



# **MCS Classicare 2025 Formulary 3 Prior Authorization Criteria**

## **MCS Classicare Grupo MA-PD (HMO-POS) y MCS Classicare RxMax (HMO)**

MCS Classicare requires you (or your physician) to get prior authorization for certain drugs. This means that you will need to get approval from MCS Classicare before you fill your prescriptions. If you don't get approval, MCS Classicare may not cover the drug.

MCS Classicare is an HMO plan subscribed by MCS Advantage, Inc.

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1.866.627.8183 (TTY: 1.866.627.8182).

ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.627.8183 (TTY: 1.866.627.8182).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.866.627.8183 (TTY: 1.866.627.8182)。

Last Updated: 09/26/2024

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## Prior Authorization Requirements

# ABIRATERONE

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### Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Castration-resistant metastatic prostate cancer (CRPC), or B.) High risk, castration-sensitive metastatic prostate cancer (CSPC). For treatment of CRPC and CSPC, abiraterone will be used in combination with prednisone AND one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g. leuprolide, triptorelin), OR 2) Patient has received bilateral orchiectomy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ACITRETIN

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## Products Affected

- *acitretin*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Severely impaired liver or kidney function, B.) Chronic abnormally elevated blood lipid values, or C.) Concomitant use of methotrexate or tetracyclines
<b>Required Medical Information</b>	Diagnosis of severe, recalcitrant psoriasis (including plaque, guttate, erythrodermic palmar- plantar and pustular) AND patient must have tried and failed, contraindication or intolerance to one formulary first line agent (e.g., Topical Corticosteroids (betamethasone, fluocinonide, desoximetasone), Topical Calcipotriene/Calcitriol, Topical Calcipotriene, OR Topical Tazarotene)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a dermatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ACTEMRA-3

## Products Affected

- ACTEMRA
- ACTEMRA ACTPEN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Giant cell arteritis, B.) Polyarticular juvenile idiopathic arthritis (PJIA) and patient has trial and failure or intolerance or contraindication to two preferred products, (i.e. Amjevita/Adalimumab-ADB/ Humira, Enbrel), C.) Rheumatoid arthritis (RA) and patient has trial and failure or intolerance or contraindication to two preferred products, (i.e. Amjevita/Adalimumab-ADB/ Humira, Enbrel, Rinvoq), D.) Systemic juvenile idiopathic arthritis (SJIA), or E.) Systemic sclerosis-associated interstitial lung disease
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	For RA, pJIA: Rheumatologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physician's certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ACTIMMUNE

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## Products Affected

- ACTIMMUNE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic granulomatous disease for use in reducing the frequency and severity of serious infections, or B.) Severe, malignant osteopetrosis (SMO)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ADALIMUMAB-ADBIM

## Products Affected

- *adalimumab-adbm (2 pen)*
- *adalimumab-adbm (2 syringe)*  
*subcutaneous prefilled syringe kit 10*  
*mg/0.2ml, 20 mg/0.4ml, 40 mg/0.8ml*
- *adalimumab-adbm(cd/uc/hs strt)*
- *adalimumab-adbm(ps/uv starter)*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<p>Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Non-infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa. For moderately to severely active rheumatoid arthritis: 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX), or corticosteroids. For active ankylosis spondylitis: patient has experienced an inadequate treatment response, intolerance, or contraindication to a non-steroidal anti-inflammatory drug(NSAID). For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).</p>

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	For Juvenile Idiopathic Arthritis: 2 years of age or older. For Pediatric Crohn's disease: 6 years of age or older. For Hidradenitis Suppurativa: 12 years of age or older. For Uveitis: 2 years of age or older. For Ulcerative Colitis: 5 years of age or older. All other indications 18 years of age or older.
<b>Prescriber Restrictions</b>	1) For PsO and HS: Dermatologist, 2) For CD and UC: Gastroenterologist, 3) For Uveitis: Ophthalmologist, 4) For RA, PJIA, and AS: Rheumatologist, 5) For PsA: Dermatologist or Rheumatologist.
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physician's certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ADEMPAS

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## Products Affected

- ADEMPAS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# AFINITOR

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Hypersensitivity to everolimus , or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus)
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, B.) Advanced hormone receptor-positive, HER2 negative breast cancer in postmenopausal women and taken in combination with exemestane, after failure with letrozole or anastrozole, C.) Progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin and disease is unresectable, locally advanced, or metastatic, D.) Pancreatic progressive neuroendocrine tumors and disease is unresectable, locally advanced, or metastatic, E.) Advanced renal cell carcinoma (RCC) after failure with sunitinib or sorafenib, F.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# AIMOVIG-3

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## Products Affected

- AIMOVIG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Chronic or episodic migraine disorder and patient has inadequate response, or contraindication to at least 1 generic formulary drugs used for migraine prevention (i.e., propranolol, topiramate, divalproex, timolol)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# AJOVY-3

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## Products Affected

- AJOVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Chronic or episodic migraine disorder and patient has inadequate response, or contraindication to at least 1 generic formulary drugs used for migraine prevention (i.e., propranolol, topiramate, divalproex, timolol)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# AKEEGA

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## Products Affected

- AKEEGA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) as detected on an FDA-approved test AND used in combination with prednisone
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ALECENSA

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## Products Affected

- ALECENSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# ALOSETRON

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## Products Affected

- *alosetron hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Constipation, B.) History of Chronic or severe constipation or sequelae from constipation, C.) History of ischemic colitis, intestinal obstruction, stricture, toxic megacolon, GI perforation, adhesions, diverticulitis, Crohn's disease, ulcerative colitis, D.) History of severe hepatic impairment, E.) History of impaired intestinal circulation, thrombophlebitis, or hypercoagulable state, or F.) Coadministration with flvoxamine
<b>Required Medical Information</b>	Diagnosis of irritable bowel syndrome, severe diarrhea-predominant
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ALUNBRIG

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## Products Affected

- ALUNBRIG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of anaplastic lymphoma kinase-positive (ALK) metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# AMBRISENTAN

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## Products Affected

- *ambrisentan*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Idiopathic pulmonary fibrosis (IPF), including those with pulmonary hypertension
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension classified as WHO Group I, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# AMJEVITA

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## Products Affected

- AMJEVITA SUBCUTANEOUS SOLUTION AUTO-INJECTOR 40 MG/0.4ML, 80 MG/0.8ML
- AMJEVITA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- AMJEVITA-PED 15KG TO <30KG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<p>Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Non-infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa. For moderately to severely active rheumatoid arthritis: 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX), or corticosteroids. For active ankylosing spondylitis: patient has experienced an inadequate treatment response, intolerance, or contraindication to a non-steroidal anti-inflammatory drug(NSAID). For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).</p>

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	For Juvenile Idiopathic Arthritis: 2 years of age or older. For Pediatric Crohn's disease: 6 years of age or older. For Hidradenitis Suppurativa: 12 years of age or older. For Uveitis: 2 years of age or older. For Ulcerative Colitis: 5 years of age or older. All other indications 18 years of age or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physician's certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# APTIOM

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## Products Affected

- APTIOM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of partial-onset seizures
<b>Age Restrictions</b>	4 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ARCALYST

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## Products Affected

- ARCALYST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# ARIKAYCE

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## Products Affected

- ARIKAYCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Known sensitivity to any aminoglycoside
<b>Required Medical Information</b>	Diagnosis of pulmonary Mycobacterium avium complex (MAC) infection and used as part of a combination antibacterial regimen in treatment refractory patients (greater than 6 months of a multidrug background regimen)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist or pulmonologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ATYPICALS

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## Products Affected

- CAPLYTA
- FANAPT
- FANAPT TITRATION PACK
- LYBALVI
- REXULTI
- SECUADO
- VERSACLOZ
- VRAYLAR ORAL CAPSULE 1.5 MG, 3 MG, 4.5 MG, 6 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# AUGTYRO

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## Products Affected

- AUGTYRO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# AUSTEDO

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Suicidal ideation and/or untreated or inadequately treated depression in a patient with Huntington's Disease, B.) Hepatic impairment, C.) Concomitant use of MAOIs, reserpine, tetrabenazine, or valbenazine
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chorea associated with Huntington's disease (Huntington's chorea), or B.) Tardive dyskinesia
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or psychiatrist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## Prior Authorization Criteria

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# AUVELITY

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## Products Affected

- AUVELITY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# AYVAKIT

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## Products Affected

- AYVAKIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Unresectable or metastatic gastrointestinal stromal tumor, with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations, B.) Advanced Systemic Mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), or mast cell leukemia (MCL), and platelet count of at least 50,000/mcL, or C.) Indolent systemic mastocytosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, allergist, or immunologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# BALVERSA

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## Products Affected

- BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# BANZEL

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## Products Affected

- *rufinamide oral tablet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Familial Short QT Syndrome
<b>Required Medical Information</b>	Diagnosis of seizures associated with Lennox-Gastaut syndrome
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# BENLYSTA

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## Products Affected

- BENLYSTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Active, autoantibody-positive, system lupus erythematosus (SLE), or B.) Active lupus nephritis and patient is receiving standard therapy (corticosteroids, antimalarials, NSAIDs, immunosuppressives)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist or rheumatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# BESREMI

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## Products Affected

- BESREMI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Existence of, or history of severe psychiatric disorders (severe depression, suicidal ideation, or suicide attempt), B.) Hypersensitivity to interferons including interferon alfa-2b or excipients, C.) Hepatic impairment (Child-Pugh B or C), D.) History or presence of active serious or untreated autoimmune disease, or E.) Immunosuppressed transplant recipients
<b>Required Medical Information</b>	Diagnosis of polycythemia vera
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# BEXAROTENE GEL

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## Products Affected

- *bexarotene*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of primary cutaneous T-cell lymphoma (CTCL Stage 1A/1B) and patient had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) indicated for cutaneous manifestations of CTCL
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# BEXAROTENE ORAL

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## Products Affected

- *bexarotene*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cutaneous T-cell lymphoma (CTCL) and patient is not a candidate for or had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) for cutaneous manifestations of CTCL
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, hematologist, or dermatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# BOSENTAN

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## Products Affected

- *bosentan*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant cyclosporine A or glyburide therapy
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (WHO Group I) and patient has New York Heart Association (NYHA) Functional Class II-IV, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# BOSULIF

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## Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or inadequate response to prior therapy, or B.) Newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) CML
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# BRAFTOVI

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## Products Affected

- BRAFTOVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) unresectable or metastatic melanoma with documented BRAF V600E or V600K mutation as detected by a FDA-approved test and used in combination with binimetinib, B.) metastatic colorectal cancer with documented BRAF V600E mutation as detected by a FDA-approved test, patient has received prior therapy, and braftovi used in combination with cetuximab, or C.) Metastatic non-small cell lung cancer with a BRAF V600E mutation as detected by an FDA-approved test and used in combination with binimetinib
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# BRIVIACT

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## Products Affected

- BRIVIACT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of partial-onset seizures, member must have history of inadequate response, contraindication, or intolerance to levetiracetam prior to approval.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# BRONCHITOL

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## Products Affected

- BRONCHITOL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# BRUKINSA

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## Products Affected

- BRUKINSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) mantle cell lymphoma (MCL) and patient has received at least one prior therapy, B.) Treatment of adult patients with Waldenstrom macroglobulinemia, C.) Treatment of adult patients with relapsed or refractory marginal zone lymphoma who have received at least one anti-CD20-based regimen (e.g., rituximab, obinutuzumab, ofatumumab), D.) Chronic lymphocytic leukemia, E.) Small lymphocytic lymphoma, or F.) Relapsed or refractory follicular lymphoma, in combination with obinutuzumab, after 2 or more lines of systemic therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# CABOMETYX

