



## | Mutual of Omaha Rx Value Plan |

# Drugs That Require Prior Authorization (PA) Before Being Approved for Coverage

You will need authorization from **Mutual of Omaha Rx<sup>SM</sup>** (PDP) before filling prescriptions for the drugs shown in the following charts. Mutual of Omaha Rx will only provide coverage after it determines that the drug is being prescribed according to the criteria specified in the chart.

Express Scripts, a pharmacy benefit manager, administers the review process for Mutual of Omaha Rx. To request a prior authorization, please have your physician visit their online portal at **esrx.com/PA**. You, your appointed representative or your prescriber can also request prior authorization by calling Express Scripts toll free at **1.844.374.7377**, 24 hours a day, 7 days a week. Customer Service is available in English and other languages. TTY users should call **1.800.716.3231**.

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

Express Scripts is the pharmacy benefit manager for Mutual of Omaha Rx and will be providing some services on behalf of Mutual of Omaha Rx.

Mutual of Omaha Rx (PDP) is a prescription drug plan with a Medicare contract.  
Enrollment in the Mutual of Omaha Rx plan depends on contract renewal.

No changes made since 12/16/2019

# ACYCLOVIR (TOPICAL)

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## Products Affected

- acyclovir topical ointment

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medication history
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ADEMPAS

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## Products Affected

- Adempas

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# AFINITOR

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## Products Affected

- Afinitor
- Afinitor Disperz oral tablet for suspension 2 mg, 3 mg, 5 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Breast Cancer-HER2 status, hormone receptor (HR) status.
<b>Age Restrictions</b>	Relapsed or refractory classical Hodgkin lymphoma-18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Breast Cancer-approve if the patient meets ALL the following criteria (A, B, C, D, E, and F): A) pt has recurrent or Stage IV, hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)] disease AND B) pt has human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND C) pt has tried at least one prior endocrine therapy (e.g., anastrozole, letrozole, or tamoxifen) AND D) pt meets ONE of the following conditions (i or ii): i. pt is a postmenopausal female or a male OR ii. pt is premenopausal or perimenopausal AND is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin)), or has had surgical bilateral oophorectomy or ovarian irradiation AND E) The patient meets ONE of the following conditions (i or ii): i. If patient is a male AND if Afinitor will be used in combination with exemestane, the patient is receiving a gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide], Trelstar [triptorelin], Zoladex (goserelin)) OR ii. Afinitor will be used in combination with exemestane, Faslodex (fulvestrant intramuscular), or tamoxifen AND F) The patient has not had disease progression while on Afinitor.</p> <p>Renal Cell Carcinoma (Clear Cell or Non-clear cell histology)-approve if the patient has relapsed or Stage IV disease and if using for clear cell disease, the patient has tried one prior systemic therapy (e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar). Tuberous sclerosis complex (TSC) Associated subependymal giant cell astrocytoma (SEGA)-approve if the patient requires therapeutic intervention but cannot be curatively resected. Thymomas and Thymic Carcinomas-approve if the patient has tried one prior chemotherapy (e.g., cisplatin plus doxorubicin, cisplatin plus etoposide, carboplatin plus paclitaxel). TSC associated renal angiomyolipoma -approve.</p> <p>WM/LPL - approve if patient has progressive or relapsed disease or if the patient has not responded to ONE primary therapy (e.g., Velcade with dexamethasone with or without Rituxan, Treanda with Rituxan, Rituxan with cyclophosphamide and dexamethasone, Treanda, Velcade with or without Rituxan, Velcade with dexamethasone,</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>Kyprolis with Rituxan and dexamethasone, Imbruvica Rituxan). Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma-approve if the patient is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if Afinitor will be used in combination with letrozole and the patient has recurrent, metastatic or high-risk disease. GIST-approve if the patient has tried TWO of the following drugs: Sutent, Stivarga, or imatinib AND there is confirmation that Afinitor will be used in combination with one of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. Tuberous sclerosis complex (TSC)-associated partial-onset seizures-approve.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	<p>Advanced, unresectable or metastatic neuroendocrine tumors of the thymus (Carcinoid tumors). Perivascular Epithelioid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangiomyomatosis, relapsed or refractory classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST) and Recurrent or progressive Meningioma, men with breast cancer</p>

# ALECENSA

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## Products Affected

- Alecensa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	metastatic NSCLC - is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ALUNBRIG

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## Products Affected

- Alunbrig oral tablet 180 mg, 30 mg, 90 mg
- Alunbrig oral tablets, dose pack

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	ALK status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Metastatic NSCLC, must be ALK-positive, as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# AMPYRA

## Products Affected

- dalfampridine

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	MS. If prescribed by, or in consultation with, a neurologist or MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ANABOLIC STEROIDS

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## Products Affected

- Anadrol-50
- oxandrolone oral tablet 10 mg, 2.5 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients w/Turner's Syndrome or Ullrich-Turner Syndrome (oxandrolone only), management of protein catabolism w/burns or burn injury (oxandrolone only), AIDS wasting and cachexia

## ANTIFUNGALS (IV)

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### Products Affected

- fluconazole in NaCl (iso-osm) intravenous piggyback 200 mg/100 mL, 400 mg/200 mL
- voriconazole intravenous

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# APOKYN

## Products Affected

- APOKYN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ARCALYST

## Products Affected

- Arcalyst

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent biologic therapy
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Initial tx CAPS-Greater than or equal to 12 years of age.
<b>Prescriber Restrictions</b>	Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist.
<b>Coverage Duration</b>	3 mos initial, 3 years cont
<b>Other Criteria</b>	CAPS renewal - approve if the patient has had a response as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ARIKAYCE

## Products Affected

- Arikayce

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous medication history
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	MAC Lung disease-approve if the patient has NOT achieved negative sputum cultures for Mycobacterium avium complex after a background multidrug regimen AND Arikayce will be used in conjunction to a background multidrug regimen. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# BALVERSA

## Products Affected

- Balversa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies, test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# BANZEL

## Products Affected

- Banzel

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Patients 1 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# BENLYSTA

## Products Affected

- Benlysta subcutaneous

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other biologics or with cyclophosphamide intravenous (IV)
<b>Required Medical Information</b>	Diagnosis, medications that will be used in combination, autoantibody status
<b>Age Restrictions</b>	18 years and older (initial).
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation)
<b>Coverage Duration</b>	Initial-4 months, cont-3 years
<b>Other Criteria</b>	Initial-The patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician. Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician AND The patient has responded to Benlysta as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# BETASERON

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## Products Affected

- Betaseron subcutaneous kit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agent used for multiple sclerosis
<b>Required Medical Information</b>	Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or after consultation with a neurologist or an MS specialist.
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# BOSULIF

## Products Affected

- Bosulif oral tablet 100 mg, 400 mg, 500 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Bosulif is being used. For chronic myelogenous leukemia (CML)/ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies tried must be reported to confirm resistance or intolerance.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For CML, patient must have Ph-positive CML. For ALL, patient must have Ph-positive ALL and has tried ONE other tyrosine kinase inhibitor that is used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia

# BRAFTOVI

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## Products Affected

- Braftovi oral capsule 75 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, BRAF V600 status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# BUPRENORPHINE (SL TABLETS)

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## Products Affected

- buprenorphine HCl sublingual

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# C1 ESTERASE INHIBITORS

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## Products Affected

- Cinryze

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CABLIVI

## Products Affected

- Cablivi injection kit

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, concurrent medications
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	aTTP-approve if the patient is currently receiving at least one immunosuppressive therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CABOMETYX

## Products Affected

- Cabometyx oral tablet 20 mg, 40 mg, 60 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, histology, RET gene rearrangement status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Advance Renal Cell Carcinoma (Predominant Clear Cell or Non-Clear Cell Histology)-Approve. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Non-Small Cell Lung Cancer with RET Gene Rearrangements



# CALQUENCE

## Products Affected

- Calquence

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Previous medications/therapies tried
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	CLL and SLL-approve if the patient has tried one prior therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chronic Lymphocytic Leukemia (CLL). Plus Small Lymphocytic Lymphoma (SLL)

# CAPRELSA

## Products Affected

- Caprelsa oral tablet 100 mg, 300 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	MTC - approve. DTC - approve if refractory to radioactive iodine therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Non-Small Cell Lung Cancer with RET Gene Rearrangements

# CARBAGLU

## Products Affected

- Carbaglu

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases
<b>Coverage Duration</b>	Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval
<b>Other Criteria</b>	Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency (NAGS) or if the patient has hyperammonemia.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CAYSTON

## Products Affected

- Cayston

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has has <i>Pseudomonas aeruginosa</i> in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CHEMET

## Products Affected

- Chemet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Blood lead level
<b>Age Restrictions</b>	Approve in patients between the age of 12 months and 18 years
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a professional experienced in the use of chelation therapy (eg, a medical toxicologist or a poison control center specialist)
<b>Coverage Duration</b>	Approve for 2 months
<b>Other Criteria</b>	Approve if Chemet is being used to treat acute lead poisoning (not as prophylaxis) and prior to starting Chemet therapy the patient's blood lead level was greater than 45 mcg/dL.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CHENODAL

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## Products Affected

- Chenodal

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	For the treatment of gallstones, approve if the patient has tried or is currently using an ursodiol product.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CHOLBAM

## Products Affected

- Cholbam oral capsule 250 mg, 50 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination Therapy with Chenodal
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with hepatologist, metabolic specialist, or GI
<b>Coverage Duration</b>	3 mos initial, 12 mos cont
<b>Other Criteria</b>	Bile acid synthesis d/o due to SEDs initial - Diagnosis based on an abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis or molecular genetic testing consistent with the diagnosis. Cont - responded to initial Cholbam tx with an improvement in LFTs AND does not have complete biliary obstruction. Bile-Acid Synthesis Disorders Due to Peroxisomal Disorders (PDs), Including Zellweger Spectrum Disorders initial - PD with an abnormal urinary bile acid analysis by FAB-MS or molecular genetic testing consistent with the diagnosis AND has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g., rickets). Cont - responded to initial Cholbam therapy as per the prescribing physician (e.g., improvements in liver enzymes, improvement in steatorrhea) AND does not have complete biliary obstruction.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CLOBAZAM

