age, was the patient born to a mother known to be HIV-infected? Is HIV seropositive or infected? For patients 2 years of age and older, has the patient experienced at least one episode of PCP?
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Must have therapeutic trial of Co-trimoxazole (trimethoprim/sulfamethoxazole).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PHENOBARBITAL

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## Products Affected

- *phenobarbital oral elixir*
- *phenobarbital oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# PIQRAY

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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
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# PIRFENIDONE

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## Products Affected

- *pirfenidone oral capsule*
- *pirfenidone oral tablet 267 mg, 801 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Prescriber must rule out other known causes of interstitial lung disease.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PLEGRIDY

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## Products Affected

- PLEGRIDY
- PLEGRIDY STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try glatiramer, Glatopa, or dimethyl fumarate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# POMALYST

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## Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# PRETOMANID

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## Products Affected

- PRETOMANID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	26 weeks
Other Criteria	Must be used in combination with linezolid and Sirturo.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# PREVYMIS

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## Products Affected

- PREVYMIS ORAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	100 days (HSCT), 200 days (kidney transplant)
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# PROLASTIN-C

## Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# PROLIA

## Products Affected

- PROLIA SUBCUTANEOUS SOLUTION  
PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Must first try and fail (defined as a decrease in BMD or new fracture while on therapy) an oral bisphosphonate or zoledronic acid. If intolerant or contraindicated to an oral bisphosphonate, zoledronic acid is required. Coverage is also provided if the patient has a creatinine clearance less than 35 mL/min. Part B before Part D Step Therapy: Use of zoledronic acid applies only to beneficiaries enrolled in an MA-PD plan.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	Yes



# PROMACTA

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Use of Promacta to normalize platelet counts is not covered.
<b>Required Medical Information</b>	Current platelet count must be provided. For ITP, initial requests: Patient has a platelet count less than 30,000/mcL - OR - less than 50,000/mcL with bleeding or one of the following risk factor(s) for bleeding: History of clinically significant bleeding at a higher platelet count, concurrent peptic ulcer disease or liver disease that increase bleeding risk, history of falling, or need for concurrent anticoagulation or anti-platelet therapy
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	For thrombocytopenia from hepatitis C infection, initial request: The degree of thrombocytopenia is preventing the initiation of interferon therapy OR limits the ability to maintain optimal interferon based therapy. For thrombocytopenia from hepatitis C infection, reauthorization: current platelet count is less than 400 x 10 <sup>9</sup> /L - and - patient is responding to therapy as evidenced by increased platelet counts - and - patient continues to receive interferon based therapy. For aplastic anemia, initial requests: Must be used with standard immunosuppressive therapy (antithymocyte globulin and cyclosporine) for first-line treatment or must have had an insufficient response to cyclosporine or cyclosporine modified for second-line or subsequent treatment. For aplastic anemia, reauthorization: current platelet count is less than 400 x 10 <sup>9</sup> /L - and - patient is responding to therapy as evidenced by increased platelet counts. For ITP, initial requests: Must have inadequate response or intolerance to steroids or immunoglobulins - AND - either rituximab or splenectomy. For ITP, reauthorization: current platelet count is less than 400 x 10 <sup>9</sup> /L - and - patient is responding to therapy as evidenced by increased platelet counts - and - patient remains at risk for bleeding complications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	Yes

# PYRUKYND

## Products Affected

- PYRUKYND
- PYRUKYND TAPER PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Not covered for a patient with any of the following: Homozygous for R479H mutation, 2 non-missense variants in PKLR gene, not regularly transfused.
<b>Required Medical Information</b>	Genetic testing confirming diagnosis - AND - Current hemoglobin less than or equal to 10mg/dL.
<b>Age Restrictions</b>	Must be 18 years of age or older.
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a hematologist.
<b>Coverage Duration</b>	Initial: 3 months, Continuation: 12 months
<b>Other Criteria</b>	For continuation: Must have documented benefit defined as hemoglobin response of greater than or equal to 1.5mg/dL over baseline and/or reduction in transfusion burden.
<b>Indications</b>	Some FDA-approved Indications Only.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# QELBREE

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## Products Affected

- QELBREE ORAL CAPSULE EXTENDED  
RELEASE 24 HOUR 100 MG, 150 MG, 200  
MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try atomoxetine.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# QINLOCK