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## Products Affected

- CABOMETYX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Advanced hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib, C.) Advanced renal cell carcinoma and used as first line treatment in combination with nivolumab or D.) treatment of adults and pediatric patients 12 years and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following VEGFR-targeted therapy (e.g., Axitinib, Lenvatinib, Pazopanib, Sorafenib, Sunitinib, vandetanib) and who are radioactive iodine-refractory or ineligible
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# CALQUENCE

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## Products Affected

- CALQUENCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least 1 prior therapy, B.) Chronic lymphocytic leukemia (CLL), or C.) Small lymphocytic lymphoma (SLL)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# CAMZYOS

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## Products Affected

- CAMZYOS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) in adult patients
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# CAPRELSA

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## Products Affected

- CAPRELSA ORAL TABLET 100 MG,  
300 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Congenital long QT syndrome
<b>Required Medical Information</b>	Diagnosis of metastatic or unresectable locally advanced medullary thyroid cancer (MTC) AND disease is symptomatic or progressive
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# CARGLUMIC ACID

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## Products Affected

- *carglumic acid*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) N-acetyl glutamate synthase (NAGS) deficiency (confirmed by appropriate genetic testing) with acute or chronic hyperammonemia, or B.) Propionic or methylmalonic acidemia with acute hyperammonemia
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# CAYSTON

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## Products Affected

- CAYSTON

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# CIMZIA-3

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## Products Affected

- CIMZIA
- CIMZIA (2 SYRINGE)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# CLOBAZAM

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of seizures associated with Lennox-Gastaut syndrome
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# CNS STIMULANTS

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## Products Affected

- *armodafinil*
- *modafinil*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Obstructive sleep apnea (OSA) confirmed by sleep lab evaluation, B.) Narcolepsy confirmed by sleep lab evaluation, or C.) Shift work disorder (SWD)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# COMETRIQ

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## Products Affected

- COMETRIQ (100 MG DAILY DOSE)
- COMETRIQ (60 MG DAILY DOSE)
- COMETRIQ (140 MG DAILY DOSE)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of progressive, metastatic medullary thyroid cancer
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# COPIKTRA

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## Products Affected

- COPIKTRA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsed or refractory chronic lymphocytic leukemia (CLL), or B.) Relapsed or refractory small lymphocytic lymphoma (SLL). For CLL or SLL, the patient must have history of at least 2 prior therapies
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# CORLANOR

## Products Affected

- CORLANOR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Decompensated acute heart failure, B.) hypotension (i.e. blood pressure less than 90/50 mmHg), C.) sick sinus syndrome or sinoatrial block or 3rd degree AV block (unless a functioning demand pacemaker is present), D.) bradycardia (i.e., resting heart rate less than 60 bpm prior to treatment), E.) Severe hepatic impairment (Child-Pugh C), F.) Pacemaker dependent (heart rate maintained exclusively by the pacemaker), G.) Concomitant use of strong CYP3A4 inhibitors
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction 35% or less, who are in sinus rhythm with resting heart rate 70 beats per minute or more and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use, or B.) Pediatric patients with stable, symptomatic heart failure due to dilated cardiomyopathy and are in sinus rhythm with an elevated heart rate
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# COSENTYX

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# COTELLIC

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## Products Affected

- COTELLIC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.)unresectable or metastatic malignant melanoma with BRAF V600E OR V600K mutation, and documentation of combination therapy with vemurafenib (Zelboraf), or B.) Histiocytic neoplasms
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# CYSTAGON

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## Products Affected

- CYSTAGON

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Known serious hypersensitivity to penicillamine or cysteamine
<b>Required Medical Information</b>	Diagnosis of nephropathic cystinosis confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a nephrologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# DALFAMPRIDINE

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## Products Affected

- *dalfampridine er*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) History of seizure. B.) Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute)
<b>Required Medical Information</b>	Diagnosis of multiple sclerosis and patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting dalfampridine
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# DAURISMO

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## Products Affected

- DAURISMO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of newly diagnosed acute myeloid leukemia (AML) and used in combination with cytarabine in patients 75 years of age or older OR in patients that have comorbidities that preclude use of intensive induction chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an Oncologist or Hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# DAYBUE

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## Products Affected

- DAYBUE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# DEFERASIROX

## Products Affected

- *deferasirox*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Creatinine clearance less than 40 mL/min, B.) Poor performance status, C.) Platelet count less than 50 x 10 <sup>9</sup> /L, D.) Advanced malignancy, E.) High-risk myelodysplastic syndrome (MDS)
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes who have liver iron concentrations of at least 5 mg Fe/g dry weight AND serum ferritin level greater than 300 mcg/L, or B.) Chronic iron overload due to blood transfusions (transfusion hemosiderosis) as evidenced by transfusion of at least 100 mL/kg packed red blood cells AND serum ferritin level greater than 1000 mcg/L
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# DEFERIPRONE

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## Products Affected

- *deferiprone*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias 2.) failure to current chelation therapy (e.g., deferoxamine)
<b>Age Restrictions</b>	8 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# DIACOMIT

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## Products Affected

- DIACOMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of severe myoclonic epilepsy in infancy (Dravet syndrome) in patients taking clobazam
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# DICLOFENAC PATCH

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## Products Affected

- *diclofenac epolamine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of acute mild to moderate pain due to minor strains, sprains and contusions
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# DIMETHYL FUMARATE

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# DRONABINOL

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## Products Affected

- *dronabinol*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Sesame oil hypersensitivity
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Anorexia associated to AIDS, or B.) Chemotherapy-induced nausea and vomiting
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# DROXIDOPA

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## Products Affected

- *droxidopa*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (e.g., Parkinson disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 1 month, Renewal: 3 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# DUPIXENT

## Products Affected

- DUPIXENT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<p>For atopic dermatitis (AD), initial therapy: 1) Patient has moderate-to-severe disease, AND 2) Patient has had an inadequate treatment response to either a topical corticosteroid or a topical calcineurin inhibitor, OR topical corticosteroids and topical calcineurin inhibitors are not advisable for the patient. For oral corticosteroid dependent asthma, initial therapy: Patient has inadequate asthma control despite current treatment with both of the following medications: 1) High-dose inhaled corticosteroid AND 2) Additional controller (i.e., long acting beta2-agonist, long-acting, muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For moderate-to-severe asthma, initial therapy: Patient has a baseline blood eosinophil count of at least 150 cells per microliter and their asthma remains inadequately controlled despite current treatment with both of the following medications: 1) Medium-to-high-dose inhaled corticosteroid, AND 2) Additional controller (i.e., long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline) unless patient has an intolerance or contraindication to such therapies. For asthma, continuation of therapy: Asthma control has improved on treatment with the requested drug, as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose. For chronic rhinosinusitis with nasal polyposis (CRSwNP): 1) The requested drug is used as add-on maintenance treatment, AND 2) Patient has experienced an inadequate treatment response to fluticasone. For Eosinophilic esophagitis failure, intolerance or contraindication to PPIs</p>
<b>Age Restrictions</b>	None

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, dermatologist, gastroenterologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# EMGALITY-3

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## Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic or episodic migraine disorder and patient has inadequate response, or contraindication to at least 1 generic formulary drugs used for migraine prevention (i.e., propranolol, topiramate, divalproex, timolol), or B.) Episodic cluster headache
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# EMSAM

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## Products Affected

- EMSAM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use with any of the following: SSRIs, SNRIs, clomipramine, imipramine, meperidine, tramadol, methadone, pentazocine, propoxyphene, dextromethorphan, carbamazepine, or B.) Pheochromocytoma
<b>Required Medical Information</b>	Diagnosis of major depressive disorder and patient had trial of at least 2 generic oral antidepressants from differing classes (at least one should be from the following list: selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, mirtazapine, or bupropion unless contraindicated), unless unable to take any oral medication AND Patient had an adequate washout period (for patients previously on agents requiring a washout period)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ENBREL

## Products Affected

- ENBREL
- ENBREL SURECLICK
- ENBREL MINI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<p>Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, or E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy. For moderately to severely active rheumatoid arthritis: 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX), or corticosteroids. For active ankylosing spondylitis: patient has experienced an inadequate treatment response, intolerance, or contraindication to a non-steroidal anti-inflammatory drug(NSAID). For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).</p>
<b>Age Restrictions</b>	2 years of age for JIA and PsA, and 4 years of age for PsO
<b>Prescriber Restrictions</b>	1) For RA, PJIA, AS: Rheumatologist, 2) For PsA: Dermatologist or Rheumatologist, 3) For PsO: Dermatologist.
<b>Coverage Duration</b>	Plan Year

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physician's certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ENSPRYNG

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## Products Affected

- ENSPRYNG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Active Hepatitis B infection, or B.) Active or untreated latent tuberculosis
<b>Required Medical Information</b>	Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist, immunologist, or ophthalmologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# EPIDIOLEX

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## Products Affected

- EPIDIOLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Lennox-Gastaut syndrome, B.) Severe myoclonic epilepsy in infancy (Dravet syndrome), or C.) Seizures associated with tuberous sclerosis complex (TSC)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# EPOETIN THERAPY

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## Products Affected

- RETACRIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# ERIVEDGE

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## Products Affected

- ERIVEDGE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic basal cell carcinoma, or B.) Locally advanced basal cell carcinoma that has recurred following surgery or the patient is not a candidate for surgery or radiation
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ERLEADA

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## Products Affected

- ERLEADA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Nonmetastatic, castration-resistant prostate cancer (nmCRPC), or B.) Metastatic, castration-sensitive prostate cancer (mCSPC). For treatment of nmCRPC and mCSPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog, OR 2) Patient has received bilateral orchiectomy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ERLOTINIB

## Products Affected

- *erlotinib hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Locally advanced, unresectable, or metastatic pancreatic cancer and erlotinib will be used in combination with gemcitabine, B.) Locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility AND one of the following 1.) Erlotinib will be used as first-line treatment, 2.) Failure with at least one prior chemotherapy regimen, OR 3.) No evidence of disease progression after four cycles of first-line platinum-based chemotherapy and erlotinib will be used as maintenance treatment
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# EVEROLIMUS SUSPENSION

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## Products Affected

- *everolimus oral tablet soluble 2 mg, 3 mg, 5 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Hypersensitivity to everolimus , or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus)
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Tuberous sclerosis complex (TSC)-associated partial-onset seizures, or B.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# EVRYSDI

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## Products Affected

- EVRYSDI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of spinal muscular atrophy (SMA)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# FASENRA

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## Products Affected

- FASENRA
- FASENRA PEN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# FEBUXOSTAT

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## Products Affected

- *febuxostat*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use of azathioprine or mercaptopurine
<b>Required Medical Information</b>	Diagnosis of Gout and all of the following 1.) documented inadequate treatment response, adverse event, or contraindication to maximally titrated dose of Allopurinol, and 2.) patients with established cardiovascular disease, prescriber attests that benefit of treatment outweighs the risk of treatment
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# FENTANYL ORAL

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## Products Affected

- *fentanyl citrate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Use in opioid non-tolerant patients, C.) Known or suspected gastrointestinal obstruction, including paralytic ileus, D.) Acute or severe bronchial asthma and used in an unmonitored setting (absence of resuscitative equipment)
<b>Required Medical Information</b>	Must meet all of the following 1.) Diagnosis of cancer-related breakthrough pain, 2.) Patient is currently receiving/tolerant to around-the-clock opioid therapy for persistent cancer pain, and 3.) Patient and prescriber are enrolled in the TIRF REMS Access Program
<b>Age Restrictions</b>	16 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# FILSPARI