## Products Affected

- clobazam oral suspension
- clobazam oral tablet
- Sympazan

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other medications tried
<b>Age Restrictions</b>	2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist (initial therapy)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Lennox-Gastaut Syndrome, initial therapy-patient has tried one of the following: lamotrigine, topiramate, rufinamide, felbamate, or Epidiolex. Treatment refractory seizures/epilepsy, initial therapy-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Continuation-prescriber confirms patient is responding to therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Dravet Syndrome and treatment-refractory seizures/epilepsy



# COMETRIQ

## Products Affected

- Cometriq oral capsule 100 mg/day(80 mg x1-20 mg x1), 140 mg/day(80 mg x1-20 mg x3), 60 mg/day (20 mg x 3/day)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma

# COPAXONE

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## Products Affected

- glatiramer subcutaneous syringe 20 mg/mL, 40 mg/mL
- Glatopa subcutaneous syringe 20 mg/mL, 40 mg/mL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agent used for multiple sclerosis
<b>Required Medical Information</b>	Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or after consultation with a neurologist or an MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# COPIKTRA

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## Products Affected

- Copiktra

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	CLL/Follicular Lymphoma/SLL-approve if the patient has tried two prior therapies
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CORLANOR

## Products Affected

- Corlanor oral tablet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Previous use of a Beta-blocker, LVEF
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Chronic HF, adults - must have LVEF of less than or equal 35 percent AND tried or is currently receiving a Beta-blocker for HF (e.g., metoprolol succinate sustained-release, carvedilol, bisoprolol, carvedilol ER) unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia). Heart failure due to dilated cardiomyopathy, children-approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# COTELLIC

## Products Affected

- Cotellic

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Melanoma initial - must have BRAF V600 mutation.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CYSTARAN

## Products Affected

- Cystaran

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# DALIRESP

## Products Affected

- Daliresp

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Chronic Obstructive Pulmonary Disease (COPD), medications tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	COPD, approve in patients who meet all of the following conditions: Patients has severe COPD or very severe COPD, AND Patient has a history of exacerbations, AND Patient has tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, indacaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# DARAPRIM

## Products Affected

- Daraprim

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Patient's immune status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis



# DAURISMO

## Products Affected

- Daurismo oral tablet 100 mg, 25 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medications that will be used in combination, comorbidities
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	AML - approve if Daurismo will be used in combination with cytarabine AND the patient meets i. OR ii: i. patient is using Daurismo for treatment induction and is greater than or equal to 75 years old or the patient has comorbidities that preclude the use of intensive induction chemotherapy according to the prescribing physician, OR ii. patient is continuing Daurismo as post-remission therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients continuing Daurismo as post-remission therapy

# DOPTELET

## Products Affected

- Doptelet (10 tab pack)
- Doptelet (15 tab pack)
- Doptelet (30 tab pack)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, platelet count, date of procedure
Age Restrictions	18 years and older
Prescriber Restrictions	N/A
Coverage Duration	Thrombo w/chronic liver disease-5 days, chronic ITP-3 years
Other Criteria	Thrombocytopenia with chronic liver disease-Approve if the patient has a current platelet count less than 50 x 10 <sup>9</sup> /L AND the patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. Chronic ITP-approve if the patient has tried one other therapy or if the patient has undergone splenectomy.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# DUPIXENT

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## Products Affected

- Dupixent

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Xolair
<b>Required Medical Information</b>	Diagnosis, prescriber specialty, other medications tried and length of trials
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	Atopic Dermatitis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist
<b>Coverage Duration</b>	AD-Initial-16 weeks, Cont-1 year, asthma/Rhinosinusitis-initial-6 months, cont 1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Atopic Dermatitis-Initial-meets both a and b: a.has used at least one medium, medium-high, high, and/or super-high-potency prescription topical corticosteroid OR has atopic dermatitis affecting ONLY the face, eyes/eyelids, skin folds, and/or genitalia and has tried tacrolimus ointment AND b.Inadequate efficacy was demonstrated with these previously tried topical prescription therapies, according to the prescribing physician.Continuation-Approve if the pt has responded to Dupixent therapy as determined by the prescribing physician. Asthma-Initial-approve if pt meets the following criteria (i, ii, and iii):i.Pt meets ONE of the following criteria (a or b):a)has a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL) therapy or Xolair OR b)has oral corticosteroid-dependent asthma, per the prescriber AND ii.has received combination therapy with BOTH of the following (a and b): a)An inhaled corticosteroid (ICS) AND b)At least one additional asthma controller/maintenance medication (NOTE:An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5 therapy or Xolair used concomitantly with an ICS. Use of a combination inhaler containing both an ICS and a LABA would fulfil the requirement for both criteria a and b) AND iii.asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy or Xolair as defined by ONE of the following (a, b, c, d or e): a)experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b)experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department visit in the previous year OR c)has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d)has an FEV1/forced vital capacity (FVC) less than 0.80 OR e)The patient's asthma worsens upon tapering of oral corticosteroid therapy. Continuation-Approve if meets the following criteria (i and ii): i.continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler AND ii.has responded to Dupixent therapy as determined by the prescribing</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>physician. Chronic rhinosinusitis with Nasal Polyposis-Initial-pt is currently receiving therapy with an intranasal corticosteroid AND is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell according to the prescriber AND meets ONE of the following (a or b): a)has received treatment with a systemic corticosteroid within the previous 2 years or has a contraindication to systemic corticosteroid therapy OR b)has had prior surgery for nasal polyps. Continuation-approve if the pt continues to receive therapy with an intranasal corticosteroid AND pt has responded to Dupixent therapy as determined by the prescriber.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ENBREL

## Products Affected

- Enbrel
- Enbrel Mini
- Enbrel SureClick

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with biologic therapy or targeted synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA/AS/JIA/JRA, prescribed by or in consult w/ rheumatologist. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist. PP, prescribed by or in consult w/ dermatologist. GVHD, prescribed by or in consult w/ oncologist, hematologist, or physician affiliated w/ transplant center. Behcet's disease, prescribed by or in consult w/ rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. Uveitis, prescribed by or in consultation with an ophthalmologist.
<b>Coverage Duration</b>	FDA approved indications - 3 months initial, 3 years cont, others 12 months.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other agent for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID, biologic DMARD or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide. Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD. Tried or currently is receiving with etanercept 1 conventional GVHD tx (high-dose systemic corticosteroid, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Uveitis-tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives, Humira or an infliximab product. RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Behcet's, GVHD, Uveitis Cont-if the patient has had a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is</p>
	<p>contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Graft versus host disease (GVHD), Behcet's disease, Uveitis

# EPCLUSA

## Products Affected

- Epclusa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin.
<b>Required Medical Information</b>	Genotype, prescriber specialty, other medications tried or used in combination with requested medication
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
<b>Coverage Duration</b>	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
<b>Other Criteria</b>	Criteria will be applied according to AASLD guidelines.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance



# EPIDIOLEX

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## Products Affected

- Epidiolex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies
<b>Age Restrictions</b>	Patients 2 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# EPOETIN ALPHA

## Products Affected

- Procrit injection solution 10,000 unit/mL, 2,000 unit/mL, 20,000 unit/mL, 3,000 unit/mL, 4,000 unit/mL, 40,000 unit/mL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	CRF anemia in patients on and not on dialysis. Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start. Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa, Mircerca or Aranesp. Anemia w/myelosuppressive chemotx. pt must be currently receiving myelosuppressive chemo and Hb 10.0 g/dL or less to start. Hb less than or equal to 12.0 g/dL if previously on epoetin alfa or Aranesp. MDS, approve if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV (with or without zidovudine), Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 mU/mL or less at tx start. Previously on EA approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - pt is unwilling or unable to donate autologous blood prior to surgery
<b>Age Restrictions</b>	MDS anemia = 18 years of age and older
<b>Prescriber Restrictions</b>	MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.
<b>Coverage Duration</b>	Anemia w/myelosuppressive = 4 mos. Transfus=1 mo. Other=6mo. HIV + zidovudine = 4 mo
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anemia due to myelodysplastic syndrome (MDS)

# ERIVEDGE

## Products Affected

- Erivedge

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	BCC (La or Met) - must not have had disease progression while on Odomzo.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	Locally advanced basal cell carcinoma (LABCC), approve if 1. the patient's BCC has recurred following surgery or radiation, OR 2. the patient is not a candidate for surgery and radiation therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ERLEADA

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## Products Affected

- Erleada

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ESBRIET

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## Products Affected

- Esbriet oral capsule
- Esbriet oral tablet 267 mg, 801 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with nintedanib
<b>Required Medical Information</b>	N/A
<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>	1 year
<b>Other Criteria</b>	IPF baseline - must have FVC greater than or equal to 50 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# EXJADE

## Products Affected

- deferasirox

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Serum ferritin level
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve if the patient is benefiting from therapy as confirmed by the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# FARYDAK

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## Products Affected

- Farydak

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# FASENRA

## Products Affected

- Fasenra

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody
<b>Required Medical Information</b>	Diagnosis, severity of disease, peripheral blood eosinophil count, previous therapies tried and current therapies, FEV1/FVC
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
<b>Coverage Duration</b>	Authorization will be for 6 months initial, 12 months continuation.