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## Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# RADICAVA ORS

## Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation confirming all required criteria (e.g., diagnosis, labs, ALSFRS-R score) must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months. Limited to 70 mLs the first 28 days and 50 mLs every 28 days thereafter.
<b>Other Criteria</b>	Patient must have a diagnosis of "definite" or "probable" amyotrophic lateral sclerosis (ALS) as defined by the revised El Escorial/Archie House criteria - AND - patient must have disease duration of less than or equal to 2 years (please provide date of diagnosis) - AND - patient must have retained most activities of daily living defined as a score of greater than or equal to 2 points on each of the 12 items of the revised ALS Functional Rating Scale (ALSFRS-R) (i.e., a minimum score of 24) - AND - patient must have normal respiratory function defined as a percent-predicted forced vital capacity (% FVC) greater than or equal to 80%. For continuation of coverage, patient must have a diagnosis of "definite" or "probable" ALS as defined by the revised El Escorial/Archie House criteria - AND - patient must have clinical benefit from therapy as determined by the provider - AND - patient must not be dependent on invasive ventilation.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# RAVICTI

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## Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# REBIF

## Products Affected

- REBIF REBIDOSE SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- REBIF REBIDOSE TITRATION PACK SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- REBIF SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- REBIF TITRATION PACK SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try glatiramer, Glatopa, or dimethyl fumarate.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# RELISTOR

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## Products Affected

- RELISTOR ORAL
- RELISTOR SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient must not have mechanical gastrointestinal obstruction.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	4 months
<b>Other Criteria</b>	Must try and fail (defined as an inadequate response or intolerance) to lactulose and polyethylene glycol (Miralax).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# RELYVRIO

## Products Affected

- RELYVRIO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation confirming all required criteria must be provided (such as ALSFRS-R criteria, date of diagnosis, etc.).
<b>Age Restrictions</b>	Must be at least 18 years of age.
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a neurologist or other specialist for the treatment of ALS.
<b>Coverage Duration</b>	Two years
<b>Other Criteria</b>	Patient must have a diagnosis of definite or probable amyotrophic lateral sclerosis (ALS) as defined by the revised El Escorial/Archie House criteria - AND - Patient must have disease duration of less than or equal to 2 years (please provide date of diagnosis) - AND - Patient must have retained most activities of daily living defined as a score of greater than or equal to 2 points on each of the 12 items of the revised ALS Functional Rating Scale (ALSFRS-R) (i.e., a minimum score of 24) - AND - Patient must not be dependent on invasive ventilation - AND - Patient must be ambulatory (able to walk with or without assistance) - AND - For reauthorization, patient must have clinical benefit from therapy as determined by the provider - AND - not be dependent on invasive ventilation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# REPATHA

## Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must submit most recent LDL-C level.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must meet one of the following: (1) Patient has tried one high-intensity statin (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than or equal to 20 mg daily) plus ezetimibe concomitantly for a minimum of 8 weeks, and LDL-C remains greater than or equal to 70mg/dL - OR - (2) Patient is statin intolerant as demonstrated by experiencing statin-associated rhabdomyolysis to one statin OR has tried both rosuvastatin and atorvastatin and has experienced skeletal-muscle related symptoms on both agents which also resolved upon discontinuation.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# RETEVMO

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## Products Affected

- RETEVMO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# REVCOVI

## Products Affected

- REVCOVI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must provide trough plasma ADA activity and trough dAXP levels. Must provide patient's current weight and requested dose.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year initial and continuation
<b>Other Criteria</b>	Provider attestation that treatment will follow FDA-approved labeling with dose adjusted to maintain trough ADA activity over 30 mmol/hr/L, trough dAXP level under 0.02 mmol/L, and/or to maintain adequate immune reconstitution based on clinical assessment of the patient.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# REVLIMID

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## Products Affected

- REVLIMID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# REZLIDHIA

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## Products Affected

- REZLIDHIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# REZUROCK

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## Products Affected

- REZUROCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year initial and continuation.
Other Criteria	Other criteria will be applied consistent with current NCCN guidance. Reauthorization for GVHD: Must have documentation of clinical benefit.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# RINVOQ