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## Products Affected

- FILSPARI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with angiotensin receptor blockers (ARBs), endothelin receptor antagonists (ERAs), or aliskiren
<b>Required Medical Information</b>	Diagnosis of treatment of primary immunoglobulin A (IgA) nephropathy at risk of rapid disease progression, generally a urine protein to creatinine ratio (UPCR) of 1.5 g/g or more, to reduce proteinuria
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# FIRMAGON

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## Products Affected

- FIRMAGON
- FIRMAGON (240 MG DOSE)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced prostate cancer
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# FOTIVDA

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## Products Affected

- FOTIVDA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory advanced renal cell cancer (RCC) following 2 or more prior systemic therapies
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# FRUZAQLA

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## Products Affected

- FRUZAQLA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic colorectal cancer (mCRC) and all of the following: A.) patient has been previously treated with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapy, B.) an anti-VEGF therapy, and C.) if RAS wild-type and medically appropriate, patient has also been previously treated with anti-EGFR therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# FULPHILA

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## Products Affected

- FULPHILA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of a non-myeloid malignancy and drug is being used as prophylaxis for chemotherapy-induced neutropenia
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# FYCOMPA

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## Products Affected

- FYCOMPA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Partial-onset seizures with or without secondary generalization, or B.) Primary generalized tonic-clonic seizure disorder as adjunctive therapy
<b>Age Restrictions</b>	4 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# GAVRETO

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## Products Affected

- GAVRETO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# GEFITINIB

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## Products Affected

- *gefitinib*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic non-small cell lung cancer (NSCLC) and must meet all of the following 1.) Tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility and 2.) Used as first-line treatment
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# GILOTRIF

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## Products Affected

- GILOTRIF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test, or B.) Metastatic squamous NSCLC with progression after platinum-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# GLATIRAMER

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## Products Affected

- *glatiramer acetate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# GLEOSTINE

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## Products Affected

- GLEOSTINE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet one of the following: A.) Hodgkin's disease in patient who has relapsed during or failed to respond to primary therapy and is being used in combination with other agents OR B.) Intracranial tumor
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# GLP1

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## Products Affected

- BYDUREON BCISE
- MOUNJARO
- OZEMPIC (0.25 OR 0.5 MG/DOSE)
- OZEMPIC (1 MG/DOSE)  
SUBCUTANEOUS SOLUTION PEN-  
INJECTOR 2 MG/1.5ML, 4 MG/3ML
- OZEMPIC (2 MG/DOSE)
- RYBELSUS
- TRULICITY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Used for weightloss
<b>Required Medical Information</b>	The drug is prescribed for an FDA-approved indication
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# GROWTH HORMONE

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## Products Affected

- OMNITROPE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Use for growth promotion in pediatric patients with closed epiphyses, B.) Acute critical illness caused by complications following open-heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure, C.) Active malignancy, D.) Active proliferative or severe nonproliferative diabetic retinopathy, E.) Prader-Willi Syndrome in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment
<b>Required Medical Information</b>	Supporting statement of diagnosis from the physician
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or nephrologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# HEPATITIS B

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## Products Affected

- *adefovir dipivoxil*
- BARACLUDE
- *entecavir*
- VEMLIDY

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of chronic hepatitis B and all of the following 1.) Patient has or had evidence of viral replication prior to initiation, 2.) Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) or histologically active disease, and 3.) Patient is receiving anti-retroviral therapy if the patient has HIV co-infection
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## Prior Authorization Criteria

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# HEPATITIS C

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## Products Affected

- *ledipasvir-sofosbuvir*
- *sofosbuvir-velpatasvir*
- MAVYRET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must submit documentation of chronic hepatitis C genotype (confirmed by HCV RNA level within the last 6 months). Must submit laboratory results within 12 weeks prior to initiating therapy including: 1) CBC w Platelets, 2) AST/ALT, 3) Total Bilirubin, 4) Serum Albumin, and 5) PT/INR. Genotype and subtype are not required for: (1) initial treatment of patients without cirrhosis if using Sofosbuvir-Velpatasvir or Mavyret OR (2) treatment of patients with compensated cirrhosis if using Mavyret
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	Duration of approval per AASLD Guidelines
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## Prior Authorization Criteria

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# HRM - ANALGESICS

## Products Affected

- *butalbital-acetaminophen*
- *butalbital-apap-caffeine*
- TENCON

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# HRM - ANTI-ARRHYTHMICS

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## Products Affected

- DIGOXIN ORAL SOLUTION
- *digoxin oral tablet 250 mcg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Formulary Non HRM alternatives: propranolol, sotalol, dofetilide, amiodarone, propafenone, mexiletine
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# HRM - ANTICHOLINERGIC

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## Products Affected

- *chlordiazepoxide-clidinium*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# HRM - ANTIDEMENTIA

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## Products Affected

- *ergoloid mesylates*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Formulary non-HRM alternatives: donepezil, galantamine, memantine, rivastigmine oral
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# HRM - ANTIDEPRESSANTS

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## Products Affected

- *chlordiazepoxide-amitriptyline*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Formulary non-HRM alternatives: mirtazapine, trazodone, fluoxetine, escitalopram, fluvoxamine, desvenlafaxine, duloxetine, sertraline, venlafaxine, bupropion
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# HRM - ANTIHISTAMINES

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## Products Affected

- *hydroxyzine hcl*
- *hydroxyzine pamoate*
- *promethazine hcl*
- *promethegan*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Formulary non-HRM alternatives FOR MANAGEMENT OF ALLERGIC CONDITIONS: desloratadine, cetirizine syp, levocetirizine. FOR MANAGEMENT OF ANXIETY/SEDATION: buspirone, trazodone. FOR MANAGEMENT OF NAUSEA/VOMITING: granisetron, ondansetron
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## Prior Authorization Criteria

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# HRM - ANTIPARKINSON AGENTS

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## Products Affected

- *benztropine mesylate*
- *trihexyphenidyl hcl*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Formulary non-HRM alternatives: amantadine, carbidopa/levodopa, entacapone, Neupro, pramipexole, ropinirole, selegiline
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# HRM - BENZODIAZEPINES

## Products Affected

- *alprazolam oral tablet 0.25 mg, 0.5 mg, 1 mg, 2 mg*
- *chlordiazepoxide hcl*
- *estazolam*
- *temazepam*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication. For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs)
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# HRM - CARDIOVASCULAR

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## Products Affected

- *guanfacine hcl er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Formulary Non HRM alternatives: atomoxetine, dexamethylphenidate, methylphenidate
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# HRM - MEGESTROL

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## Products Affected

- *megestrol acetate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Formulary Non HRM alternatives: dronabinol
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# HRM - PCD - BENZODIAZEPINES

## Products Affected

- *clonazepam oral tablet 0.5 mg, 1 mg, 2 mg*
- *clonazepam oral tablet dispersible 0.125 mg, 0.25 mg, 0.5 mg, 1 mg, 2 mg*
- *clorazepate dipotassium*
- *diazepam intensol*
- *diazepam oral solution*
- *diazepam oral tablet*
- *lorazepam*
- *lorazepam intensol*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of seizure disorder or must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication. For all indications: The prescriber must acknowledge the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to AT LEAST TWO agents from the following classes: a) selective serotonin reuptake inhibitors (SSRIs), b) serotonin-norepinephrine reuptake inhibitors (SNRIs).
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# HRM - SEDATIVE HYPNOTICS

## Products Affected

- *zaleplon*
- *zolpidem tartrate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to doxepin (3 mg or 6 mg)3.)The prescriber must acknowledge that the benefit of therapy with this prescribed medication outweighs the potential risks for the patient. (Note: The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.)
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Formulary non-HRM alternatives: Belsonra, doxepin 3mg and 6mg tablets, trazodone
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# HRM - SKELETAL MUSCLE RELAXANTS

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## Products Affected

- *cyclobenzaprine hcl*
- *orphenadrine citrate er*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Formulary Non HRM alternatives: baclofen
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# HUMIRA

## Products Affected

- HUMIRA (2 PEN) SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.4ML, 40 MG/0.8ML, 80 MG/0.8ML
- HUMIRA (2 SYRINGE) SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML
- HUMIRA-CD/UC/HS STARTER
- HUMIRA-PED $\geq$ 40KG UC STARTER
- HUMIRA-PSORIASIS/UVEIT STARTER

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<p>Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Non-infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa. For moderately to severely active rheumatoid arthritis: 1) patient has experienced an inadequate treatment response, intolerance, or has a contraindication to methotrexate (MTX), or corticosteroids. For active ankylosis spondylitis: patient has experienced an inadequate treatment response, intolerance, or contraindication to a non-steroidal anti-inflammatory drug(NSAID). For moderate to severe plaque psoriasis (new starts only): 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has</p>

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<b>PA Criteria</b>	<b>Criteria Details</b>
	severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected)
<b>Age Restrictions</b>	For Juvenile Idiopathic Arthritis: 2 years of age or older. For Pediatric Crohn's disease: 6 years of age or older. For Hidradenitis Suppurativa: 12 years of age or older. For Uveitis: 2 years of age or older. For Ulcerative Colitis: 5 years of age or older. All other indications 18 years of age or older.
<b>Prescriber Restrictions</b>	1) For PsO and HS: Dermatologist, 2) For CD and UC: Gastroenterologist, 3) For Uveitis: Ophthalmologist, 4) For RA, PJIA, and AS: Rheumatologist, 5) For PsA: Dermatologist or Rheumatologist.
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physician's certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# HYFTOR

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## Products Affected

- HYFTOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Facial angiofibroma associated with tuberous sclerosis
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# IBRANCE

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## Products Affected

- IBRANCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with fulvestrant and disease has progressed following endocrine therapy, or B.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and used in combination with an aromatase inhibitor in a male or female patient as initial endocrine-based therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ICATIBANT

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## Products Affected

- *icatibant acetate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hereditary angioedema AND medication will be used for the treatment of acute attacks
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, hematologist, or immunologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ICLUSIG

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# IDHIFA

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## Products Affected

- IDHIFA ORAL TABLET 100 MG, 50 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase 2 (IDH2) mutation as detected by an FDA approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# IMATINIB

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# IMBRUVICA

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## Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL), B.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion, C.) Waldenstrom's macroglobulinemia (WM), or D.) Chronic graft vs host disease (cGVHD) after failure of at least one first-line corticosteroid therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# IMPAVIDO

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## Products Affected

- IMPAVIDO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Sjogren-Larsson-Syndrome
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) Visceral leishmaniasis caused by <i>Leishmania donovani</i> , B.) Cutaneous leishmaniasis caused by <i>Leishmania braziliensis</i> , <i>Leishmania guyanensis</i> , and <i>Leishmania panamensis</i> , or C.) Mucosal leishmaniasis caused by <i>Leishmania braziliensis</i>
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# INCRELEX

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## Products Affected

- INCRELEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Active or suspected malignancy, B.) Use for growth promotion in patients with closed epiphyses, or C.) Intravenous administration
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Severe primary insulin-like growth factor-1 (IGF-1) deficiency and utilized for pediatric treatment of growth failure, or B.) Growth hormone (GH) gene deletion and patient has developed neutralizing antibodies to GH and utilized for pediatric treatment of growth failure
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# INJECTABLE TESTOSTERONE