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>Initial - must have peripheral blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks (prior to treatment with any anti-interleukin (IL)-5 therapy) AND meet both of the following criteria: 1) Patient has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following: inhaled LABA, inhaled long-acting muscarinic antagonist, Leukotriene receptor antagonist, or Theophylline, AND 2) Patient's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by ONE of the following: a) patient experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, OR b) patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, OR c) patient has a FEV1 less than 80 percent predicted, OR d) Patient has an FEV1/FVC less than 0.80, OR e) Patient's asthma worsens upon tapering of oral corticosteroid therapy. NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an ICS for at least 3 consecutive months.</p> <p>Continuation - The patient has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy) AND patient continues to receive therapy with an inhaled corticosteroid.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# FERRIPROX

## Products Affected

- Ferriprox oral tablet 500 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Serum ferritin level
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial therapy - approve if prior to starting therapy the serum ferritin level was greater than 2,500 mcg/L. Continuation therapy - approve if the patient is benefiting from therapy as confirmed by the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# FIRAZYR

## Products Affected

- Firazyr
- icatibant

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant-the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# FIRDAPSE

## Products Affected

- Firdapse

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	History of seizures (initial therapy)
<b>Required Medical Information</b>	Diagnosis, seizure history, lab and test results
<b>Age Restrictions</b>	18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a neuromuscular specialist (initial therapy)
<b>Coverage Duration</b>	Initial-3 months, Cont-1 year
<b>Other Criteria</b>	Initial therapy-Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive nerve stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. Continuation-patient continues to derive benefit (e.g., improved muscle strength, improvements in mobility) from Firdapse, according to the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# FYCOMPA

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## Products Affected

- Fycompa oral suspension
- Fycompa oral tablet 10 mg, 12 mg, 2 mg, 4 mg, 6 mg, 8 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Patients 4 years of age or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# GATTEX

## Products Affected

- Gattex 30-Vial

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	1 year and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist (initial and continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced at least a 20 percent decrease from baseline in the weekly volume of parenteral nutrition.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# GILOTRIF

## Products Affected

- Gilotrif

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For NSCLC - EGFR exon deletions or mutations or if NSCLC is squamous cell type
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	NSCLC EGFR pos - For the treatment of metastatic non small cell lung cancer (NSCLC) must be used in tumors with non-resistant EGFR mutation positive NSCLC as detected by an approved test. NSCLC metastatic squamous cell must have disease progression with first line treatment with platinum based chemotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# GLUCAGON-LIKE PEPTIDE-1 AGONISTS

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## Products Affected

- Bydureon BCise
- Bydureon subcutaneous pen injector
- Byetta subcutaneous pen injector 10 mcg/dose(250 mcg/mL) 2.4 mL, 5 mcg/dose (250 mcg/mL) 1.2 mL
- Trulicity

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A



# GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

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## Products Affected

- Lupron Depot
- Lupron Depot (3 month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For the treatment of cancer diagnosis must be prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	For abnormal uterine bleeding/uterine leiomyomata approve 6 months/all other dx 12 mo
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Ovarian cancer, breast cancer, prophylaxis or treatment of uterine bleeding in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors

# GROWTH HORMONES

## Products Affected

- Norditropin FlexPro subcutaneous pen injector 10 mg/1.5 mL (6.7 mg/mL), 15 mg/1.5 mL (10 mg/mL), 5 mg/1.5 mL (3.3 mg/mL)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	GHD in Children/Adolescents. Pt meets one of the following-1-had 2 GH stim tests with the following-levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are inadequate as defined by a peak GH response which is below the normal reference range of the testing laboratory OR had at least 1 GH test and results show inadequate response and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). 2.brain radiation or tumor resection and pt has 1 GH stim test and results is inadequate response or has def in at least 1 other pituitary hormone (that is, ACTH, TSH, gonadotropin deficiency [LH and/or FSH] are counted as 1 def], or prolactin).3. congenital hypopituitarism and has one GH stim test with inadequate response OR def in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk 4.pt has panhypopituitarism and has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on MRI or CT or pt has 3 or more pituitary hormone deficiencies or pt has had one GH test and results were inadequate 5.pt had a hypophysectomy. Cont-pt responding to therapy
<b>Age Restrictions</b>	ISS 5 y/o or older, SGA 2 y/o or older, SBS 18 y/o or older
<b>Prescriber Restrictions</b>	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.
<b>Coverage Duration</b>	ISS - 6 mos intial, 12 months cont tx, SBS-1 month, others 12 mos

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>GHD initial in adults and adolescents 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. childhood onset has known mutations, embryonic lesions, congenital defects or irreversible structural hypothalamic pituitary lesion/damage, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25) or less than or equal to 1 mcg/L (BMI is greater than 25), for transitional adults glucagon peak less than or equal to 3 (BMI is less than 25) or less than or equal to 3 if BMI is greater than or equal to 25 and must also have a second GH stim test with low results, if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 (adults only) AND if a transitional adolescent must be off tx for at least one month before retesting. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal to 5 or b. growth velocity is less than 10th percentile for age/gender. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). SBS initial pt receiving specialized nutritional support.</p>
	Continuation of tx-approve if the patient has experienced improvement, according to the prescribing physician.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	SHOX, SBS, CKD

# HARVONI

## Products Affected

- Harvoni oral tablet 90-400 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	12 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
<b>Coverage Duration</b>	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance

# HETLIOZ

## Products Affected

- HetlioZ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	patient is totally blind with no perception of light
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders
<b>Coverage Duration</b>	6 mos initial, 12 mos cont
<b>Other Criteria</b>	Initial - dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy plus evaluation of sleep logs. Cont - Approve if pt has achieved adequate results with HetlioZ therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# HIGH RISK MEDICATIONS - BENZODIAZEPINES

## Products Affected

- clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg
- diazepam oral concentrate
- diazepam oral solution 5 mg/5 mL (1 mg/mL)
- diazepam oral tablet
- lorazepam oral concentrate
- lorazepam oral tablet 0.5 mg, 1 mg, 2 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Procedure-related sedation = 1mo. All other conditions = 12 months.
<b>Other Criteria</b>	All medically accepted indications other than insomnia, authorize use. Insomnia, may approve lorazepam if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HIGH RISK MEDICATIONS - BENZTROPINE

## Products Affected

- benztropine oral

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For all medically-accepted indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing benztropine for the patient and he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

## Products Affected

- cyclobenzaprine oral tablet 10 mg, 5 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	The physician has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

## Products Affected

- hydroxyzine HCl oral tablet
- promethazine oral tablet 25 mg

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. Approve hydroxyzine hydrochloride if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

# HIGH RISK MEDICATIONS - PHENOBARBITAL

## Products Affected

- phenobarbital oral elixir
- phenobarbital oral tablet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for use in sedation/insomnia.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For the treatment of seizures, approve only if the patient is currently taking phenobarbital.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HIGH RISK MEDICATIONS - TERTIARY TRICYCLIC ANTIDEPRESSANTS

## Products Affected

- amitriptyline
- clomipramine
- doxepin oral
- imipramine HCl
- trimipramine

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For the treatment of depression, approve if the patient has tried at least two of the following agents: citalopram, escitalopram, fluoxetine, paroxetine, sertraline, venlafaxine, desvenlafaxine, duloxetine, bupropion, mirtazapine or trazodone. For the treatment of pain, may approve amitriptyline (single-entity only, not amitriptyline combination products), or imipramine if the patient has tried at least two of the following agents: duloxetine, pregabalin, gabapentin, venlafaxine or venlafaxine Er. For the treatment of obsessive compulsive disorder (OCD), may approve clomipramine if the patient has tried at least one of the following medications: fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram, or venlafaxine. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HIGH RISK MEDICATIONS- ESTROGENS

## Products Affected

- Dotti
- estradiol oral
- estradiol transdermal patch weekly
- norethindrone ac-eth estradiol oral tablet 0.5-2.5 mg-mcg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Previous medication use
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	For the treatment of Vulvar Vaginal Atrophy, approve if the patient has had a trial of one of the following for vulvar vaginal atrophy (brand or generic): Estradiol Vaginal Cream or estradiol valerate. For prophylaxis of Postmenopausal Osteoporosis, approve if the patient has had a trial of one of the following (brand or generic): alendronate, ibandronate, risidronate or Raloxifene. The physician has assessed risk versus benefit in using this High Risk medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HUMIRA

## Products Affected

- Humira Pediatric Crohns Start subcutaneous syringe kit 40 mg/0.8 mL, 40 mg/0.8 mL (6 pack)
- Humira Pen
- Humira Pen Crohns-UC-HS Start
- Humira Pen Psor-Uveits-Adol HS
- Humira subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL
- Humira(CF) Pedi Crohns Starter subcutaneous syringe kit 80 mg/0.8 mL, 80 mg/0.8 mL-40 mg/0.4 mL
- Humira(CF) Pen Crohns-UC-HS
- Humira(CF) Pen Psor-Uv-Adol HS
- Humira(CF) Pen subcutaneous pen injector kit 40 mg/0.4 mL
- Humira(CF) subcutaneous syringe kit 10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/0.4 mL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried
<b>Age Restrictions</b>	Crohn's disease (CD), 6 or older (initial therapy only). Ulcerative colitis (UC), adults.
<b>Prescriber Restrictions</b>	RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist. UV-ophthalmologist
<b>Coverage Duration</b>	initial 3 mo, cont tx 3 years.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. PP initial, approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other agent for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ileocolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or was intolerant to one of these agents, or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. FDA approve indications cont tx - must respond to tx as determined by prescriber. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Clinical criteria incorporated into the Humira 40 mg quantity limit edit allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# IBRANCE

## Products Affected

- Ibrance

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer - approve advanced (metastatic) hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer for patients who have not had disease progression while on Ibrance, Kisqali or Verzenio when the pt meets ONE of the following 1. Pt is postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, or letrozole 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND patient meets one of the following criteria: Ibrance will be used in combination with anastrozole, exemestane, or letrozole or Ibrance will be used in combination with Faslodex 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH agonist AND Ibrance with be used in combination with anastrozole, exemestane or letrozole or Ibrance will be used in combination with Faslodex 4. Pt is postmenopausal AND Ibrance will be used in combination with Faslodex
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Liposarcoma

# ICLUSIG

## Products Affected

- Iclusig oral tablet 15 mg, 45 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
<b>Age Restrictions</b>	CML/ALL - Adults
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	CML Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Philadelphia chromosome positive CML (e.g., Gleevec, Sprycel, Tasigna). ALL Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Ph+ ALL (e.g. Gleevec, Sprycel.)
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# IDHIFA

## Products Affected

- Idhifa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	IDH2-mutation status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	AML - approve if the patient is IDH2-mutation status positive as detected by an approved test
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# IMATINIB

## Products Affected

- imatinib oral tablet 100 mg, 400 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	For ALL/CML, new patient must have Ph-positive for approval of imatinib. AIDS related Kaposi's Sarcoma-approve if the patient has tried one prior regimen AND has relapsed or refractory disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chordoma, advanced or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, AIDS Related Kaposi's Sarcoma, chronic and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor.