## Products Affected

- RINVOQ ORAL TABLET EXTENDED  
RELEASE 24 HOUR 15 MG, 30 MG, 45 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis and non-radiographic axial spondyloarthritis (NRAS): Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For Crohn's disease: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For atopic dermatitis: Must try and fail (defined above) one medium or higher potency topical steroid (e.g., clobetasol) - or - one topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) - AND - must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine) - AND - for continuation of therapy, must have documented clinical benefit (e.g. less exacerbations, improved symptoms, less steroid use).
<b>Indications</b>	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	
Part B Prerequisite	No

# ROFLUMILAST

## Products Affected

- *roflumilast*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have an FEV1 less than 50%. Patient must have had more than one COPD exacerbation in the past year.
<b>Age Restrictions</b>	Must be age 18 or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must have tried and failed triple therapy with an inhaled corticosteroid (ICS), long-acting beta agonist (LABA), and a long-acting antimuscarinic (LAMA) in the past 6 months (failure is defined as no improvement, a worsening of the condition, or an intolerance after trying triple therapy at the maximum dosages for at least 4 weeks consistently). For continuation, documentation must be provided showing a reduction in COPD exacerbations.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ROZLYTREK

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## Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# RUBRACA

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## Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# RUFINAMIDE

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## Products Affected

- *rufinamide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# RYDAPT

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## Products Affected

- RYDAPT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For diagnosis of acute myeloid leukemia (AML), patient must have FLT3 mutation-positive disease as detected by an FDA-approved test.
<b>Age Restrictions</b>	Must be age 18 or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year. For AML, limited to 6 cycles.
<b>Other Criteria</b>	For diagnosis of AML, patient must be using Rydapt in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SCEMBLIX

## Products Affected

- SCEMBLIX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For all indications, Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. For PH+ CML-CP with T315I mutation, documentation confirming mutation must be provided.
<b>Age Restrictions</b>	Must be 18 years of age or older.
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	1 year. Limit 60 tabs per 30 days. For CML with T315L mutation, limit to 300 tabs per 30 days.
<b>Other Criteria</b>	For PH+ CML-CP with T315I mutation, must submit documentation of a trial & failure (defined as disease progression, inadequate response or intolerance) of Iclusig.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# SEROSTIM

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## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# SIGNIFOR

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## Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must be too ill for pituitary surgery or patient must have had surgery that failed to completely removed the tumor. Patient must have a documented trial with ketoconazole to reduce cortisol secretion.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SILDENAFIL CITRATE

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## Products Affected

- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SIVEXTRO

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## Products Affected

- SIVEXTRO ORAL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Culture and sensitivity results showing the patient's infection is not susceptible to alternative antibiotic treatments.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber must be an infectious disease specialist or have consulted with an infectious disease specialist.
<b>Coverage Duration</b>	6 days
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SKYCLARYS

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## Products Affected

- SKYCLARYS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation of genetically confirmed diagnosis - AND - Baseline modified Friedreich's Ataxia Rating Scale (mFARS) score between 20 to 80.
<b>Age Restrictions</b>	Must be age 16 or older.
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a neurologist.
<b>Coverage Duration</b>	One year initial and reauthorization
<b>Other Criteria</b>	Patient must be ambulatory. For reauthorization, documentation that medication is providing clinical benefit based on the patient's baseline mFARS score.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SKYRIZI

## Products Affected

- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS SOLUTION CARTRIDGE 180 MG/1.2ML, 360 MG/2.4ML
- SKYRIZI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For Crohn's disease: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SODIUM OXYBATE

## Products Affected

- SODIUM OXYBATE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient must not be receiving sedative hypnotics with sodium oxybate. Patient must not suffer from succinic semialdehyde dehydrogenase deficiency.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. Documentation of MSLT and polysomnography confirming diagnosis of narcolepsy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber must be a sleep specialist or neurologist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For narcolepsy with excessive daytime sleepiness, must first try and fail (defined as an intolerance or inability to improve the condition) amphetamine salts, dextroamphetamine or methylphenidate - AND - either modafinil or armodafinil. For reauthorization requests, must provide documentation demonstrating a decrease in excessive daytime sleepiness with narcolepsy or a decrease in cataplexy episodes.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SORAFENIB

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## Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# SPEVIGO