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## Products Affected

- *testosterone cypionate*
- *testosterone enanthate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Carcinoma of the breast (males only), or B.) Known or suspected carcinoma of the prostate
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, B.) Inoperable metastatic breast cancer in women who are postmenopausal (testosterone enanthate), C.) Primary hypogonadism, or D.) Delayed puberty (testosterone enanthate). Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# INLYTA

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## Products Affected

- INLYTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma and patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens), or B.) Advanced renal cell carcinoma and used as first-line therapy in combination with avelumab or pembrolizumab
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# INQOVI

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## Products Affected

- INQOVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# INREBIC

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## Products Affected

- INREBIC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# INVEGA HAFYERA

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## Products Affected

- INVEGA HAFYERA
- PREFILLED SYRINGE 1092 MG/3.5ML,
- INTRAMUSCULAR SUSPENSION
- 1560 MG/5ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following A.) Diagnosis of schizophrenia, and B.) Adequate treatment has been established with Invega Sustenna for at least 4 months or Invega Trinza for at least one three-month injection cycle
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an psychiatrist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	For continuation of therapy member must be re-evaluated by the psychiatrist to assess clinical response. Treatment should be discontinued if failure to therapy or an adverse event is documented or the member does not demonstrate adherence to treatment
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# INVEGA SUSTENNA

## Products Affected

- INVEGA SUSTENNA 156 MG/ML, 234 MG/1.5ML, 39  
INTRAMUSCULAR SUSPENSION MG/0.25ML, 78 MG/0.5ML  
PREFILLED SYRINGE 117 MG/0.75ML,

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet one of the following A.) Diagnosis of schizophrenia and all of the following 1.) trial and failure, contraindication, or intolerance to two oral second-generation antipsychotics, 2.) Trial and failure to respond to haloperidol decanoate and fluphenazine decanoate, 3.) Member has established response and tolerability to oral paliperidone, and 4.) Patient presents history of noncompliance with oral medications and documentation is provided on the efforts to improve medication adherence, or B.) Diagnosis of schizoaffective disorder and both of the following 1.) Member has established response and tolerability to oral paliperidone and 2.) Patient presents history of noncompliance with oral medications and documentation is provided on the efforts to improve medication adherence
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an psychiatrist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	For continuation of therapy member must be re-evaluated by the psychiatrist to assess clinical response. Treatment should be discontinued if failure to therapy or an adverse event is documented or the member does not demonstrate adherence to treatment
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

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

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# INVEGA TRINZA

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## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following A.) Diagnosis of schizophrenia, and B.) Adequate treatment has been established with Invega Sustenna for at least 4 months
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an psychiatrist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	For continuation of therapy member must be re-evaluated by the psychiatrist to assess clinical response. Treatment should be discontinued if failure to therapy or an adverse event is documented or the member does not demonstrate adherence to treatment
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ITRACONAZOLE

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## Products Affected

- *itraconazole*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# IVABRADINE

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## Products Affected

- *ivabradine hcl*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# IVERMECTIN

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## Products Affected

- *ivermectin*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Prevention or treatment of COVID-19
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) Strongyloidiasis of the intestinal tract or B.) Onchocerciasis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# IWILFIN

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## Products Affected

- IWILFIN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of high-risk neuroblastoma to be used to reduce the risk of relapse in adult and pediatric patients who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# JAKAFI

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## Products Affected

- JAKAFI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis, B.) Polycythemia vera AND patient has had an inadequate response to or is intolerant of hydroxyurea, C.) Acute graft versus host disease AND disease is refractory to steroid therapy, or D.) Chronic graft-versus-host disease (cGVHD) after failure of corticosteroid therapy (alone or in combination with a calcineurin inhibitor) and up to one additional line of systemic therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# JAYPIRCA

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## Products Affected

- JAYPIRCA ORAL TABLET 100 MG, 50 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) relapsed or refractory mantle cell lymphoma (MCL) and is being used after at least two lines of systemic therapy, including a BTK inhibitor or B.) chronic lymphocytic leukemia or small lymphocytic lymphoma who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase inhibitor and a B-cell lymphoma 2 inhibitor.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## Prior Authorization Criteria

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# JOENJA

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## Products Affected

- JOENJA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# KALYDECO

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## Products Affected

- KALYDECO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (CF) and the patient has 1 mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# KERENDIA

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## Products Affected

- KERENDIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	none
<b>Required Medical Information</b>	Diagnosis of Chronic kidney disease associated with Type 2 diabetes mellitus AND patient is currently receiving the following standard of care A.) A maximally tolerated dose of ACE inhibitor, ARB, or a combination medication containing an ACE or ARB AND B.) Antidiabetic agent (e.g., metformin or an agent containing metformin, SGLT2 inhibitor, GLP-1 RA)
<b>Age Restrictions</b>	none
<b>Prescriber Restrictions</b>	none
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	none
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# KISQALI

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# KISQALI FEMARA

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and one of the following A.) The patient is pre-or perimenopausal woman or male and the requested drug will be used as initial endocrine-based therapy, B.) The patient is postmenopausal, the requested drug will be used as initial endocrine-based therapy, and the patient has experienced disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# KORLYM

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## Products Affected

- KORLYM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Coadministration with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, B.) Concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses, C.) History of unexplained vaginal bleeding, D.) Endometrial hyperplasia with atypia or endometrial carcinoma
<b>Required Medical Information</b>	Diagnosis of endogenous Cushing syndrome in patients with type 2 diabetes mellitus or glucose intolerance and must meet all of the following 1.) Used to control hyperglycemia secondary to hypercortisolism, AND 2.) Patient has failed or is not a candidate for surgery
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# KOSELUGO

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## Products Affected

- KOSELUGO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of neurofibromatosis type 1 (NF1) in a patient who has symptomatic, inoperable plexiform neurofibromas (PN)
<b>Age Restrictions</b>	2 years of age to 17 years of age
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# KRAZATI

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## Products Affected

- KRAZATI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# LAPATINIB

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## Products Affected

- *lapatinib ditosylate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced or metastatic breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND meets one of the following A.) Used in combination with capecitabine in a patient who has received prior therapy including an anthracycline, a taxane, and trastuzumab, OR B.) Used in combination with letrozole in a postmenopausal female for whom hormonal therapy is indicated
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# LENALIDOMIDE

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## Products Affected

- *lenalidomide*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# 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
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, B.) Advanced renal cell carcinoma, in combination with everolimus, following one prior anti-angiogenic therapy, C.) Unresectable hepatocellular carcinoma, first-line therapy, D.) Advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, in combination with pembrolizumab, when disease has progressed following prior systemic therapy and patient is not a candidate for curative surgery or radiation, or E.) Advanced renal cell carcinoma, in combination with pembrolizumab and used as first-line therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# LEUKINE

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## Products Affected

- LEUKINE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Patient has undergone allogeneic or autologous bone marrow transplant (BMT) and engraftment is delayed or failed, B.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, C.) Medication will be used for myeloid reconstitution after an autologous or allogeneic BMT, D.) Patient has acute myeloid leukemia and administration will be after completion of induction chemotherapy, E.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS) or F.) Autologous peripheral blood stem cell transplant, Following myeloablative chemotherapy.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# LEUPROLIDE

## Products Affected

- ELIGARD SUBCUTANEOUS KIT 22.5 MG, 30 MG, 45 MG, 7.5 MG
- *leuprolide acetate*
- LEUPROLIDE ACETATE (3 MONTH)
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)
- LUPRON DEPOT-PED (1-MONTH)
- LUPRON DEPOT-PED (3-MONTH)
- LUPRON DEPOT-PED (6-MONTH)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet one of the following: 1.) Eligard only: Advanced or metastatic prostate cancer, or 2.) For Lupron depot and leuprolide products only: A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard or Trelstar (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, and 45 mg 6-month depots only), B.) Endometriosis (3.75 mg 1-month and 11.25 mg 3-month depots only), C.) Anemia due to uterine leiomyomata (Fibroids) (3.75 mg 1-month and 11.25 mg 3-month depots only) and patient is preoperative, or D.) Central precocious puberty (idiopathic or neurogenic) in children
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# L-GLUTAMINE

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## Products Affected

- *l-glutamine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# LIDOCAINE EXT

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## Products Affected

- *lidocaine external ointment*
- *lidocaine hcl*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Amide hypersensitivity
<b>Required Medical Information</b>	The requested drug will be used for or topical anesthesia of skin or mucous membranes
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# LINEZOLID

## Products Affected

- *linezolid intravenous*
- *linezolid oral tablet*
- *linezolid oral suspension reconstituted*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Community acquired pneumonia, B.) Hospital-acquired pneumonia, C.) Vancomycin-resistant Enterococcus faecium infection, D.) Complicated skin and skin structure infections, or E.) Uncomplicated skin and skin structure infections
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# LIVTENCITY

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## Products Affected

- LIVTENCITY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# LONSURF

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## Products Affected

- LONSURF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic colorectal cancer, previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based regimens, an anti-VEGF therapy, and if RAS wild-type, an anti-EGFR therapy, or B.) Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# LORBRENA

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## Products Affected

- LORBRENA ORAL TABLET 100 MG,  
25 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with strong CYP3A4 inducers
<b>Required Medical Information</b>	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# LUMAKRAS

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## Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 320 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) as determined by an FDA-approved test, and patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# LYNPARZA

## Products Affected

- LYNPARZA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<p>Diagnosis of one of the following A.) HER2-negative, deleterious or suspected deleterious germline BRCA mutated high-risk early or metastatic breast cancer AND patient has been previously treated with chemotherapy in neoadjuvant, adjuvant, or metastatic setting, B.) Recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer AND used for maintenance treatment in patients who are in complete or partial response to platinum-based chemotherapy (e.g. cisplatin, carboplatin), C.) Deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients with complete or partial response to first-line platinum-based chemotherapy, D.) Deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma and disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen, E.) Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA-mutation and/or genomic instability AND are using in combination with bevacizumab for maintenance treatment, F.) Deleterious or suspected deleterious germline or somatic homologous recombination repair gene mutated metastatic castration-resistant prostate cancer in patients who have progressed following prior treatment with enzalutamide or abiraterone, or G.) Deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer in combination with abiraterone and prednisone or prednisolone</p>
<b>Age Restrictions</b>	18 years of age and older

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria  
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# LYTGOBI

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements and previously treated
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# MATULANE

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## Products Affected

- MATULANE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Inadequate marrow reserve
<b>Required Medical Information</b>	Diagnosis of Hodgkin's Disease, Stages III and IV and used in combination with other anticancer drugs
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# MAYZENT

## Products Affected

- MAYZENT ORAL TABLET 0.25 MG, 1 MG, 2 MG
- MAYZENT STARTER PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) CYP2C9*3/*3 genotype, B.) In the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III-IV heart failure, or C.) Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

### Prior Authorization Criteria

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# MEKINIST

## Products Affected

- MEKINIST

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and used in combination with dabrafenib and no locoregional treatment options, B.) Malignant melanoma with lymph node involvement and following complete resection with BRAF V600E or V600K mutations and used in combination with dabrafenib, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutations and used in combination with dabrafenib or as monotherapy, D.) Metastatic non-small cell lung cancer, with BRAF V600E mutation, in combination with dabrafenib, E.) Unresectable or metastatic solid tumors with BRAF V600E mutation, in combination with dabrafenib, and have progressed following prior treatment and have no satisfactory alternative treatment options, F.) Low-grade glioma with a BRAF V600E mutation and require systemic therapy, in combination with dabrafenib
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# MEKTOVI