# IMBRUVICA

## Products Affected

- Imbruvica oral capsule 140 mg, 70 mg
- Imbruvica oral tablet

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	GVHD-1 year, all others-3 years
Other Criteria	Marginal Zone Lymphoma - Approve if the patient has tried Rituxan (rituximab for intravenous infusion) or according to the prescribing physician, Rituxan is contraindicated for use in this patient. GVHD- Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, imatinib). Diffuse large B-cell lymphoma-approve if the patient is using Imbruvica as second-line or subsequent therapy according to the prescribing physician.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Relapsed or refractory Central Nervous System Lymphoma (Primary). Plus relapsed or refractory Hairy Cell Leukemia. Plus Diffuse Large B-Cell Lymphoma (e.g., follicular lymphoma, gastric MALT lymphoma, nongastric MALT lymphoma, primary DLBCL of the central nervous system).

# INCRELEX

## Products Affected

- Increlex

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Patients 2 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# INJECTABLE TESTOSTERONE PRODUCTS

## Products Affected

- testosterone cypionate
- testosterone enanthate

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, lab results
<b>Age Restrictions</b>	Delayed puberty or induction of puberty in males-14 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Delayed puberty or induction of puberty in males-6 months, all others-12 months
<b>Other Criteria</b>	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. Delayed puberty or induction of puberty in males - Approve testosterone cypionate or testosterone enanthate. Palliative treatment of inoperable metastatic breast cancer in females. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# INLYTA

## Products Affected

- Inlyta oral tablet 1 mg, 5 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Advanced Renal cell carcinoma-approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma

# INREBIC

## Products Affected

- Inrebic

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has intermediate-2 or high-risk disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# IRESSA

## Products Affected

- Iressa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Metastatic NSCLC - The patient has epidermal growth factor receptor (EGFR) exon 19 deletions OR has exon 21 (L858R) substitution mutations as detected by an FDA-approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# IVIG

## Products Affected

- Privigen

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Part B versus D determination per CMS guidance to establish if drug used for PID in pts home.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# JAKAFI

## Products Affected

- Jakafi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	For polycythemia vera patients must have tried hydroxyurea
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# KALYDECO

## Products Affected

- Kalydeco oral granules in packet
- Kalydeco oral tablet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with Orkambi or Symdeko.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	6 months of age and older
<b>Prescriber Restrictions</b>	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	CF - must have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, D1270N, G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, G1349D, 2789+5G A, 3272-26A G, 3849+10kbC T, 711+3A G, E831X OR R117H AND must NOT be Homozygous for the F508del Mutation in the CFTR Gene or have unknown CFTR gene mutations.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# KISQALI

## Products Affected

- Kisqali Femara Co-Pack oral tablet 200 mg/day(200 mg x 1)-2.5 mg, 400 mg/day(200 mg x 2)-2.5 mg, 600 mg/day(200 mg x 3)-2.5 mg
- Kisqali oral tablet 200 mg/day (200 mg x 1), 400 mg/day (200 mg x 2), 600 mg/day (200 mg x 3)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	Breast cancer - approve advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer in patients who have not had disease progression while on Kisqali, Ibrance or Verzenio when the pt meets ONE of the following 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH agonist AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient is postmenopausal, pre/perimenopausal or a man and Kisqali (not Co-Pack) will be used in combination with Faslodex 5. Patient is pre/perimenopausal and Kisqali (not Co-Pack) will be used in combination with tamoxifen as first line therapy. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Men with breast cancer.

# KORLYM

## Products Affected

- Korlym

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior surgeries
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome.
<b>Coverage Duration</b>	Endogenous Cushing's Synd-1 year. Pt awaiting surgery or response after radiotherapy-4 months
<b>Other Criteria</b>	Endogenous Cushing's Syndrome-Approve if, according to the prescribing physician, the patient is not a candidate for surgery or surgery has not been curative AND if Korlym is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Endogenous Cushing's Syndrome, awaiting surgery. Patients with Endogenous Cushing's syndrome, awaiting a response after radiotherapy

# KUVAN

## Products Affected

- Kuvan

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Palynziq
<b>Required Medical Information</b>	Diagnosis, Phe concentration
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)
<b>Coverage Duration</b>	Initial-12 weeks, Continuation-1 year
<b>Other Criteria</b>	Initial - approve. Continuation - approve if the patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescribing physician OR patient had a 20% or greater reduction in blood Phe concentration from baseline.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# LENVIMA

## Products Affected

- Lenvima oral capsule 10 mg/day (10 mg x 1), 12 mg/day (4 mg x 3), 14 mg/day(10 mg x 1-4 mg x 1), 18 mg/day (10 mg x 1-4 mg x2), 20 mg/day (10 mg x 2), 24 mg/day(10 mg x 2-4 mg x 1), 4 mg, 8 mg/day (4 mg x 2)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 years
Other Criteria	DTC - must be refractory to radioactive iodine treatment for approval. RCC (clear cell or non-clear cell) - approve if the pt meets ALL of the following criteria: 1) pt has relapsed or stage IV disease, 2)if disease is predominant clear-cell histology then the pt has tried one antiangiogenic therapy (eg, Inlyta, Votrient, Sutent, Cabometyx) AND 3)Lenvima will be used in combination with everolimus (Afinitor). MTC-approve if the patient has tried Caprelsa or Cometriq. Anaplastic thyroid cancer-approve if the disease does not have a curative option.
Indications	All FDA-approved Indications, Some Medically-accepted Indications.
Off-Label Uses	Patients with Medullary Thyroid Carcinoma (MTC) and anaplastic thyroid carcinoma.



# LETAIRIS/TRACLEER

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## Products Affected

- ambrisentan
- Tracleer

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) WHO Group 1-results of right heart cath
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For treatment of pulmonary arterial hypertension, ambrisentan must be prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# LIDOCAINE PATCH

## Products Affected

- lidocaine topical adhesive patch,medicated

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	Chronic back pain-approve if the patient has tried two pharmacologic therapies with each one from a different class of medication used to treat low back pain (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], muscle relaxants, celecoxib, duloxetine, gabapentin).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Diabetic neuropathic pain, chronic back pain

# LONG ACTING OPIOIDS

## Products Affected

- buprenorphine transdermal patch weekly 10 mcg/hour, 15 mcg/hour, 20 mcg/hour, 5 mcg/hour
- Butrans transdermal patch weekly 7.5 mcg/hour
- methadone oral solution 10 mg/5 mL, 5 mg/5 mL
- methadone oral tablet 10 mg, 5 mg
- morphine oral tablet extended release
- oxymorphone oral tablet extended release 12 hr

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute (ie, non-chronic) pain
<b>Required Medical Information</b>	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A

# LONSURF

## Products Affected

- Lonsurf oral tablet 15-6.14 mg, 20-8.19 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Gastric or Gastroesophageal Junction Adenocarcinoma, Metastatic-approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# LORBRENA

## Products Affected

- Lorbrena oral tablet 100 mg, 25 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, ALK status, previous therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	NSCLC - Approve if the patient has ALK-positive metastatic NSCLC and meets one of the following: a) patient has disease progression on Xalkori (crizotinib capsules) and at least one other ALK inhibitor (e.g., Zykadia [ceritinib capsules], Alecensa [alectinib capsules], Alunbrig [brigatinib tablets]), or b) patient has disease progression on Alecensa (alectinib capsules) as the first ALK inhibitor therapy, or c) patient has disease progression on Zykadia (ceritinib capsules) as the first ALK inhibitor therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# LYNPARZA

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## Products Affected

- Lynparza oral tablet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>Ovarian Cancer - Treatment-initial-Approve if the patient meets the following criteria (i and ii): i. The patient has a germline BRCA-mutation as confirmed by an approved test AND per product labeling the patient has progressed on three or more prior lines of chemotherapy. Continuation-approve if the patient has a BRCA mutation (germline) as confirmed by an approved test. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance Therapy-Approve if the patient meets one of the following criteria (A or B): A) The patient meets both of the following criteria for first-line maintenance therapy (i and ii): i. The patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND ii. The patient is in complete or partial response to first-line platinum-based chemotherapy regimen (e.g., carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin) OR B) The patient meets both of the following criteria (i and ii): i. The patient has recurrent disease AND ii. The patient is in complete or partial response after at least two platinum-based chemotherapy regimens (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Breast Cancer-Approve if the patient meets the following criteria (A, B, C, and D)-A. The patient has metastatic, germline BRCA mutation-positive breast cancer AND B. The patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND C. The patient meets ONE of the following criteria (i or ii)- i. The patient meets BOTH of the following criteria (a and b)-a) The patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease AND b) The patient meets ONE of the following criteria (1 or 2)-1-The patient has been treated with prior endocrine therapy OR-2 The patient is considered inappropriate for endocrine therapy OR ii. Patient has triple negative disease (i.e., ER-negative, PR-negative, and HER2-negative) AND D. The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# MEGACE

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## Products Affected

- megestrol oral suspension 400 mg/10 mL (40 mg/mL), 625 mg/5 mL
- megestrol oral tablet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for weight gain for cosmetic reasons.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# MEKINIST

## Products Affected

- Mekinist oral tablet 0.5 mg, 2 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Melanoma must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC requires BRAF V600E Mutation and use in combination with Tafenlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafenlar, unless intolerant AND the patient has BRAF V600-positive disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# MEKTOVI

## Products Affected

- Mektovi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, BRAF V600 status, concomitant medications
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# MEMANTINE

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## Products Affected

- memantine oral capsule,sprinkle,ER 24hr
- memantine oral solution
- memantine oral tablet
- memantine oral tablets,dose pack
- Namzaric

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Indication for which memantine is being prescribed.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with mild to moderate vascular dementia.