## Products Affected

- SPEVIGO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla. No more than 2 infusions are covered.
<b>Required Medical Information</b>	Medical records supporting the request must be provided. Diagnosis of generalized pustular psoriasis has been confirmed by the following: (1) skin biopsy, (2) systemic symptoms such as fever and fatigue, and (3) relapsing episodes.
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 infusion. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	Must first try and fail (defined as an inability to improve flare) one traditional non-biologic immunomodulator drug - AND - must try and fail (defined above) a generic retinoid (ex: acitretin, isotretinoin). For reauthorization of 1 additional infusion: Must have documentation of persistent symptoms and dose must be given 1 week after initial dose.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SPRYCEL

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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	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# STELARA

## Products Affected

- STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML MG/ML
- STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 45 MG/0.5ML, 90

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For all medically accepted indications, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to two of the following: adalimumab, Rinvoq, Skyrizi, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia or Enbrel.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# STIVARGA

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## Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# SUNITINIB MALATE

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## Products Affected

- *sunitinib malate*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# SYMDEKO

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## Products Affected

- SYMDEKO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have laboratory confirmation of homozygous F508del mutation or have at least one tezacaftor/ivacaftor-responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
<b>Age Restrictions</b>	Must be age 6 or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year.
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# SYMPAZAN

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## Products Affected

- SYMPAZAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be age 2 years or older.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must first try and fail generic clobazam.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# SYNRIBO

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## Products Affected

- SYNRIPO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Authorized for one year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# TABRECTA

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## Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# tadalafil 2.5mg and 5mg (Cialis)

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## Products Affected

- *tadalafil oral tablet 2.5 mg, 5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Patient must have tried and failed either 6 months of finasteride or 3 months of dutasteride and must have tried and failed 28 days of alfuzosin, doxazosin, tamsulosin, or terazosin.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# tadalafil 20mg (Adcirca)

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## Products Affected

- *tadalafil (pah)*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TAFINLAR

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## Products Affected

- TAFINLAR ORAL CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TAFINLAR TABLET FOR ORAL SUPENSION

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## Products Affected

- TAFINLAR ORAL TABLET SOLUBLE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be less than 18 years old.
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TAGRISO

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## Products Affected

- TAGRISO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have laboratory confirmation of epidermal growth factor receptor T790M mutation, or exon 19 deletion or exon 21 (L858R) substitution mutations
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TAKHZYRO

## Products Affected

- TAKHZYRO SUBCUTANEOUS SOLUTION
- TAKHZYRO SUBCUTANEOUS SOLUTION  
 PREFILLED SYRINGE 150 MG/ML, 300  
 MG/2ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used along with an angiotensin-converting enzyme inhibitor (ACEI). Must not be used along with other preventative therapies for HAE (e.g., Orladeyo, Haegarda).
<b>Required Medical Information</b>	Requires submission of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For reauthorization: Must also have documentation showing a decrease in the frequency of attacks - and - if attack free, dosing is limited to 1 syringe every 4 weeks.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TALZENNA

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## Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# TASIGNA

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## Products Affected

- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TASIMELTEON

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## Products Affected

- *tasimelteon*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by a sleep specialist or a neurologist.
<b>Coverage Duration</b>	Two years
<b>Other Criteria</b>	Patient must be totally blind. For continuation: must have documented benefit from use of tasimelteon. Not covered for a diagnosis of Smith-Magenis Syndrome (SMS).
<b>Indications</b>	Some FDA-approved Indications Only.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TAVNEOS

## Products Affected

- TAVNEOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation of the following to support the diagnosis must be provided: (1) eGFR greater than or equal to 15 mL/min/1.72 m <sup>2</sup> , (2) at least 1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria on the Birmingham Vasculitis Activity Score (BVAS) - AND - (3) positive test for either anti-PR3 or anti-MPO.
<b>Age Restrictions</b>	Must be 18 years of age or older.
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a neurologist or rheumatologist.
<b>Coverage Duration</b>	Initial 6 months. Continuation 12 months.
<b>Other Criteria</b>	Tavneos must be used as an add-on to standard therapy including cyclophosphamide, rituximab, and steroids (such as methylprednisolone or prednisone) - AND - patient must have a medical need to reduce steroid use if not previously relapsed (ie. infection, osteoporosis) - AND - patient does not currently require dialysis, have kidney transplant, or have received plasma exchange in the past 12 weeks. For continuation: Must have a reduction in the Birmingham Vasculitis Activity Score (BVAS) - AND - steroid dose.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TAZVERIK