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## Products Affected

- MEKTOVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Unresectable or metastatic malignant melanoma with documented BRAF V600E or V600K mutation as detected by an FDA approved test AND used in combination with encorafenib or B.) Metastatic non-small cell lung cancer with a BRAF V600E mutation as detected by an FDA-approved test AND used in combination with encorafenib
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# MIFEPRISTONE

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## Products Affected

- *mifepristone*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Coadministration with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, B.) Concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses, C.) History of unexplained vaginal bleeding, D.) Endometrial hyperplasia with atypia or endometrial carcinoma
<b>Required Medical Information</b>	Diagnosis of endogenous Cushing syndrome in patients with type 2 diabetes mellitus or glucose intolerance and must meet all of the following 1.) Used to control hyperglycemia secondary to hypercortisolism, and 2.) Patient has failed or is not a candidate for surgery
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# MIGLUSTAT

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## Products Affected

- *miglustat*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of mild to moderate type 1 Gaucher disease and patient is not a candidate for enzyme replacement therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# NAYZILAM

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## Products Affected

- NAYZILAM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Acute narrow angle glaucoma
<b>Required Medical Information</b>	Diagnosis of epilepsy and documentation of acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures), that are distinct from a patient's usual seizure pattern
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	This criteria applies to new starts only
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# NERLYNX

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## Products Affected

- NERLYNX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Early stage HER2-positive breast cancer and used following adjuvant trastuzumab therapy, or B.) Advanced or metastatic HER2-positive breast cancer, used in combination with capecitabine, AND patient has received 2 or more prior anti-HER2-based regimens in the metastatic setting
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# NINLARO

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## Products Affected

- NINLARO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of multiple myeloma, used in combination with lenalidomide and dexamethasone, AND patient has history of at least 1 prior therapy . Examples include bortezomib, cyclophosphamide, Kyprolis (carfilzomib intravenous infusion), lenalidomide, Darzalex (daratumumab intravenous infusion).
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# NUBEQA

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## Products Affected

- NUBEQA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Non-metastatic, castration-resistant prostate cancer (nmCRPC) or B.) Metastatic hormone-sensitive prostate cancer in combination with docetaxel. For treatment of nmCRPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient has received bilateral orchiectomy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# NUEDEXTA

## Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) History of prolonged QT interval, congenital long QT syndrome or Torsades de pointes, B.) Heart failure, C.) Complete AV block without an implanted pacemaker or high risk of complete AV block, D.) Concomitant use with quinidine, quinine, mefloquine, or drugs that prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), E.) Concomitant use with MAOIs or within 14 days of MAOI therapy, F.) History of quinine-, mefloquine-, or quinidine-induced thrombocytopenia, bone marrow depression, or lupus-like syndrome
<b>Required Medical Information</b>	Diagnosis of pseudobulbar affect
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# NUPLAZID

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## Products Affected

- NUPLAZID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Parkinson's disease and both of the following apply A.) Used for treatment of hallucinations and/or delusions associated with Parkinson's disease psychosis, and B.) Diagnosis of Parkinson's disease was made prior to the onset of psychotic symptoms
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# OCTREOTIDE

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## Products Affected

- *octreotide acetate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# ODOMZO

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## Products Affected

- ODOMZO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced basal cell carcinoma of the skin and one of the following A.) Cancer has recurred following surgery or radiation therapy, B.) Patient is not a candidate for surgery or radiation therapy.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# OFEV

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## Products Affected

- OFEV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Idiopathic pulmonary fibrosis (IPF), B.) Systemic sclerosis-associated interstitial lung disease (ILD), or C.) Chronic fibrosing interstitial lung disease with a progressive phenotype
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# OGSIVEO

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of progressing desmoid tumors who require systemic treatment
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# OJEMDA

## Products Affected

- OJEMDA ORAL SUSPENSION RECONSTITUTED
- OJEMDA ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# OJJAARA

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## Products Affected

- OJJAARA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [postpolycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# ONUREG

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## Products Affected

- ONUREG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of acute myeloid leukemia (AML) used in maintenance treatment for adult patients who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# OPSUMIT

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## Products Affected

- OPSUMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: Plan Year
<b>Other Criteria</b>	Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# OPSYNVI

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## Products Affected

- OPSYNVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: Plan Year
<b>Other Criteria</b>	Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# ORENCIA

## Products Affected

- ORENCIA CLICKJECT
- 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>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, or D.) Prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in patients undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor.
<b>Age Restrictions</b>	For RA: 18 years of age or older. All other indications 2 years of age or older.
<b>Prescriber Restrictions</b>	For RA and PJIA: Rheumatologist, For PsA: Dermatologist or Rheumatologist, For aGVHD: Hematologist or Transplant Specialist.
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physician's certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# ORGOVYX

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## Products Affected

- ORGOVYX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced prostate cancer
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ORILISSA

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## Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following: A.) Known osteoporosis, B.) Severe hepatic impairment, or C.) Concurrent use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors
<b>Required Medical Information</b>	Diagnosis of moderate to severe pain associated with endometriosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# ORKAMBI

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## Products Affected

- ORKAMBI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# ORSERDU

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## Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced or metastatic, ER-positive, HER2-negative, ESR1-mutated, breast cancer in postmenopausal women or adult man after at least 1 line of endocrine therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# OTEZLA

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## Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# PANRETIN

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## Products Affected

- PANRETIN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# PAZOPANIB

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## Products Affected

- *pazopanib hcl*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma (RCC), or B.) Advanced soft tissue sarcoma (STS), has received prior chemotherapy and does not have adipocytic soft tissue sarcoma (STS) or gastrointestinal stromal tumors (GIST)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# PEGYLATED INTERFERON

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## Products Affected

- PEGASYS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# PEMAZYRE

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## Products Affected

- PEMAZYRE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or B.) Relapsed or refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor 1 rearrangement
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, gastroenterologist, or hepatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# PENICILLAMINE

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## Products Affected

- *penicillamine*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Breastfeeding, B.) Hypersensitivity to penicillamine products, C.) Penicillamine-related aplastic anemia/agranulocytosis, or D.) Rheumatoid arthritis patients with history or evidence of renal insufficiency
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Cystinuria, B.) Severe, active rheumatoid arthritis, or C.) Wilson's disease
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# PIQRAY

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# PIRFENIDONE

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## Products Affected

- *pirfenidone*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of idiopathic pulmonary fibrosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# POMALYST

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## Products Affected

- POMALYST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) AIDS-related Kaposi sarcoma and patient has failure on highly active antiretroviral therapy (HAART), B.) Kaposi sarcoma in HIV-negative adults, or C.) Multiple myeloma and in combination with dexamethasone in adults who have received at least 2 prior therapies (including lenalidomide and a proteasome inhibitor) and have demonstrated disease progression on or within 60 days of completion of the last therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# POSACONAZOLE

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## Products Affected

- *posaconazole*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# PREVYMIS

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## Products Affected

- PREVYMIS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use with pimozone or ergot alkaloids (ergotamine, dihydroergotamine), B.) Concomitant use with pitavastatin or simvastatin when coadministered with cyclosporine
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant, or B.) Prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# PROLIA

## Products Affected

- PROLIA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Hypocalcemia (calcium less than 8.0 mg/dL)
<b>Required Medical Information</b>	Must meet all of the following A.) Diagnosis of one of the following 1.) Treatment of osteoporosis in postmenopausal females at high risk of fracture, 2.) Treatment of osteoporosis in males at high risk of fracture 3.) Treatment of bone loss in males receiving androgen-deprivation therapy for nonmetastatic prostate cancer, 4.) Treatment of bone loss in females receiving aromatase inhibitor therapy for breast cancer, or 5.) Treatment of glucocorticoid-induced osteoporosis in patients at high risk of fracture who are initiating or continuing systemic glucocorticoids at a daily dose greater than or equal to 7.5 mg of prednisone for an anticipated duration of at least 6 months B.) Bone density scan (DEXA) documenting a T-score less than -1.0 at lumbar spine, total hip, femoral neck, or 33% radius and member has high risk factors (high risk defined as osteoporotic fracture history, multiple risk factors for fracture, or failure of or intolerance to other available osteoporosis therapy) or T-score less than or equal to -2.5 in the lumbar spine, total hip, femoral neck, or 33% radius
<b>Age Restrictions</b>	none
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

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

Prior Authorization Criteria  
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# PROMACTA

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic idiopathic thrombocytopenic purpura (ITP), B.) Chronic hepatitis C infection associated thrombocytopenia, or C.) Severe aplastic anemia with insufficient response to immunosuppressive therapy or in combination with standard immunosuppressive therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# PULMOZYME

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## Products Affected

- PULMOZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (CF)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## Prior Authorization Criteria

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# PURIXAN

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## Products Affected

- PURIXAN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) Diagnosis of acute lymphocytic leukemia, 2.) Using in combination with methotrexate, 3.) Patient has tried/failed or has contraindication/intolerance to mercaptopurine tablets
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# PYRIMETHAMINE

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## Products Affected

- *pyrimethamine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Documented megaloblastic anemia due to folate deficiency
<b>Required Medical Information</b>	Diagnosis of Toxoplasmosis and treatment in combination with a sulfonamide
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	10 weeks
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# QINLOCK

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## Products Affected

- QINLOCK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced gastrointestinal stromal tumor (GIST) and patient has received prior treatment with 3 or more kinase inhibitors, including imatinib
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# QUININE SULFATE

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## Products Affected

- *quinine sulfate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# RAVICTI

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## Products Affected

- RAVICTI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of urea cycle disorders
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# REGRANEX

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## Products Affected

- REGRANEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Known neoplasm at the site of application
<b>Required Medical Information</b>	Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply
<b>Age Restrictions</b>	16 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# REPATHA

## Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH), B.) homozygous familial hypercholesterolemia, C.) established cardiovascular disease and myocardial infarction prophylaxis, stroke prophylaxis, or coronary revascularization prophylaxis is required, or D.) clinical atherosclerotic cardiovascular disease (CVD) as defined as one of the following 1.) acute coronary syndrome, 2.) history of myocardial infarction, 3.) stable/unstable angina, 4.) coronary or other arterial revascularization, 5.) stroke, 6.) transient ischemic stroke (TIA), or 7.) peripheral arterial disease presumed to be atherosclerotic region
<b>Age Restrictions</b>	10 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# RETEVMO

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in patients who require systemic therapy, B.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC), C.) Advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and are refractory to radioactive iodine, if appropriate, or D.) Locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# REVLIMID

## Products Affected

- REVLIMID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# REZLIDHIA

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## Products Affected

- REZLIDHIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

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# REZUROCK

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## Products Affected

- REZUROCK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of chronic graft-vs-host disease and patient has failed at least 2 prior lines of systemic therapy (e.g., prednisone, methotrexate, cyclosporine, tacrolimus, mycophenolate, Imbruvica (ibrutinib), Jakafi (ruxolitinib), etc.)
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# RILUZOLE

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## Products Affected

- *riluzole*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of amyotrophic lateral sclerosis (ALS)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# RINVOQ

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## Products Affected

- RINVOQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# RINVOQ LQ

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## Products Affected

- RINVOQ LQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Active psoriatic arthritis with inadequate response or intolerance to 1 or more TNF blockers, or B.) Active polyarticular juvenile idiopathic arthritis with inadequate response or intolerance to 1 or more TNF blockers
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a rheumatologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	Screening for latent tuberculosis infection is required prior to initiation of treatment
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## Prior Authorization Criteria