# MYALEPT

## Products Affected

- Myalept

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an endocrinologist or a geneticist physician specialist
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NATPARA

## Products Affected

- Natpara

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Chronic hypoparathyroidism, initial therapy - approve if before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician. Chronic hypoparathyroidism, continuing therapy - approve if during Natpara therapy, the patient's 25-hydroxyvitamin D stores are sufficient per the prescribing physician AND the patient is responding to Natapara therapy, as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NERLYNX

## Products Affected

- Nerlynx

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Stage of cancer, HER2 status, previous or current medications tried
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Approve for 12 months
<b>Other Criteria</b>	Breast cancer - approve if the patient meets all of the following criteria: 1. Patient has early stage disease, AND 2. Patient has HER2-positive breast cancer, AND 3. Patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NEULASTA

## Products Affected

- Neulasta subcutaneous syringe

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist. PBPC - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation. Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome.
<b>Coverage Duration</b>	Cancer pts receiving chemo-6 mo. PBPC/Radiation Syndrome-1 mo
<b>Other Criteria</b>	Cancer patients receiving chemotherapy, approve if the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years), prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, OR the patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients undergoing PBPC collection and therapy



# NEUPOGEN

## Products Affected

- Neupogen

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	AML, HIV/AIDS, MDS - adults
<b>Prescriber Restrictions</b>	Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.
<b>Coverage Duration</b>	chemo/SCN/AML-6 mo.HIV/AIDS-4 months.MDS-3 mo.PBPC,Drug induce A/N,AA,ALL,BMT-3 mo.All others=12mo.
<b>Other Criteria</b>	Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver or renal dysfunction, poor performance status, HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm <sup>3</sup> ], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL).

# NEXAVAR

## Products Affected

- Nexavar

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Osteosarcoma, approve if the patient has tried standard chemotherapy and have relapsed/refractory or metastatic disease. GIST, approve if the patient has tried TWO of the following: imatinib mesylate (Gleevec), sunitinib (Sutent), or regorafenib (Stivarga). Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test. Renal cell carcinoma (RCC)-approve if the patient has relapsed or Stage IV clear cell histology and the patient has tried at least one prior systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and Nexavar is used in combination with topotecan.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Osteosarcoma, angiosarcoma, desmoids tumors (aggressive fibromatosis), gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, Chordoma with recurrent disease, solitary fibrous tumor and hemangiopericytoma, ovarian, fallopian tube, primary peritoneal cancer

# NINLARO

## Products Affected

- Ninlaro

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	MM - be used in combination with Revlimid and dexamethasone AND pt had received at least ONE previous therapy for multiple myeloma (e.g., Thalomid, Revlimid, Pomalyst, Alkeran, dexamethasone, prednisone). Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with systemic light chain amyloidosis

# NORTHERA

## Products Affected

- Northera oral capsule 100 mg, 200 mg, 300 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medication history
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a cardiologist or a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	NOH, approve if the patient meets ALL of the following criteria: a) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinsons disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND b) Patient has tried midodrine
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NUBEQA

## Products Affected

- Nubeqa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NUEDEXTA

## Products Affected

- Nuedexta

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NUPLAZID

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## Products Affected

- Nuplazid oral capsule
- Nuplazid oral tablet 10 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# NUVIGIL/PROVIGIL

## Products Affected

- modafinil oral tablet 100 mg, 200 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients must be greater than or equal to 17 years of age.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Excessive sleepiness due to SWSD if the patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Excessive daytime sleepiness (EDS) due to myotonic dystrophy - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only.

# OCALIVA

## Products Affected

- Ocaliva

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prescriber specialty, lab values, prior medications used for diagnosis and length of trials
<b>Age Restrictions</b>	18 years and older (initial and continuation therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial and continuation therapy)
<b>Coverage Duration</b>	6 months initial, 3 years cont.
<b>Other Criteria</b>	Initial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following:a)Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b)Positive anti-mitochondrial antibodies (AMAs) c)Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# OCTREOTIDE

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## Products Affected

- octreotide acetate injection solution

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ODOMZO

## Products Affected

- Odomzo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	BCC - Must not have had disease progression while on Erivedge (vismodegib).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metastatic BCC - approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Metastatic BCC

# OFEV

## Products Affected

- Ofev

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with pirfenidone
<b>Required Medical Information</b>	N/A
<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>	1 year
<b>Other Criteria</b>	IPF baseline - must have FVC greater than or equal to 50 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ORENCIA

## Products Affected

- Orenzia
- Orenzia ClickJect

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA and JIA/JRA prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist.
<b>Coverage Duration</b>	3 mos initial, 3 years cont
<b>Other Criteria</b>	RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], approve if the patient meets one of the following criteria: 1) Patient has tried adalimumab. [Note: the patient does not have to have a trial with Humira if they have had a trial with Enbrel, Actemra IV or infliximab in the past.], OR 2) According to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder, or a previous serious infection. Cont tx - responded to therapy as per the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ORKAMBI

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## Products Affected

- Orkambi oral granules in packet
- Orkambi oral tablet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with Kalydeco or Symdeko
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	CF - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation)
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# OXERVATE

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## Products Affected

- Oxervate

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, an ophthalmologist.
<b>Coverage Duration</b>	2 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# PALYNZIQ

## Products Affected

- Palylnziq subcutaneous syringe 10 mg/0.5 mL, 2.5 mg/0.5 mL, 20 mg/mL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, phenylalanine concentrations
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases
<b>Coverage Duration</b>	1 year (initial and continuation)
<b>Other Criteria</b>	Initial therapy - approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., prior treatment with Kuvan). Maintenance therapy - approve if the patient's blood phenylalanine concentration is less than or equal to 600 micromol/L OR the patient has achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PEGASYS

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## Products Affected

- Pegasys ProClick subcutaneous pen injector 180 mcg/0.5 mL
- Pegasys subcutaneous solution
- Pegasys subcutaneous syringe

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous medications tried, liver disease compensation status, concomitant medications for HCV
<b>Age Restrictions</b>	HCV - patients 5 years of age or older, HBV - patients 3 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PHEOCHROMOCYTOMA

## Products Affected

- Demser

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior medication trials
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial therapy for phenoxybenzamine, initial and continuation therapy for Demser)
<b>Coverage Duration</b>	Authorization will be for 1 year
<b>Other Criteria</b>	If the requested drug is Demser for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin) AND the patient has tried phenoxybenzamine (brand or generic). If the requested drug is Demser for continuation therapy, approve if the patient is currently receiving Demser or has received Demser in the past.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

## Products Affected

- Alyq
- sildenafil (Pulmonary Arterial Hypertension) oral suspension for reconstitution 10 mg/mL
- sildenafil (Pulmonary Arterial Hypertension) oral tablet 20 mg
- tadalafil (pulm. hypertension)

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, right heart cath results
Age Restrictions	N/A
Prescriber Restrictions	For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist.
Coverage Duration	Authorization will be for 1 year.
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets and suspension require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# PIQRAY

## Products Affected

- Piqray

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, and E): A) The patient is a postmenopausal female or a male AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, Faslodex, tamoxifen, toremifene).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# POMALYST

## Products Affected

- Pomalyst

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Myelofibrosis, Systemic Light Chain Amyloidosis, AIDS-Related Kaposi Sarcoma, relapsed or refractory disease, Central Nervous System (CNS) Lymphoma, relapsed or refractory disease

# PROLASTIN-C

## Products Affected

- Prolastin-C intravenous recon soln

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, pretreatment AAT serum concentration
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Alpha 1-Antitrypsin (AAT) Deficiency with Emphysema (or COPD) - approve in patients with baseline (pretreatment) AAT serum concentration of less than 80 mg/dL (11 micromol/L).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PROLIA

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## Products Affected

- Prolia

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Fortical]), abaloparatide, except calcium and Vitamin D.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 1 year.