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## Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TEGSEDI

## Products Affected

- TEGSEDI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy, diagnosis confirmed by the following: documented transthyretin (TTR) mutation (e.g., V30M) by genetic testing AND documented amyloid deposits in biopsy tissue. Must provide documentation of one of the following: Baseline polyneuropathy disability (PND) score less than or equal to IIIb or baseline FAP Stage 1 or 2. Patient must have a platelet count of greater than or equal to 100 x 10 <sup>9</sup> /L. Patient must have a urine protein to creatinine ratio (UPCR) less than 1,000 mg/g.
<b>Age Restrictions</b>	Must be age 18 or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months on initial and continuation requests
<b>Other Criteria</b>	Patient must present with clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.). Patient must not be receiving Tegsedi in combination with tafamidis (Vyndaqel, Vyndamax) or Onpattro. For continuation, patient must show clinical benefit from Tegsedi (e.g., improved neuropathy symptoms, slowing of disease progression).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TEPMETKO

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## Products Affected

- TEPMETKO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TERIFLUNOMIDE

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## Products Affected

- *teriflunomide*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two years
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TERIPARATIDE

## Products Affected

- TERIPARATIDE (RECOMBINANT)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Cumulative use of teriparatide and other parathyroid hormone analogs (e.g., Tymlos) of more than 2 years is not covered.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. Patient's T-score must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by endocrinologist.
<b>Coverage Duration</b>	Two years total therapy (inclusive of all parathyroid hormone analogs).
<b>Other Criteria</b>	Must try and fail alendronate, risedronate, or ibandronate - AND - either zoledronic acid or Prolia. Failure is defined as intolerance, decrease in BMD in comparison to previous DEXA scan, new fracture while on therapy OR a contraindication to therapy (e.g., creatinine clearance less than 35 mL/min, inability to sit upright for 30 minutes, esophageal stricture).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# testosterone gel

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Approved if the following are met: 1) Patient is male AND 2) has pre-treatment clinical signs or symptoms of low testosterone other than erectile dysfunction or decreased libido (e.g., depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis), AND 3) has been screened for prostate cancer according to current guidelines, AND 4) has a documented trial and failure (defined as an intolerance or an inability to improve symptoms or testosterone levels) with a generic injectable testosterone product. Part B before Part D Step Therapy. Trial with injectable testosterone applies only to members who are enrolled in a MAPD plan.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# testosterone solution

## Products Affected

- *testosterone transdermal solution*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Approved if the following are met: 1) Patient is male AND 2) has pre-treatment clinical signs or symptoms of low testosterone other than erectile dysfunction or decreased libido (e.g., depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis), AND 3) has been screened for prostate cancer according to current guidelines, AND 4) has a documented trial and failure (defined as an intolerance or an inability to improve symptoms or testosterone levels) with a generic injectable testosterone product. Part B before Part D Step Therapy. Trial with injectable testosterone applies only to members who are enrolled in a MAPD plan.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# tetrabenazine

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## Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with Austedo.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year.
Other Criteria	CYP2D6 genotype must be provided for doses greater than 50mg/day.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TEZSPIRE

## Products Affected

- TEZSPIRE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biologic drugs.
<b>Required Medical Information</b>	For initial coverage of severe eosinophilic asthma: elevated eosinophil level of greater than or equal to 150 cells/ $\mu$ L at therapy start, OR greater than or equal to 300 cells/ $\mu$ L in the previous 12 months. Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year initial and continuation. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For asthma: Must try and fail with 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks) - and - for reauthorization, must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# THALOMID

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## Products Affected

- THALOMID

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TIBSOVO

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## Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have documentation of IDH1 mutation status
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# tolvaptan

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## Products Affected

- *tolvaptan*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 days
Other Criteria	Treatment must be initiated in an inpatient setting.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TRETINOIN CAPSULES