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# RIVFLOZA

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## Products Affected

- RIVFLOZA SUBCUTANEOUS SOLUTION
- RIVFLOZA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 128 MG/0.8ML, 160 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Primary hyperoxaluria type 1 and the patient has relatively preserved kidney function (eGFR is greater than or equal to 30mL/min/1.73m <sup>2</sup> )
<b>Age Restrictions</b>	9 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a NEPHROLOGIST
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ROZLYTREK

## Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PACKET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) ROS1-positive metastatic non-small cell lung cancer (NSCLC), or B.) Solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have either progressed following treatment or have no satisfactory alternative therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Verify the pregnancy status of females of reproductive potential prior to initiating ROZLYTREK
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# RUBRACA

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## Products Affected

- RUBRACA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, used as maintenance treatment, and patient is in complete or partial response to platinum-based chemotherapy, or B.) Deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer and patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# RUFINAMIDE

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## Products Affected

- *rufinamide oral suspension*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Familial Short QT Syndrome
<b>Required Medical Information</b>	Diagnosis of seizures associated with Lennox-Gastaut syndrome and used as adjunctive treatment
<b>Age Restrictions</b>	1 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# RYDAPT

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## Products Affected

- RYDAPT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# SAPROPTERIN

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## Products Affected

- *sapropterin dihydrochloride*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hyperphenylalaninemia (HPA) caused by tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 2 months, Renewal: Plan year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# SCSEMBLIX

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## Products Affected

- SCSEMBLIX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), or B.) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with the T315I mutation
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# SIGNIFOR

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## Products Affected

- SIGNIFOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Cushing disease and patient has had inadequate response to or is not a candidate for surgery. For renewal: Documentation of a clinically meaningful reduction in 24-hour urinary free cortisol (UFC) levels or improvement in signs or symptoms of the disease
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# SILDENAFIL

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## Products Affected

- *sildenafil citrate oral tablet 20 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Nitrate therapy, including intermittent use, B.) Concomitant use with riociguat or other guanylate cyclase stimulators, C.) Concomitant use with HIV protease inhibitors or elvitegravir/cobicistat/tenofovir/emtricitabine
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# SIRTURO

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## Products Affected

- SIRTURO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Must meet all of the following 1.) Diagnosis of pulmonary multidrug resistant tuberculosis (MDR-TB) and 2.) Used in combination with at least 3 other antibiotics for the treatment of pulmonary multi-drug resistant tuberculosis
<b>Age Restrictions</b>	5 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	24 weeks
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# SKYRIZI

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## Products Affected

- SKYRIZI (150 MG DOSE)
- 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>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# SODIUM OXYBATE

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## Products Affected

- *sodium oxybate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant treatment with sedative hypnotic agents, B.) Succinic semialdehyde dehydrogenase deficiency
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to a central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate) or a CNS wakefulness promoting drug (e.g., armodafinil, modafinil), or B.) Cataplexy and narcolepsy
<b>Age Restrictions</b>	7 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# SOLTAMOX

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## Products Affected

- SOLTAMOX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant coumarin-type anticoagulant therapy, B.) history of thromboembolic disease such as DVT or PE
<b>Required Medical Information</b>	Diagnosis of breast cancer and documentation of inability to swallow tablet formulation
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# SOMAVERT

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## Products Affected

- SOMAVERT SUBCUTANEOUS SOLUTION RECONSTITUTED 10 MG, 15 MG, 20 MG, 25 MG, 30 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of acromegaly confirmed by high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range and patient has had an inadequate response to or is ineligible for surgery or radiation therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# SORAFENIB

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## Products Affected

- *sorafenib tosylate*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Squamous cell lung cancer being treated with carboplatin and paclitaxel
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment, or C.) Unresectable hepatocellular carcinoma
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# SPRYCEL

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, B.) Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy, C.) Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy, or D.) Newly diagnosed Ph+ ALL in combination with chemotherapy
<b>Age Restrictions</b>	1 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# STELARA

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderate to severely active Crohn's disease, B.) Moderate to severe plaque psoriasis, C.) Active psoriatic arthritis, or D.) Moderate to severe active ulcerative colitis. For moderate to severe plaque psoriasis: 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected)
<b>Age Restrictions</b>	For PSO or PsA: 6 years of age or older, For all other indications: 18 years of age or older
<b>Prescriber Restrictions</b>	For PsO: Dermatologist, For PsA: Dermatologist or Rheumatologist, For CD and UC: Gastroenterologist.
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physician's certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray.

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<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# STIVARGA

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## Products Affected

- STIVARGA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic colorectal cancer in patients previously treated with fluoropyrimidine, oxaliplatin, and irinotecan containing chemotherapy, anti-VEGF therapy, and if RAS wild type, anti-EGFR therapy, B.) Liver carcinoma in patients previously treated with sorafenib, or C.) Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) after treatment with imatinib and sunitinib
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# SUNITINIB

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## Products Affected

- *sunitinib malate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Gastrointestinal stromal tumor after disease progression on or intolerance to imatinib, B.) Pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease, C.) Advanced renal cell carcinoma, or D.) Renal cell carcinoma and used as adjuvant therapy following nephrectomy in patients who are at high risk for recurrence
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# SUNOSI

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## Products Affected

- SUNOSI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Narcolepsy with excessive daytime drowsiness confirmed by a sleep study and has trial of/or contraindication to modafinil or armodafinil or B.) Obstructive sleep apnea (OSA) with excessive daytime drowsiness confirmed by a sleep study and has trial of/or contraindication to modafinil or armodafinil
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# SYMLIN

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## Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Confirmed diagnosis of gastroparesis, B.) Hypoglycemia unawareness
<b>Required Medical Information</b>	Diagnosis of type 1 or type 2 diabetes mellitus and patient uses mealtime insulin therapy and has failed to achieve desired glucose control
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# SYNAREL

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## Products Affected

- SYNAREL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Breastfeeding, or B.) undiagnosed abnormal vaginal bleeding
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Central precocious puberty, or B.) Endometriosis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TABRECTA

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## Products Affected

- TABRECTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TADALAFIL

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## Products Affected

- *tadalafil*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) concurrent use of nitrates, including intermittent use, or B.) diagnosis of erectile dysfunction without signs and symptoms of BPH
<b>Required Medical Information</b>	Diagnosis of benign prostatic hyperplasia (BPH) and patient has experienced intolerance to or treatment failure to ONE alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) AND to ONE 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# TAFINLAR

## Products Affected

- TAFINLAR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid carcinoma with BRAF V600E mutation, in combination with trametinib and no satisfactory locoregional treatment options, B.) Metastatic non-small cell lung cancer with BRAF V600E mutation, in combination with trametinib OR in patients previously treated as monotherapy, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutation, D.) Unresectable or metastatic solid tumors with BRAF V600E mutation, in combination with trametinib, and have progressed following prior treatment and have no satisfactory alternative treatment options, or E.) Low-grade glioma with a BRAF V600E mutation and require systemic therapy, in combination with trametinib
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# TAGRISO

## Products Affected

- TAGRISO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R mutation and used as first line therapy, B.) Metastatic non-small cell lung cancer with T790M EGFR mutation (as confirmed by an FDA-approved test) AND whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy, C.) Non-small cell lung cancer (NSCLC) with tumor epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations (as confirmed by an FDA-approved test) AND patient requires adjuvant therapy after tumor resection, or D.) First-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test, in combination with pemetrexed and platinum-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# 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>	None
<b>Required Medical Information</b>	Diagnosis of one of the following and used as routine prophylaxis A.) Hereditary angioedema (HAE) with C1 inhibitor deficiency (Type 1) confirmed by laboratory testing, B.) HAE with C1 inhibitor dysfunction (Type 2) confirmed by laboratory testing, or C.) HAE with normal C1 inhibitor (Type 3) confirmed by laboratory testing and one of the following 1.) Positive test for an F12, angiotensin-1, or plasminogen gene mutation, or 2.) Family history of angioedema and the angioedema was refractory to a trial of an antihistamine for at least one month
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist, immunologist, or allergist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TALZENNA

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## Products Affected

- TALZENNA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer, or B.) Homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer in combination with enzalutamide
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TASIGNA

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## Products Affected

- TASIGNA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML), B.) Chronic phase or accelerated phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior therapy that included imatinib, or C.) Chronic phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior tyrosine-kinase inhibitor therapy
<b>Age Restrictions</b>	1 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# TAVNEOS

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## Products Affected

- TAVNEOS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) and both of the following apply 1.) Used as adjunctive treatment, and 2.) Used in combination with standard therapy including glucocorticoids
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TAZAROTENE

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## Products Affected

- *tazarotene external cream*
- *tazarotene external gel*
- TAZORAC

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Acne vulgaris and patient has trial with at least one generic topical acne product, or B.) Stable moderate to severe plaque psoriasis with 20% or less body surface area involvement and patient has trial with at least one other topical psoriasis product (e.g., medium to high potency corticosteroid and/or vitamin D analogs)
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TAZVERIK

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## Products Affected

- TAZVERIK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic or locally advanced epithelioid sarcoma in patients not eligible for complete resection, B.) Relapsed or refractory follicular lymphoma in patients whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, or C.) Relapsed or refractory follicular lymphoma in patients who have no satisfactory alternative treatment options
<b>Age Restrictions</b>	16 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TEPMETKO

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## Products Affected

- TEPMETKO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic non-small cell lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TERIPARATIDE

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## Products Affected

- TERIPARATIDE (RECOMBINANT)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# TETRABENAZINE

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## Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Actively suicidal, B.) Untreated or inadequately treated depression, C.) Impaired hepatic function, D.) Concomitant use of monoamine oxidase inhibitors, E.) Concomitant use of reserpine or within 20 days of discontinuing reserpine
<b>Required Medical Information</b>	Diagnosis of chorea associated with Huntington's disease
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# THALOMID

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## Products Affected

- THALOMID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Multiple myeloma that is newly diagnosed, or B.) Erythema nodosum leprosum (ENL)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, infectious disease specialist, or dermatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TIBSOVO

## Products Affected

- TIBSOVO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test), B.) Previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test.), C.) Acute myeloid leukemia (newly-diagnosed) with susceptible isocitrate dehydrogenase-1 mutation and meets one of the following: 1.) Patient is 75 years of age or older, or 2.) Patient has comorbidities that preclude intensive induction chemotherapy, or D.) Relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hematologist, hepatologist, or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# TOBI

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## Products Affected

- TOBI PODHALER

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Known sensitivity to any aminoglycoside
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has suspected or confirmed <i>Pseudomonas aeruginosa</i> infection in the lungs
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# TOPICAL RETINOIDS

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## Products Affected

- *adapalene*
- *tretinoin external*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of mild to moderate acne vulgaris
<b>Age Restrictions</b>	PA applies to patients older than 26 years of age
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# TOPICAL TESTOSTERONE

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## 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%)*
- *testosterone transdermal solution*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Carcinoma of the breast (males only), or B.) Known or suspected carcinoma of the prostate
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, or B.) Primary hypogonadism. Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TOREMIFENE

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## Products Affected

- *toremifene citrate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Any of the following A.) Acquired or congenital long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia
<b>Required Medical Information</b>	Diagnosis of metastatic breast cancer and patient must have previous inadequate response or intolerance to tamoxifen
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# TRELSTAR