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>Treatment of postmenopausal osteoporosis/Treatment of osteoporosis in men (to increase bone mass) [a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression], approve if the patient meets one of the following: 1. has had inadequate response after 12 months of therapy with an oral bisphosphonate, had osteoporotic fracture or fragility fracture while receiving an oral bisphosphonate, or intolerability to an oral bisphosphonate, OR 2. the patient cannot take an oral bisphosphonate because they cannot swallow or have difficulty swallowing, they cannot remain in an upright position, or they have a pre-existing GI medical condition, OR 3. pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR 4. the patient has severe renal impairment (eg, creatinine clearance less than 35 mL/min) or chronic kidney disease, or if the patient has an osteoporotic fracture or fragility fracture. Treatment of bone loss in patient at high risk for fracture receiving ADT for nonmetastatic prostate cancer, approve if the patient has prostate cancer that is not metastatic to the bone and the patient is receiving ADT (eg, leuprolide, triptorelin, goserelin) or the patient has undergone a bilateral orchiectomy. Treatment of bone loss (to increase bone mass) in patients at high risk for fracture receiving adjuvant AI therapy for breast cancer, approve if the patient has breast cancer that is not metastatic to the bone and in receiving concurrent AI therapy (eg, anastrozole, letrozole, exemestane). Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PROMACTA

## Products Affected

- Promacta oral powder in packet
- Promacta oral tablet 12.5 mg, 25 mg, 50 mg, 75 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Use in the management of thrombocytopenia in myelodysplastic syndrome (MDS).
<b>Required Medical Information</b>	Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Thrombocytopenia due to chronic ITP or Aplastic Anemia, approve if prescribed by, or after consultation with, a hematologist. Thrombocytopenia due to HCV-related cirrhosis, approve if prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease.
<b>Coverage Duration</b>	Chronic ITP - 3 years, others 12 months.
<b>Other Criteria</b>	Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura, approve if the patient has tried ONE other therapy or has undergone a splenectomy. Treatment of thrombocytopenia due to HCV-related cirrhosis, approve to allow for initiation of antiviral therapy if the patient has low platelet counts (eg, less than 75,000 mm <sup>3</sup> ) and the patient has chronic HCV infection and is a candidate for hepatitis C therapy. Aplastic anemia - has low platelet counts at baseline/pretreatment (e.g., less than 30,000 mm <sup>3</sup> ) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate mofetil, sirolimus) OR patient will be using Promacta in combination with standard immunosuppressive therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# QUININE

## Products Affected

- quinine sulfate

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# RELISTOR INJECTION

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## Products Affected

- Relistor subcutaneous solution
- Relistor subcutaneous syringe

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Patients 18 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# REPATHA

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## Products Affected

- Repatha
- Repatha SureClick

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use of Juxtapid, Kynamro, or Praluent.
<b>Required Medical Information</b>	LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history
<b>Age Restrictions</b>	ASCVD/HeFH/Primary Hyperlipidemia - 18 yo and older, HoFH 13 yo and older.
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
<b>Coverage Duration</b>	Approve for 3 years for ASCVD/HeFH/HoFH. Approve for 1 year for primary hyperlipidemia.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>Hyperlipidemia with HeFH - approve if: 1) diagnosis of HeFH AND 2) tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or Crestor greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the symptoms resolved upon discontinuation. Hyperlipidemia with ASCVD -approve if: 1) has one of the following conditions: prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) tried ONE high intensity statin (defined above) and LDL remains 70 mg/dL or higher unless pt is statin intolerant (defined above). HoFH - approve if: 1) has one of the following: a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha, Kynamro or Juxtapid), OR d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity statin (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if all of the following are met: 1) coronary artery calcium or calcification (CAC) score 300 Agatston units or higher, AND 2) tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above).</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# REVLIMID

## Products Affected

- Revlimid

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis and previous therapies or drug regimens tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	MCL-approve if the patient meets one of the following 1) Pt has tried two prior therapies or therapeutic regimens OR 2) Pt has tried one prior therapy or therapeutic regimen and cannot take Velcade according to the prescribing physician. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). Diffuse, Large B Cell Lymphoma (Non-Hodgkin's Lymphoma)-approve if the pt has tried one other medication treatment regimen. Myelofibrosis-approve if the pt has tried one other therapy. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried one other chemotherapy regimen.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma.

# RINVOQ

## Products Affected

- Rinvoq ER

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants.
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	RA, prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	Authorization will be for 3 months initial, 3 years cont.
<b>Other Criteria</b>	RA initial-approve if the patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). Continuation Therapy - Patient must have responded, as determined by the prescriber
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# RUBRACA

## Products Affected

- Rubraca

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3years
<b>Other Criteria</b>	Ovarian, Fallopian Tube or Primary Peritoneal Cancer-treatment- Approve if the patient meets the following criteria (i and ii): i.The patient has a BRCA-mutation (germline or somatic) as confirmed by an approved test, AND ii.The patient has progressed on two or more prior lines of chemotherapy. Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient has recurrent disease and the patient is in complete or partial response after at least two lines of platinum-based chemotherapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# RYDAPT

## Products Affected

- Rydapt

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For AML, FLT3 status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	AML-approve if the patient is FLT3-mutation positive as detected by an approved test AND the patient is receiving Rydapt in one of the following settings (i, ii, iii, or iv)-i. Induction therapy in combination with cytarabine and daunorubicin OR ii. After standard-dose cytarabine induction/reinduction, along with cytarabine and daunorubicin OR iii. Post remission or consolidation therapy in combination with cytarabine OR iv. Maintenance therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SABRIL

## Products Affected

- vigabatrin
- Vigadrone

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medication history (complex partial seizures)
<b>Age Restrictions</b>	Refractory complex partial seizures - patients 10 years of age or older. Infantile spasms/West Syndrome - patients 1 month to 2 years of age
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SAMSCA

## Products Affected

- Samsca oral tablet 15 mg, 30 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Jynarque.
<b>Required Medical Information</b>	Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 30 days
<b>Other Criteria</b>	Hyponatremia - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on Samsca and has received less than 30 days of therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SIGNIFOR

## Products Affected

- Signifor

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome.
<b>Coverage Duration</b>	Cushing's dis-Initial-4 mo, Cont-1 year. Pt awaiting surgery or response after radiotherapy-4 mo
<b>Other Criteria</b>	Cushing's disease, initial therapy - approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushing's disease, continuation therapy - approve if the patient has already been started on Signifor and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SIRTURO

## Products Affected

- Sirturo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, concomitant therapy
<b>Age Restrictions</b>	Patients 18 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SKYRIZI

## Products Affected

- Skyrizi subcutaneous syringe kit

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
<b>Required Medical Information</b>	Diagnosis, Previous medication use
<b>Age Restrictions</b>	18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	PP-Prescribed by or in consultation with a dermatologist (initial therapy)
<b>Coverage Duration</b>	3 mos initial, 3 years cont
<b>Other Criteria</b>	Initial Therapy-The patient meets ONE of the following conditions (a or b): a) The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant. NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g., an adalimumab product [Humira], a certolizumab pegol product [Cimzia], an etanercept product [Enbrel, Erelzi], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Stelara [ustekinumab SC injection], Taltz [ixekizumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional systemic agent for psoriasis)b) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician.Continuation Therapy - Patient must have responded, as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SOMATULINE DEPOT (INJECTION AND SC INJECTION)

## Products Affected

- Somatuline Depot

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous treatments/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Acromegaly-approve if the patient has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Neuroendocrine tumors of the gastrointestinal tract, lung, thymus (carcinoid tumor) and pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)



# SOMAVERT

## Products Affected

- Somavert

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SPRYCEL

## 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>	N/A
<b>Required Medical Information</b>	Diagnosis for which Sprycel is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	For CML, new patient must have Ph-positive CML for approval of Sprycel. For ALL, new patient must have Ph-positive ALL for approval of Sprycel. GIST - has D842V mutation AND previously tried Sutent and Gleevec.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	GIST, chondrosarcoma or chordoma

# STELARA

## Products Affected

- Stelara subcutaneous

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	Adults-PsA and CD. PP-12 years and older.
<b>Prescriber Restrictions</b>	PP-Prescr/consult w/derm.PsA-prescr/consult w/rheum or derm.CD-prescr/consult w/gastro.
<b>Coverage Duration</b>	PP/PsA Init-3mo,CD load-approve 1 dose IV,CD post IV load-approve SC 3 mo,cont tx-approve SC 3 yr
<b>Other Criteria</b>	PP initial - approve Stelara SC.CD, initial therapy - approve 3 months of the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD. PP/PsA/CD cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# STIVARGA

## Products Affected

- Stivarga

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	For GIST, patient must have previously been treated with imatinib (Gleevec) and sunitinib (Sutent). For HCC, patient must have previously been treated with at least one tyrosine kinase inhibitor (e.g., Nexavar, Lenvima). Soft tissue sarcoma-approve if the patient has non-adipocytic extremity/superficial trunk, head/neck or retroperitoneal/intra-abdominal sarcoma OR pleomorphic rhabdomyosarcoma.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Soft tissue Sarcoma

# SUTENT

## Products Affected

- Sutent

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Gastrointestinal stromal tumors (GIST), approve if the patient has tried imatinib (Gleevec). Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried chemotherapy or radiation therapy. Renal Cell Carcinoma (RCC), clear cell or non-clear cell histology-approve if the patient is at high risk of recurrent clear cell RCC following nephrectomy and Sutent is used for adjuvant therapy or if the patient has relapsed or Stage IV disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and Hurthle) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma.

# SYLATRON

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## Products Affected

- Sylatron

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, time elapsed since surgical resection including complete lymphadenectomy
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SYMDEKO

## Products Affected

- Symdeko

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Patients with unknown CFTR gene mutations
<b>Required Medical Information</b>	Diagnosis, specific CFTR gene mutations
<b>Age Restrictions</b>	Six years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	CF - must have at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A G, S945L, S977F, F1052V, E831X, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G A, 3272-26A G, or 3849 + 10kbC T OR the patient has two copies of the F508del mutation
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SYMLIN

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## Products Affected

- SymlinPen 120
- SymlinPen 60

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# SYPRINE

## Products Affected

- trientine

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medication history, pregnancy status, disease manifestations
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	For Wilson's Disease, approve if the patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TAFINLAR

## Products Affected

- Tafinlar

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Tafinlar is being used. BRAF V600 mutations
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC, must have BRAF V600E mutation. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Differentiated Thyroid Cancer

# TAGRISSO

## Products Affected

- Tagrisso

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	NSCLC - prior therapies and EGFR T790M mutation or EGFR exon 19 deletion or exon 21 (L858R) substitution
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	NSCLC - Must have metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC as detected by an approved test AND has progressed on one of the EGFR tyrosine kinase inhibitors (e.g., Tarceva, Iressa, Vizimpro or Gilotrif) therapy OR Advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have EGFR exon 19 deletion or exon 21 (L858R) substitution as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TALZENNA

## Products Affected

- Talzenna oral capsule 0.25 mg, 1 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, BRCA mutation status, HER2 status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Locally-advanced or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive AND human epidermal growth factor receptor 2 (HER2) negative disease
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TARCEVA

## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Advanced, recurrent, or metastatic non small cell lung cancer (NSCLC), EGFR mutation or gene amplification status.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Metastatic NSCLC, approve if the patient meets both of the following: 1. patient is EGFR mutation positive, AND 2. patient has EGFR exon 19 deletions OR exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Advanced RCC, approve if the patient has non-clear cell histology.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Renal Cell Carcinoma and Bone Cancer-Chordoma.