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## Products Affected

- *tretinoin oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# TRIKAFTA

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## Products Affected

- TRIKAFTA ORAL TABLET THERAPY PACK
- TRIKAFTA ORAL THERAPY PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For diagnosis of cystic fibrosis, must provide documentation of a F508del mutation or at least one mutation responsive to Trikafta.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# trimipramine

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## Products Affected

- *trimipramine maleate oral*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# TRUDHESA

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## Products Affected

- TRUDHESA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must try and fail (defined as inability to improve symptoms or condition) one triptan drug AND Ubrelvy or Reyvow.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# TUKYSA

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## Products Affected

- TUKYSA ORAL TABLET 150 MG, 50 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TURALIO

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## Products Affected

- TURALIO ORAL CAPSULE 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# TYMLOS

## Products Affected

- TYMLOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Cumulative use of Tymlos and other parathyroid hormone analogs (e.g., teriparatide) of more than 2 years is not covered.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. Patient's T-score must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by endocrinologist.
<b>Coverage Duration</b>	Two years total (inclusive of all parathyroid hormone analogs)
<b>Other Criteria</b>	Must try and fail alendronate, risedronate, or ibandronate - AND - either zoledronic acid or Prolia. Failure is defined as intolerance, decrease in BMD in comparison to previous DEXA scan, new fracture while on therapy OR a contraindication to therapy (e.g., creatinine clearance less than 35 mL/min, inability to sit upright for 30 minutes, esophageal stricture).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TYVASO

## Products Affected

- TYVASO
- TYVASO REFILL
- TYVASO STARTER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment. For PH-ILD, confirmation of diagnosis by right heart catheterization, 6-minute walk test, and medical record documentation must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a specialist for the condition.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For PAH, trial and failure (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND and endothelin receptor antagonist (e.g., ambrisentan or bosentan). For PH-ILD, (1) must have attestation from the provider that ILD has been optimally managed prior to use of Tyvaso, (2) only covered for PH-ILD associated with IPF or CTD, and (3) for continuation of coverage, documentation that patient has had a positive clinical response as determined by the provider and includes improvement in the 6MWT compared to baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# TYVASO DPI

## Products Affected

- TYVASO DPI MAINTENANCE KIT
- TYVASO DPI TITRATION KIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For PH-ILD, confirmation of diagnosis by right heart catheterization, 6-minute walk test, and medical record documentation must be provided.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a specialist for the condition.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For PH-ILD, (1) must have attestation from the provider that the underlying condition (i.e., IPF, CTD, CPFE) has been treated and addition of Tyvaso DPI is medically necessary, (2) only covered for PH-ILD associated with IPF, CTD, or combined IPF and emphysema (CPFE), and (3) for continuation of coverage, documentation that patient has had a positive clinical response as determined by the provider and includes improvement in the 6MWD compared to baseline.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# UBRELVY

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## Products Affected

- UBRELVY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other CGRP antagonist therapy.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Unless contraindicated per the FDA label, trial and failure (defined as intolerance or an inability to improve symptoms) with two different triptan medications. Ubrelvy will not be covered for migraine prevention. Quantities to treat more than 8 migraines per month are not covered.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# UPTRAVI

## Products Affected

- UPTRAVI INTRAVENOUS
- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Trial and failure (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND an endothelin receptor antagonist (e.g., ambrisentan or bosentan).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VALCHLOR

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## Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must have tried one of the following: topical corticosteroids, topical chemotherapy such as BiCNU an mechlorethamine), topical retinoids, or topical imiquimod.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# VANFLYTA

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## Products Affected

- *vanflyta*

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# VENCLEXTA

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## Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# VENTAVIS

## Products Affected

- VENTAVIS INHALATION SOLUTION 10 MCG/ML, 20 MCG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Trial and failure (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND an endothelin receptor antagonist (e.g., ambrisentan or bosentan).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VERZENIO

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## Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# VIJOICE

## Products Affected

- VIJOICE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	All the following must be met: (1) Patient has a physician-confirmed and documented diagnosis of PROS including evidence of a mutation in the PIK3CA gene, and (2) Patient has at least one target lesion identified on imaging, and (3) Patient's baseline measurable target lesion volume is documented.
<b>Age Restrictions</b>	Must be at least 2 years old.
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a neurologist, vascular specialist, or geneticist.
<b>Coverage Duration</b>	Initial: 6 months, Reauthorization: 1 year.
<b>Other Criteria</b>	All the following must be met: (1) Patient's condition is severe or life-threatening and systemic treatment is deemed necessary by the treating physician, and (2) for reauthorization of previously approved requests, documentation of a positive response to therapy as determined by the provider.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# VITRAKVI