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## Products Affected

- TRELSTAR MIXJECT RECONSTITUTED 11.25 MG, 22.5 MG,  
INTRAMUSCULAR SUSPENSION 3.75 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced prostate cancer
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Plan Year
Other Criteria	B vs D determination required per CMS guidance
Indications	All FDA-approved Indications.
Off-Label Uses	N/A
Part B Prerequisite	No

### Prior Authorization Criteria

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# TREMFYA

## Products Affected

- TREMFYA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderate to severe plaque psoriasis, B.) Active psoriatic arthritis. For moderate to severe plaque psoriasis: 1) at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) are affected at the time of diagnosis, AND 2) the patient meets any of the following: a) the patient has experienced an inadequate treatment response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin, b) pharmacologic treatment with methotrexate, cyclosporine, or acitretin is contraindicated, c) the patient has severe psoriasis that warrants a biologic as first-line therapy (i.e., at least 10% of the BSA or crucial body areas [e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas] are affected).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	For PsO: Dermatologist, For PsA Dermatologist or Rheumatologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Only for biologic therapy-naive patients: Physician's certification stating tuberculosis (TB) negative status or negative result of a TB detection test with a reading date less than 12 months before the start of therapy or chest x ray.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

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

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# TRIENTINE

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## Products Affected

- *trientine hcl*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Wilson's disease in patients that are intolerant to penicillamine
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TRIKAFTA

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## Products Affected

- TRIKAFTA ORAL TABLET THERAPY PACK
- TRIKAFTA ORAL THERAPY PACK 100-50-75 & 75 MG, 80-40-60 & 59.5 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis (CF) and patient has at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to elexacaftor/tezacaftor/ivacaftor verified by an FDA-cleared CF mutation test
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TRUQAP

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## Products Affected

- TRUQAP

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with 1 or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test and, A.) patient has had disease progression following 1 or more endocrine-based regimen(s) in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy, and B.) will be used in combination with fulvestrant injection.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# TUKYSA

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## Products Affected

- TUKYSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following: A.) advanced unresectable or metastatic HER2-positive breast cancer (including brain metastases) in patients who have received one or more prior anti-HER2-based regimens in the metastatic setting and drug is being used in combination with trastuzumab and capecitabine, or B.) unresectable or metastatic RAS wild-type, HER2-positive colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy and drug is being used in combination with trastuzumab
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TURALIO

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## Products Affected

- TURALIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery. Liver function tests prior to initiation.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# TYMLOS

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## Products Affected

- TYMLOS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of osteoporosis in men or postmenopausal women and one of the following A.) osteoporotic fracture or multiple risk factors for fracture, or B.) previous trial of/or contraindication to bisphosphonate
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan year (Maximum 24 month treatment per patient lifetime)
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# UBRELVY

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## Products Affected

- UBRELVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
<b>Required Medical Information</b>	Diagnosis of migraine disorder with or without aura and patient has documented trial, inadequate response, or contraindication to at least 1 generic formulary triptan
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VALCHLOR

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## Products Affected

- VALCHLOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PA Criteria: Pending CMS Approval
<b>Required Medical Information</b>	PA Criteria: Pending CMS Approval
<b>Age Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Prescriber Restrictions</b>	PA Criteria: Pending CMS Approval
<b>Coverage Duration</b>	PA Criteria: Pending CMS Approval
<b>Other Criteria</b>	PA Criteria: Pending CMS Approval
<b>Indications</b>	PA Criteria: Pending CMS Approval
<b>Off-Label Uses</b>	PA Criteria: Pending CMS Approval
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VALTOCO

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## Products Affected

- VALTOCO 20 MG DOSE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Acute narrow angle glaucoma
<b>Required Medical Information</b>	Diagnosis of epilepsy and documentation of use for acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern.
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VANFLYTA

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## Products Affected

- VANFLYTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Patient must have all of the following A.) Newly diagnosed acute myeloid leukemia with FLT3-ITD mutation, B.) Used in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, and C.) Must be enrolled in the VANFLYTA REMS program
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VENCLEXTA

## Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with strong CYP3A inhibitor during the initial and titration phase in patients with CLL or SLL
<b>Required Medical Information</b>	Diagnosis of one of the following A.) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), or B.) Newly-diagnosed acute myeloid leukemia (AML) and used in combination with azacitidine, decitabine or low-dose cytarabine in patients 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VEOZAH

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## Products Affected

- VEOZAH

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) and A.) Initial treatment: The patient is experiencing 7 or more hot flashes per day and has a trial, failure or contraindication to hormonal therapy such as estradiol patch or oral conjugated estrogens, or B.) Continuing therapy: The patient has continued need for VMS treatment and experienced a reduction in VMS frequency or severity due to Veozah treatment
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VERQUVO

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## Products Affected

- VERQUVO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use of other soluble guanylate cyclase (sGC) stimulators
<b>Required Medical Information</b>	Diagnosis of chronic heart failure (HF), NYHA Class II to IV and all of the following 1.) Left ventricular ejection fraction less than 45%, 2.) Previous hospitalization for HF within 6 months or outpatient IV diuretic treatment for HF within 3 months
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VERZENIO

## Products Affected

- VERZENIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer and ALL of the following: 1.) Patient is at high risk of recurrence, and 2.) Requested drug will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for adjuvant treatment, OR B.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and one of the following 1.) Used in combination with fulvestrant in a patient with disease progression following endocrine therapy, 2.) Used as monotherapy in a patient with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting, or 3.) For postmenopausal women, and men, used as initial endocrine-based treatment in combination with an aromatase inhibitor
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VIGABATRIN

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## Products Affected

- *vigabatin*
- *vigadrone*
- *vigpoder*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Infantile spasms, or B.) Refractory complex partial seizures and the drug is being used as adjunctive therapy in patients who have responded inadequately to two alternative treatments
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VIJOICE

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## Products Affected

- VIJOICE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) in patients who require systemic therapy
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# VITRAKVI

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic or surgically unresectable neurotrophic receptor tyrosine kinase (NTRK) gene fusion positive solid tumors without a known acquired resistance mutation and used in patients with unsatisfactory alternative treatments or who have progressed following treatment
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VIZIMPRO

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## Products Affected

- VIZIMPRO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic non-small cell lung cancer with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VONJO

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## Products Affected

- VONJO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of intermediate or high-risk primary or secondary myelofibrosis in adults AND a platelet count less than $50 \times 10^9/L$
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VORICONAZOLE

## Products Affected

- VORICONAZOLE INTRAVENOUS
- *voriconazole oral tablet 200 mg, 50 mg*
- *voriconazole oral suspension reconstituted*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Any of the following A.) Concomitant use of carbamazepine, CYP3A4 substrates (e.g., terfenadine, astemizole, cisapride, pimozide, or quinidine), B.) Concomitant use with high-dose ritonavir (400mg every 12 hours), C.) Concomitant use with ergot alkaloids, D.) Concomitant use with long-acting barbiturates, E.) Concomitant use with rifabutin or rifampin, F.) Concomitant use with sirolimus, or G.) Concomitant use with efavirenz at standard doses of 400mg/day or higher
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Invasive aspergillosis, B.) Candidemia, C.) Esophageal Candidiasis, D.) Invasive candidiasis of the skin and abdomen, kidney, bladder wall, and wounds, or E.) Serious fungal infection due to <i>Scedosporium apiospermum</i> or <i>Fusarium</i> species
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an infectious disease specialist
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VOTRIENT

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## Products Affected

- VOTRIENT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Advanced renal cell carcinoma, or B.) Advanced soft tissue sarcoma and patient received at least one prior chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VOWST

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## Products Affected

- VOWST

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of prevention of recurrent Clostridioides difficile infection (CDI) and one of the following 1.) Patient has completed antibiotic treatment for at least 3 CDI episodes, or 2.) Previously received Vowst and both of the following A.) Treatment failure (defined as the presence of CDI diarrhea within 8 weeks of first dose of Vowst and a positive stool test for C. Difficile, and B.) Patient has not received more than one treatment course of vovst which was at least 12 days and not more than 8 weeks prior
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# VUMERITY

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## Products Affected

- VUMERITY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# WELIREG

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## Products Affected

- WELIREG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Von Hippel-Lindau (VHL) disease and therapy is required for any of the following disease associated tumors that do not require immediate surgery 1.) Renal cell carcinoma (RCC), 2.) Central nervous system (CNS) hemangioblastoma, or 3.) Pancreatic neuroendocrine tumor (pNET), or B.) Advanced renal cell carcinoma following a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist or oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# XALKORI

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## Products Affected

- XALKORI ORAL CAPSULE
- XALKORI ORAL CAPSULE SPRINKLE 150 MG, 20 MG, 50 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive or ROS1-positive as detected by an FDA-approved test, B.) Relapsed or refractory systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test, or C.) Unresectable, recurrent, or refractory inflammatory myofibroblastic tumors that are anaplastic lymphoma kinase (ALK)-positive
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# XCOPRI

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## Products Affected

- XCOPRI (250 MG DAILY DOSE)
- XCOPRI (350 MG DAILY DOSE)
- XCOPRI ORAL TABLET 100 MG, 150 MG, 200 MG, 25 MG, 50 MG
- XCOPRI ORAL TABLET THERAPY PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Familial short QT syndrome
<b>Required Medical Information</b>	Diagnosis of partial-onset seizures
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# XDEMVY

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## Products Affected

- XDEMVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Demodex blepharitis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# XELJANZ

## Products Affected

- XELJANZ ORAL SOLUTION
- XELJANZ ORAL TABLET 10 MG, 5 MG
- XELJANZ XR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis (RA), B.) Active psoriatic arthritis, C.) Moderate to severe ulcerative colitis (UC), D.) Polyarticular course juvenile idiopathic arthritis (pcJIA), or E.) Active ankylosing spondylitis. Screening for latent tuberculosis infection is required prior to initiation of treatment.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	Screening for latent tuberculosis infection is required prior to initiation of treatment
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# XERMELO

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## Products Affected

- XERMELO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of carcinoid syndrome diarrhea and both of the following 1.) Diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide, lanreotide) for at least 3 months, and 2.) Used in combination with SSA therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
<b>Coverage Duration</b>	Plan year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# XGEVA

## Products Affected

- XGEVA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Hypocalcemia (calcium less than 8.0 mg/dL)
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Bone metastases from a solid tumor, used for the prevention of skeletal related events and must have an inadequate treatment response, adverse event, or contraindication to zoledronic acid, B.) Multiple myeloma, used for the prevention of skeletal related events and must have an inadequate treatment response, adverse event, or contraindication to zoledronic acid, C.) Hypercalcemia of malignancy refractory to bisphosphonate therapy and must have an inadequate treatment response, adverse event, or contraindication to zoledronic acid, or D.) Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	B vs D determination required per CMS guidance
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	Yes

Prior Authorization Criteria

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# XOLAIR

## Products Affected

- XOLAIR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chronic idiopathic urticaria in patients who remain symptomatic despite H1 antihistamine therapy for patients 12 years of age and older, B.) Moderate to severe persistent asthma in patients 6 years of age or older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids or Dupixent, C.) Nasal polyps in patients 18 years of age or older with inadequate response to nasal corticosteroids, or D.) Reduction of allergic reactions (type I), including anaphylaxis, that may occur with accidental exposure to 1 or more foods in with IgE-mediated food allergy and is being used in conjunction with food allergen avoidance in patient 1 year of age or older
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist
<b>Coverage Duration</b>	Initial: 6 months, Renewal: Plan Year
<b>Other Criteria</b>	B vs D coverage determination per CMS guidelines
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# XOSPATA