# TARGRETIN ORAL

## Products Affected

- bexarotene

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies tried
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Initial therapy- approve if the following criteria are met: Patient has tried ONE oral retinoid, methotrexate, or phototherapy. (NOTE: An exception to the requirement for a trial of an oral retinoid, methotrexate, or phototherapy can be made if the patient has already used one of the following: interferons, histone deacetylase [HDAC] inhibitors, Poteligeo or extracorporeal photopheresis. These patients are not required to step back and try an oral retinoid, methotrexate, or phototherapy) OR the patient has a type of CTCL (e.g., folliculotropic disease, advanced disease) that, according to the prescribing physician, requires treatment with oral bexarotene capsules. If brand Targretin is requested, the patient has tried and cannot take generic bexarotene capsules due to a formulation difference in the inactive ingredient(s) between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction. Continuation therapy- approve if brand Targretin is requested, the patient has tried and cannot take generic bexarotene capsules due to a formulation difference in the inactive ingredient(s) between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TARGRETIN TOPICAL

## Products Affected

- Targretin topical

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
Coverage Duration	3 years
Other Criteria	Initial therapy-approve if the patient has tried a topical corticosteroid and topical imiquimod cream (Aldara, generics, Zyclara). (NOTE: An exception to the requirement for a trial of a topical corticosteroid and topical imiquimod cream can be made if the patient has already used one of the following: a skin-directed therapy, e.g., topical chemotherapy, topical retinoids, local radiation, phototherapy [UVB, NB-UVB, PUVA], TSEBT, or a systemic therapy, e.g., oral retinoids, interferons, histone deacetylase [HDAC] inhibitors, extracorporeal photopheresis, methotrexate, systemic chemotherapeutic agents, Poteligeo). These patients are not required to step back and try a topical corticosteroid and topical imiquimod cream).
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# TASIGNA

## Products Affected

- Tasigna oral capsule 150 mg, 200 mg, 50 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and ALL, prior therapies tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	For CML, new patient must have Ph-positive CML for approval of Tasigna. For GIST, patient must have tried TWO of the following - sunitinib (Sutent), imatinib (Gleevec), or regorafenib (Stivarga). For ALL, Approve if the patient has tried one other tyrosine kinase inhibitor that is used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST)



# TAZORAC

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## Products Affected

- tazarotene
- Tazorac topical cream 0.05 %

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Cosmetic uses
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TECFIDERA

## Products Affected

- Tecfidera

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
<b>Required Medical Information</b>	MS, patient must have a relapsing form of MS (RRMS, SPMS with relapses, or PRMS).
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or MS specialist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# THALOMID

## Products Affected

- Thalomid oral capsule 100 mg, 150 mg, 200 mg, 50 mg

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	<p>Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]).</p> <p>Myelofibrosis, approve if the patient has tried one other therapy (eg, ruxolitinib [Jakafi], danazol, epoetin alfa [Epogen/Procrit], prednisone, lenalidomide [Revlimid], hydroxyurea). Prurigo nodularis, approve.</p> <p>Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). AIDS Related Kaposi's Sarcoma-approve if the patient has tried one regimen and has relapsed or refractory disease.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, Systemic Light Chain Amyloidosis, AIDS related Kaposi's Sarcoma, Castleman's Disease (relapsed/refractory or progressive).

# TIBSOVO

## Products Affected

- Tibsovo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, IDH1 Status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive, as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TOPICAL AGENTS FOR ATOPIC DERMATITIS

## Products Affected

- tacrolimus topical

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TOPICAL RETINOID PRODUCTS

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## Products Affected

- tretinoin topical

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for cosmetic use.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TOPICAL TESTOSTERONE PRODUCTS

## Products Affected

- testosterone transdermal gel in metered-dose pump 20.25 mg/1.25 gram (1.62 %)
- testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. hypogonadism has been confirmed by a low for age serum testosterone (total or free) level defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
<b>Indications</b>	All FDA-approved Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	N/A



# TOPIRAMATE/ZONISAMIDE

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## Products Affected

- topiramate oral capsule, sprinkle
- topiramate oral tablet
- zonisamide

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for weight loss or smoking cessation.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TRANSDERMAL FENTANYL

## Products Affected

- fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Acute (i.e., non-chronic) pain
<b>Required Medical Information</b>	Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naïve, AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TRANSMUCOSAL FENTANYL DRUGS

## Products Affected

- fentanyl citrate buccal lozenge on a handle

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer pain (ie, FDA labeled use) prior to reviewing for quantity exception.
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# TYKERB

## Products Affected

- Tykerb

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Tykerb is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	HER2-positive advanced or metastatic breast cancer, approve if Tykerb will be used in combination with Xeloda or Herceptin and the patient has received prior therapy with Herceptin. HER2-positive HR positive metastatic breast cancer, approve if the patient is a man receiving a GnRH agonist, a premenopausal or perimenopausal woman receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian radiation or a postmenopausal woman and Tykerb will be used in combination with an aromatase inhibitor, that is letrozole (Femara), anastrozole, or exemestane. In this criteria, man/woman is defined as an individual with the biological traits of a man/woman, regardless of the individual's gender identity or expression.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Bone cancer-chordoma

# TYMLOS

## Products Affected

- Tymlos

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, calcitonin nasal spray [Fortical], Forteo), except calcium and Vitamin D. Previous use of Tymlos and/or Forteo for a combined total no greater than 2 years duration during a patient's lifetime.
<b>Required Medical Information</b>	Previous medications tried, renal function
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 2 years of therapy over a patient's lifetime
<b>Other Criteria</b>	Treatment of PMO, approve if the patient meets ONE of the following criteria: patient has tried one oral bisphosphonate or cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or patient cannot remain in an upright position post oral bisphosphonate administration or patient has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR patient has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR patient has severe renal impairment or CKD, OR patient has had an osteoporotic fracture or fragility fracture
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# UPTRAVI

## Products Affected

- Uptravi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Confirmation of right heart catheterization, medication history.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to therapy must meet a) OR b): a) tried TWO or is currently taking TWO oral therapies for PAH (either alone or in combination) each for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VALCHLOR

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## Products Affected

- Valchlor

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VENCLEXTA

## Products Affected

- Venclexta oral tablet 10 mg, 100 mg, 50 mg
- Venclexta Starting Pack

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapy
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	CLL with or without 17p deletion - approve. SLL-approve. Mantle Cell Lymphoma-approve if the patient has tried one prior therapy. AML-approve if the patient is using Venclexta in combination with either azacitidine, decitabine, or cytarabine.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Mantle Cell Lymphoma



# VERZENIO

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## Products Affected

- Verzenio

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>Breast cancer - approve advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer in patients who have not had disease progression while on Kisqali, Ibrance or Verzenio when the pt meets ONE of the following</p> <ol style="list-style-type: none"> <li>1. Pt is postmenopausal and Verzenio will be used in combination with anastrozole, exemestane, or letrozole</li> <li>2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Verzenio will be used in combination with anastrozole, exemestane, or letrozole</li> <li>3. Patient is postmenopausal and meets the following conditions: Verzenio will be used in combination with Faslodex.</li> <li>4. patient is premenopausal or perimenopausal and meets the following conditions: The patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND Verzenio will be used in combination with Faslodex</li> <li>5. patient is postmenopausal, premenopausal/perimenopausal (patient is receiving ovarian suppression/ablation with GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) and meets the following conditions: Verzenio will be used as monotherapy AND patient's breast cancer has progressed on at least one prior endocrine therapy (e.g., anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol) AND patient has tried chemotherapy for metastatic breast cancer.</li> <li>6. pt is a man who is receiving GnRH agonist AND Verzenio will be used in combination with anastrozole, exemestane or letrozole</li> <li>7. Patient is a man and Verzenio will be used in combination with Faslodex</li> </ol>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Men with breast cancer

# VITRAKVI

## Products Affected

- Vitrakvi oral capsule 100 mg, 25 mg
- Vitrakvi oral solution

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, NTRK gene fusion status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Solid tumors - approve if the tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity AND there are no satisfactory alternative treatments or the patient has disease progression following treatment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VIZIMPRO

## Products Affected

- Vizimpro

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, EGFR status, exon deletions or substitutions
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Metastatic-NSCLC-Epidermal Growth Factor Receptor (EGFR) mutation positive AND has epidermal growth factor receptor (EGFR) exon 19 deletion as detected by an approved test OR exon 21 (L858R) substitution mutations as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VOTRIENT

## Products Affected

- Votrient

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Soft tissue sarcoma other than GIST [angiosarcoma, Pleomorphic rhabdomyosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive, soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma, or solitary fibrous tumor/hemangiopericytoma or alveolar soft part sarcoma], approve. Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has recurrent, advanced or metastatic disease. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or stage IV disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has tried TWO of the following: Gleevec, Sutent, or Strivarga. Medullary Thyroid Carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma.

# XALKORI

## Products Affected

- Xalkori

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For the FDA-approved indication of NSCLC for patients new to therapy, ALK status, high level MET amplification status, MET Exon 14 skipping mutation, and ROS1 rearrangement required. For soft tissue sarcoma IMT, ALK translocation.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	NSCLC, patient new to therapy must be ALK-positive, have high level MET amplification, have MET Exon 14 skipping mutation, or have ROS1 rearrangement for approval. For IMT, patient new to therapy must have ALK translocation for approval.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Soft tissue sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation, Plus peripheral T-Cell Lymphoma - Anaplastic Large Cell Lymphoma (ALCL), ALK Positive Plus NSCLC with high level MET amplification or MET Exon 14 skipping mutation.