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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	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# VIZIMPRO

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## Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# VONJO

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## Products Affected

- VONJO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Criteria will be applied consistent with current NCCN guidance.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# VOTRIENT

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## Products Affected

- VOTRIENT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# VOWST

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## Products Affected

- VOWST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation of at least 2 recurrent episodes of CDI (3 or more total CDI episodes) after failure of appropriate antibiotic treatments.
<b>Age Restrictions</b>	Patient must be 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months. Limited to 1 treatment course (12 capsules over 3 days).
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VOXZOGO

## Products Affected

- VOXZOGO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient's current weight. Documentation of current annualized growth velocity (AGV). Recent documentation of open epiphyses. Documentation of achondroplasias confirmed by genetic testing.
<b>Age Restrictions</b>	Patient is 5 to 17 years of age.
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a board-certified geneticist, endocrinologist, neurologist, orthopedic surgeon, or specialist with experience in treating achondroplasia.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For continuation: Must have documentation of a positive clinical response as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VYNDAMAX

## Products Affected

- VYNDAMAX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) must be confirmed by tissue biopsy, genetic testing, or radionuclide imaging (99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan) (documentation must be provided). Diagnosis by radionuclide imaging requires all of the following to be met (documentation must be provided): Grade 2 or 3 cardiac uptake on radionuclide imaging and either an echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness). Patient must have clinical symptoms or cardiomyopathy and heart failure (e.g., dyspnea, edema, angina).
<b>Age Restrictions</b>	Must be age 18 or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months on initial and continuation requests
<b>Other Criteria</b>	Vyndamax will not be approved if the patient has primary (light-chain) amyloidosis or if Vyndamax is being used with Onpattro or Tegsedi. For continuation: must continue to meet initial criteria - and - have had a positive clinical response to Vyndamax compared to baseline evidenced by objective (e.g., reduced cardiovascular-related hospitalizations, cardiac function) and subjective measures (e.g., function, quality of life).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# VYNDAQEL

## Products Affected

- VYNDAQEL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) must be confirmed by tissue biopsy, genetic testing, or radionuclide imaging (99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan) (documentation must be provided). Diagnosis by radionuclide imaging requires all of the following to be met (documentation must be provided): Grade 2 or 3 cardiac uptake on radionuclide imaging and either an echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness). Patient must have clinical symptoms or cardiomyopathy and heart failure (e.g., dyspnea, edema, angina).
<b>Age Restrictions</b>	Must be age 18 or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 months on initial and continuation requests
<b>Other Criteria</b>	Vyndaqel will not be approved if the patient has primary (light-chain) amyloidosis or if Vyndaqel is being used with Onpattro or Tegsedi. For continuation: must continue to meet initial criteria - and - have had a positive clinical response to Vyndaqel compared to baseline evidenced by objective (e.g., reduced cardiovascular-related hospitalizations, cardiac function) and subjective measures (e.g., function, quality of life).
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No



# WELIREG

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## Products Affected

- WELIREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# XALKORI

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## Products Affected

- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# XATMEP

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## Products Affected

- XATMEP

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Must try and fail (defined as an intolerance or inability to improve the condition) generic methotrexate.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

# XELJANZ

## Products Affected

- XELJANZ ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Xeljanz concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XELJANZ SOLUTION

## Products Affected

- XELJANZ ORAL SOLUTION

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Xeljanz concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XELJANZ XR

## Products Affected

- XELJANZ XR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biological drugs or Otezla.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Xeljanz XR concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XERMELO

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## Products Affected

- XERMELO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must be experiencing 4 or more bowel movements per day.
<b>Age Restrictions</b>	Must be 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Patient must have been receiving stable dose SSA therapy (either long-acting release (LAR), depot, or infusion pump) for at least 3 months.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XGEVA