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## Products Affected

- XOSPATA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an Oncologist or Hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

MCS Classicare Formulary 3 - Formulary ID: 25512

Effective date: 01/01/2025 Last Updated: 09/26/2024

# XPOVIO

## Products Affected

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY)
- XPOVIO (60 MG ONCE WEEKLY)
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY)
- XPOVIO (80 MG TWICE WEEKLY)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Relapsed or refractory multiple myeloma being used in combination with dexamethasone in a patient who has received at least 4 prior therapies and is refractory to at least 2 proteasome inhibitors, at least 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody, B.) Multiple myeloma being used in combination with bortezomib and dexamethasone in a patient who has received at least 1 prior therapy, C.) Relapsed or refractory diffuse large B-cell lymphoma not otherwise specified, or D.) Relapsed or refractory DLBCL arising from follicular lymphoma and patient has received at least 2 lines of systemic therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

Prior Authorization Criteria

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# XTANDI

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## Products Affected

- XTANDI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Castration-resistant prostate cancer (CRPC), B.) Metastatic, castration-sensitive prostate cancer (mCSPC). For treatment of CRPC and mCSPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient has received bilateral orchiectomy, or C.) Nonmetastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# YONSA

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## Products Affected

- YONSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic, castration-resistant prostate cancer (mCRPC) and used in combination with methylprednisolone. For treatment of mCRPC, one of the following applies: 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient has received bilateral orchiectomy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ZARXIO

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## Products Affected

- ZARXIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Chemotherapy induced febrile neutropenia (prophylaxis), B.) Severe chronic neutropenia, C.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, or D.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ZEJULA

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## Products Affected

- ZEJULA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of Advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and used as maintenance therapy in a patient who is in a complete or partial response to platinum-based chemotherapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ZELBORAF

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## Products Affected

- ZELBORAF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of one of the following A.) Unresectable or metastatic melanoma and patient has positive BRAF-V600E mutation documented by an FDA-approved test, or B.) Erdheim-Chester disease and patient has documented BRAF V600 mutation
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ZIEXTENZO

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## Products Affected

- ZIEXTENZO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of a non-myeloid malignancy and drug is being used as prophylaxis for chemotherapy-induced neutropenia
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ZOLINZA

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## Products Affected

- ZOLINZA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of primary cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease on or following two systemic therapies (e.g., bexarotene, romidepsin, etc)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ZTALMY

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## Products Affected

- ZTALMY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ZURZUVAE

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## Products Affected

- ZURZUVAE ORAL CAPSULE 20 MG, 25 MG, 30 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of postpartum depression
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

## Prior Authorization Criteria

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# ZYDELIG

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## Products Affected

- ZYDELIG ORAL TABLET 100 MG, 150 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	History of toxic epidermal necrosis with any drug
<b>Required Medical Information</b>	Diagnosis of Chronic lymphocytic leukemia, used in combination with rituximab and patient has relapsed on at least one prior therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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# ZYKADIA

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## Products Affected

- ZYKADIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	Plan Year
<b>Other Criteria</b>	None
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A
<b>Part B Prerequisite</b>	No

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## PART B VERSUS PART D

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### Products Affected

- ABILIFY ASIMTUFII  
INTRAMUSCULAR PREFILLED  
SYRINGE 720 MG/2.4ML, 960  
MG/3.2ML
- ABILIFY MAINTENA  
INTRAMUSCULAR PREFILLED  
SYRINGE 300 MG, 400 MG
- ABILIFY MAINTENA  
INTRAMUSCULAR SUSPENSION  
RECONSTITUTED ER 300 MG, 400 MG
- *acetylcysteine inhalation solution 10 %, 20 %*
- *acyclovir sodium intravenous solution 50 mg/ml*
- *albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml*
- *amphotericin b intravenous solution reconstituted 50 mg*
- *amphotericin b liposome intravenous suspension reconstituted 50 mg*
- *ampicillin sodium injection solution reconstituted 1 gm, 125 mg*
- *aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg*
- *azathioprine oral tablet 50 mg*
- *azithromycin intravenous solution reconstituted 500 mg*
- *budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml*
- *calcitonin (salmon) nasal solution 200 unit/act*
- *calcitriol oral capsule 0.25 mcg, 0.5 mcg*
- *calcitriol oral solution 1 mcg/ml*
- *cefoxitin sodium intravenous solution reconstituted 1 gm, 10 gm, 2 gm*
- *cefuroxime sodium injection solution reconstituted 750 mg*
- *cefuroxime sodium intravenous solution reconstituted 1.5 gm*
- *cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg*
- CINRYZE INTRAVENOUS SOLUTION RECONSTITUTED 500 UNIT
- *ciprofloxacin in d5w intravenous solution 200 mg/100ml*
- *clindamycin phosphate injection solution 900 mg/6ml*
- CLINIMIX/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- *colistimethate sodium (cba) injection solution reconstituted 150 mg*
- *cromolyn sodium inhalation nebulization solution 20 mg/2ml*
- CYCLOPHOSPHAMIDE ORAL CAPSULE 25 MG
- *cyclophosphamide oral capsule 50 mg*
- *cyclophosphamide oral tablet 25 mg*
- CYCLOPHOSPHAMIDE ORAL TABLET 50 MG
- *cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg*
- *cyclosporine modified oral solution 100 mg/ml*
- *cyclosporine oral capsule 100 mg, 25 mg*
- *dextrose intravenous solution 10 %, 5 %*
- DEXTROSE-SODIUM CHLORIDE INTRAVENOUS SOLUTION 10-0.2 %, 10-0.45 %, 2.5-0.45 %
- *doxy 100 intravenous solution reconstituted 100 mg*

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- ENGERIX-B INJECTION SUSPENSION 20 MCG/ML
- ENGERIX-B INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/0.5ML, 20 MCG/ML
- ENVARUSUS XR ORAL TABLET EXTENDED RELEASE 24 HOUR 0.75 MG, 1 MG, 4 MG
- *everolimus oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg*
- *fluconazole in sodium chloride intravenous solution 200-0.9 mg/100ml-%, 400-0.9 mg/200ml-%*
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA INTRAVENOUS SOLUTION RECONSTITUTED 10 GM, 5 GM
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- *granisetron hcl oral tablet 1 mg*
- *heparin sodium (porcine) injection solution 10000 unit/ml, 20000 unit/ml, 5000 unit/ml*
- HEPLISAV-B INTRAMUSCULAR SOLUTION PREFILLED SYRINGE 20 MCG/0.5ML
- IMOVAX RABIES INTRAMUSCULAR SUSPENSION RECONSTITUTED 2.5 UNIT/ML
- *ipratropium bromide inhalation solution 0.02 %*
- *ipratropium-albuterol inhalation solution 0.5-2.5 (3) mg/3ml*
- ISOLYTE-P IN D5W INTRAVENOUS SOLUTION
- ISOLYTE-S PH 7.4 INTRAVENOUS SOLUTION
- JYLAMVO ORAL SOLUTION 2 MG/ML
- *kcl in dextrose-nacl intravenous solution 10-5-0.45 meq/l-%-%, 20-5-0.2 meq/l-%-%, 20-5-0.45 meq/l-%-%, 20-5-0.9 meq/l-%-%, 30-5-0.45 meq/l-%-%, 40-5-0.45 meq/l-%-%*
- KCL IN DEXTROSE-NACL INTRAVENOUS SOLUTION 40-5-0.9 MEQ/L-%-%
- KCL-LACTATED RINGERS-D5W INTRAVENOUS SOLUTION 20 MEQ/L
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
- *methotrexate sodium injection solution 50 mg/2ml*
- *metronidazole intravenous solution 500 mg/100ml*
- *multiple electro type 1 ph 5.5 intravenous solution*
- *mycophenolate mofetil oral capsule 250 mg*
- *mycophenolate mofetil oral suspension reconstituted 200 mg/ml*
- *mycophenolate mofetil oral tablet 500 mg*
- *mycophenolate sodium oral tablet delayed release 180 mg, 360 mg*
- NUTRILIPID INTRAVENOUS EMULSION 20 %
- *ondansetron hcl oral solution 4 mg/5ml*
- *ondansetron hcl oral tablet 4 mg, 8 mg*
- *ondansetron oral tablet dispersible 4 mg, 8 mg*
- *paricalcitol oral capsule 1 mcg, 2 mcg, 4 mcg*
- *penicillin g potassium injection solution reconstituted 20000000 unit*
- *penicillin g sodium injection solution reconstituted 5000000 unit*
- *pentamidine isethionate inhalation solution reconstituted 300 mg*

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- *pentamidine isethionate injection solution reconstituted 300 mg*
- PERSERIS SUBCUTANEOUS PREFILLED SYRINGE 120 MG, 90 MG
- PLASMA-LYTE A INTRAVENOUS SOLUTION
- POTASSIUM CHLORIDE IN NACL INTRAVENOUS SOLUTION 20-0.45 MEQ/L-%, 40-0.9 MEQ/L-%
- *potassium chloride in nacl intravenous solution 20-0.9 meq/l-%*
- POTASSIUM CHLORIDE INTRAVENOUS SOLUTION 10 MEQ/100ML, 20 MEQ/100ML, 40 MEQ/100ML
- *potassium chloride intravenous solution 2 meq/ml, 2 meq/ml (20 ml)*
- *potassium cl in dextrose 5% intravenous solution 20 meq/l*
- PREHEVBRIO INTRAMUSCULAR SUSPENSION 10 MCG/ML
- PROGRAF ORAL PACKET 0.2 MG, 1 MG
- PROLASTIN-C INTRAVENOUS SOLUTION 1000 MG/20ML
- RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED
- RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 40 MCG/ML, 5 MCG/0.5ML
- RECOMBIVAX HB INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/ML, 5 MCG/0.5ML
- RISPERDAL CONSTA INTRAMUSCULAR SUSPENSION RECONSTITUTED ER 12.5 MG, 25 MG, 37.5 MG, 50 MG
- *sirolimus oral solution 1 mg/ml*
- *sirolimus oral tablet 0.5 mg, 1 mg, 2 mg*
- *tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg*
- TEFLARO INTRAVENOUS SOLUTION RECONSTITUTED 400 MG, 600 MG
- TIGECYCLINE INTRAVENOUS SOLUTION RECONSTITUTED 50 MG
- *tobramycin inhalation nebulization solution 300 mg/5ml*
- *tobramycin sulfate injection solution 10 mg/ml, 80 mg/2ml*
- TPN ELECTROLYTES INTRAVENOUS CONCENTRATE
- TRAVASOL INTRAVENOUS SOLUTION 10 %
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- *ziprasidone mesylate intramuscular solution reconstituted 20 mg*

## Details

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

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## Alphabetical Listing

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acyclovir sodium intravenous solution 50 mg/ml .....	302	aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg.....	302
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**B**

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BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG.....	33
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calcitriol oral capsule 0.25 mcg, 0.5 mcg.....	302
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cefoxitin sodium intravenous solution reconstituted 1 gm, 10 gm, 2 gm .....	302
cefuroxime sodium injection solution reconstituted 750 mg .....	302
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CINRYZE INTRAVENOUS SOLUTION RECONSTITUTED 500 UNIT.....	302
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clindamycin phosphate injection solution 900 mg/6ml .....	302
CLINIMIX/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 % .....	302
CLINIMIX/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 % ...	302
CLINIMIX/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 % ...	302
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