# XELJANZ

## Products Affected

- Xeljanz
- Xeljanz XR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a biologic or with a Targeted Synthetic DMARD for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA, prescr/consult w/rheum. PsA-prescr/consult w/rheum or a derm. UC-prescr/consult w/gastro.
<b>Coverage Duration</b>	PsA/RA-3 months initial, UC-16 weeks initial, All diagnoses-3 years cont.
<b>Other Criteria</b>	RA/PsA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). UC-Approve Xeljanz (not XR) if the patient has had a trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid) or was intolerant to one of these agents. Note-a previous trial of a biologic also counts as a trial of one systemic agent. Continuation Therapy - Patient must have responded, as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# XENAZINE

## Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.



# XERMELO

## Products Affected

- Xermelo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapy, concomitant therapy
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial therapy - approve if the patient meets ALL of the following criteria: 1) patient has been on long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]), AND 2) while on long-acting SSA therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day, AND 3) Xermelo will be used concomitantly with a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with a long-acting SSA therapy for carcinoid syndrome diarrhea.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# XIFAXAN

## Products Affected

- Xifaxan oral tablet 200 mg, 550 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Traveler's diarrhea - 12 years of age or older. Hepatic encephalopathy, irritable bowel syndrome - 18 years of age or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# XOLAIR

## Products Affected

- Xolair subcutaneous recon soln
- Xolair subcutaneous syringe 150 mg/mL, 75 mg/0.5 mL

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with an Interleukin (IL) Antagonist Monoclonal Antibody
<b>Required Medical Information</b>	Moderate to severe persistent asthma and SAR/PAR, baseline IgE level of at least 30 IU/mL. For asthma, patient has a baseline positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay (eg, immunoCAP, ELISA) or the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). For SAR/PAR, patient has baseline positive skin testing (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach) and/or baseline positive in vitro testing (ie, a blood test for allergen-specific IgE antibodies) for one or more relevant allergens (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach). CIU - must have urticaria for more than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine).
<b>Age Restrictions</b>	Moderate to severe persistent asthma-6 years and older. All other diagnoses-12 years and older
<b>Prescriber Restrictions</b>	Moderate to severe persistent asthma/SAR/PAR if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist.
<b>Coverage Duration</b>	Initial tx 4 months, continued tx 12 months

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>Moderate to severe persistent asthma approve if pt meets criteria 1 and 2: 1) pt has received at least 3 months of combination therapy with an inhaled corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2)patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS for at least 3 consecutive months. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. SAR/PAR - approve if pt has tried concurrent therapy with at least one drug from two of the following classes: an oral non-sedating or low-sedating antihistamine, a nasal antihistamine, a nasal corticosteroid, or montelukast. For continued tx SAR/PAR - pt must have responded to therapy as determined by the prescribing physician. For CIU cont tx - must have responded to therapy as determined by the prescribing physician.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Seasonal or perennial allergic rhinitis (SAR or PAR).

# XOSPATA

## Products Affected

- Xospata

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, FLT3-mutation status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	AML - approve if the patient has relapsed or refractory disease AND the disease is FLT3-mutation positive as detected by an approved test.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# XPOVIO

## Products Affected

- Xpovio

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Approve if the if the patient meets ALL of the following (A, B, and C): A) The patient has tried at least two proteasome inhibitors. Note: Examples include Velcade (bortezomib injection), Kyprolis (carfilzomib infusion), Ninlaro (ixazomib capsules) AND B) The patient has tried at least two immunomodulatory drugs. Note: Examples include Revlimid (lenalidomide capsules), Pomalyst (pomalidomide capsules), Thalomid (thalidomide capsules) AND C) The patient has tried an anti-CD38 monoclonal antibody. Note: For example, Darzalex (daratumumab infusion).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# XTANDI

## Products Affected

- Xtandi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Xtandi is being used. For metastatic castration-resistant prostate cancer, prior therapies tried.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# XYREM

## Products Affected

- Xyrem

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Medication history
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by a sleep specialist physician or a Neurologist
<b>Coverage Duration</b>	12 months.
<b>Other Criteria</b>	For Excessive daytime sleepiness (EDS) in patients with narcolepsy - approve if the patient has tried TWO CNS stimulants (e.g., methylphenidate, dexamethylphenidate, dextroamphetamine), modafinil, or armodafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# ZEJULA

## Products Affected

- Zejula

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy-approve if the patient has recurrent disease and is in complete or partial response after at least two lines of platinum-based chemotherapy regimen.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ZELBORAF

## Products Affected

- Zelboraf

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	BRAFV600 mutation status required.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresctable, advanced or metastatic melanoma. HCL - must have relapsed or refractory disease AND tried at least two therapies for hairy cell leukemia. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. Erdheim-Chester disease, in patients with the BRAF V600 mutation-approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or Hurthle cell) with BRAF-positive disease

# ZEPATIER

## Products Affected

- Zepatier

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin or Sovaldi.
<b>Required Medical Information</b>	Genotype, prior medication therapy, concurrent medications, NS5A polymorphism status, prescriber specialty
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation w/ GI, hepatologist, ID, or liver transplant MD.
<b>Coverage Duration</b>	Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance

# ZOLINZA

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## Products Affected

- Zolinza

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	CTCL - approve if the patient has progressive, persistent, or recurrent disease on or following treatment with systemic therapies.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ZYDELIG

## Products Affected

- Zydelig

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	CLL-approve if the patient has tried one prior therapy. Marginal Zone Lymphoma/Follicular B-Cell Non-Hodgkin Lymphoma/SLL - approve if the patient has tried two prior therapies.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Marginal Zone Lymphoma

# ZYKADIA

## Products Affected

- Zykadia

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Must have metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test or ROS1 Rearrangement. IMT - ALK Translocation status.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Soft Tissue Sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement-First-line therapy.

# ZYPREXA RELPREVV

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## Products Affected

- Zyprexa Relprevv intramuscular suspension for reconstitution 210 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Dementia-related psychosis
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ZYTIGA

## Products Affected

- abiraterone

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 3 years.



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>Prostate Cancer-Metastatic, Castration-Resistant (mCRPC) and Metastatic, Castration-Sensitive (mCSPC), high risk-Approve if abiraterone is being used in combination with prednisone. Prostate Cancer - Regional Risk Group or Locally Advanced. Approve if the patient meets all of the following criteria (A, B, and C): A) abiraterone is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii): i. abiraterone with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant]) OR ii. Patient has had an orchiectomy. Prostate Cancer - Metastatic (Castration-Resistant or Castration-Sensitive), Post-External Beam Radiation Therapy (EBRT)-Approve if the patient meets all of the following criteria (A, B, C, D, and E): A) abiraterone is used in combination with prednisone AND B) Patient meets one of the following criteria (i, ii, or iii): i. abiraterone with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant]) OR ii. abiraterone with prednisone is used in combination with GnRH antagonist (e.g., Firmagon [degarelix for injection]) OR iii. Patient has had an orchiectomy. C) Patient meets one of the following criteria (i or ii): i. There is an increase in prostate specific antigen (PSA) after EBRT OR ii Patient has had a positive digital rectal exam (DRE) after EBRT AND D) Patient is not a candidate for local therapy AND E) Patient has had a positive bone scan.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Prostate Cancer-Regional Risk Group or Locally Advanced. Plus Prostate Cancer - Metastatic (Castration-Resistant or Castration-Sensitive), Post-External Beam Radiation Therapy (EBRT).

## PART B VERSUS PART D

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### Products Affected

- Abelcet
- acetylcysteine
- Actimmune
- acyclovir sodium intravenous solution
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 mL, 1.25 mg/3 mL, 2.5 mg /3 mL (0.083 %), 2.5 mg/0.5 mL
- AmBisome
- Aminosyn II 10 %
- Aminosyn II 15 %
- Aminosyn-PF 10 %
- Aminosyn-PF 7 % (sulfite-free)
- amphotericin B
- aprepitant
- azathioprine
- budesonide inhalation suspension for nebulization 0.25 mg/2 mL, 0.5 mg/2 mL, 1 mg/2 mL
- caspofungin
- cromolyn inhalation
- cyclophosphamide oral capsule
- cyclosporine modified
- cyclosporine oral capsule
- dronabinol
- Emend oral suspension for reconstitution
- Engerix-B (PF) intramuscular syringe
- Engerix-B Pediatric (PF) intramuscular syringe
- Firmagon kit w diluent syringe
- Freamine HBC 6.9 %
- Gengraf oral capsule 100 mg, 25 mg
- Gengraf oral solution
- Hepatamine 8%
- Intralipid intravenous emulsion 20 %
- Intralipid intravenous emulsion 30 %
- Intron A injection
- ipratropium bromide inhalation
- ipratropium-albuterol
- methotrexate sodium
- methotrexate sodium (PF) injection solution
- methylprednisolone oral tablet
- mycophenolate mofetil
- mycophenolate sodium
- Nebupent

- Nephramine 5.4 %
- ondansetron
- ondansetron HCl oral solution
- ondansetron HCl oral tablet
- Perforomist
- Plenamine
- Prednisone Intensol
- prednisone oral tablet
- Premasol 10 %
- Premasol 6 %
- Prograf oral granules in packet
- Pulmozyme
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL
- Recombivax HB (PF) intramuscular syringe
- Sandimmune oral solution
- sirolimus
- Synribo
- tacrolimus oral
- tobramycin in 0.225 % NaCl
- Travasol 10 %
- Trelstar intramuscular suspension for reconstitution
- TrophAmine 10 %
- Trophamine 6%
- Xatmep
- Xgeva
- Zortress oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 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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