## Products Affected

- XGEVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For all medically-accepted indications (except for Giant Cell Tumor of the bone, and for bone metastases from breast, prostate, and lung cancer), must first try zoledronic acid. Trial with zoledronic acid applies only to members enrolled in an MA-PD (Medicare Advantage Prescription Drug) plan. Part B before Part D Step Therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	Yes



# XIFAXAN

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## Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	For IBS-D, no more than three, 14-day treatment courses are covered.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year. For IBS-D, limited to 42 tablets/14 days.
<b>Other Criteria</b>	For travelers diarrhea: Member has tried and failed (defined as an intolerance or inability to improve the condition) azithromycin. For hepatic encephalopathy, member has tried and failed (defined above) lactulose.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# XOLAIR

## Products Affected

- XOLAIR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Must not be used in combination with other biologic drugs.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. For asthma and nasal polyps: Must provide patient's current weight and baseline IgE level.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
<b>Coverage Duration</b>	1 year initial and continuation. Dosing must follow the FDA-approved labeling.
<b>Other Criteria</b>	For asthma: Must try and fail with 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks) - and - for reauthorization, must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). For nasal polyps: Must try and fail (defined as an inability to improve symptoms for least 8 weeks) with intranasal steroids - AND - Must be used in combination with an intranasal steroid - and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). For chronic urticaria: Must try and fail (defined as an intolerance or inability to improve symptoms) with at least two H1 antihistamines (e.g., levocetirizine, desloratadine) - OR - one H1 antihistamine and at least 1 of the following: H2 antihistamine (e.g., famotidine), oral steroid, or leukotriene modifier - and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	

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

# XOSPATA

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## Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# XPOVIO

## Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# XTANDI

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## Products Affected

- XTANDI ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# XYREM ORAL

## Products Affected

- XYREM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patient must not be receiving sedative hypnotics with Xyrem. Patient must not suffer from succinic semialdehyde dehydrogenase deficiency.
<b>Required Medical Information</b>	Documentation of prior therapies and responses to treatment. Documentation of MSLT and polysomnography confirming diagnosis of narcolepsy.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber must be a sleep specialist or neurologist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For narcolepsy with excessive daytime sleepiness, must first try and fail (defined as an intolerance or inability to improve the condition) amphetamine salts, dextroamphetamine or methylphenidate - AND - either modafinil or armodafinil. For reauthorization requests, must provide documentation demonstrating a decrease in excessive daytime sleepiness with narcolepsy or a decrease in cataplexy episodes.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZEJULA

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## Products Affected

- ZEJULA ORAL CAPSULE
- ZEJULA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# ZELBORAF

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## Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ZEMAIRA

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## Products Affected

- ZEMAIRA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZEPATIER

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## Products Affected

- ZEPATIER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist.
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Must first try Epclusa. Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZOLINZA

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## Products Affected

- ZOLINZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	For diagnosis of primary cutaneous T-cell lymphoma, patient must have prior use of two of the following systemic therapies: a retinoid (bexarotene, all-trans retinoic acid, isotretinoin, acitretin), an interferon (IFN-alpha, IFN-gamma), methotrexate, or extracorporeal photopheresis.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZONISADE

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## Products Affected

- ZONISADE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For doses above 400 mg per day, documentation confirming need for further seizure reduction is required.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Must have tried generic zonisamide capsules with inability to swallow capsule - AND - must have tried and failed (defined as an inability to improve the condition) one other generic antiseizure medication.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZORBTIVE

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## Products Affected

- ZORBTIVE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Four weeks only
Other Criteria	Patient must be receiving TPN in conjunction with Zorbtive.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

# ZTALMY

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## Products Affected

- ZTALMY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Must provide confirmation of CDKL5 deficiency based on genetic testing - AND - Patient's current weight.
<b>Age Restrictions</b>	Must be 2 years of age or older.
<b>Prescriber Restrictions</b>	Must be prescribed by a neurologist.
<b>Coverage Duration</b>	One year
<b>Other Criteria</b>	Documented therapeutic failure of at least 2 previous antiepileptic drugs.
<b>Indications</b>	All FDA-approved Indications.
<b>Off Label Uses</b>	
<b>Part B Prerequisite</b>	No

# ZYDELIG

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## Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No



# ZYKADIA

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## Products Affected

- ZYKADIA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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