



| Value |

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

You will need authorization from **Express Scripts Medicare**<sup>®</sup> (PDP) before filling prescriptions for the drugs shown in the following chart. Express Scripts Medicare will only provide coverage after it determines that the drug is being prescribed according to the criteria specified in the chart.

You, your appointed representative or your prescriber can request prior authorization by calling Express Scripts Medicare 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 Medicare (PDP) is a prescription drug plan with a Medicare contract.  
Enrollment in Express Scripts Medicare depends on contract renewal.

# ACTEMRA

## Products Affected

- Actemra

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on tocilizumab for a Covered Use.
Exclusion Criteria	Concurrent Use with a Biologic Disease-Modifying Antirheumatic Drug (DMARD) or Targeted Synthetic DMARD.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	RA, SJIA, PJIA - Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Initial - RA/SJIA 3 mos, 4 mos PJIA. Cont - RA, SJIA, PJIA - 3 years.
Other Criteria	<p>RA, approve for patients who have tried two of the following: etanercept, adalimumab, certolizumab, anakinra, abatacept IV, abatacept SC, infliximab, rituximab, golimumab IV, golimumab SC, unless the patient has CHF or a previously treated lymphoproliferative disease. If the patient has not tried two of these drugs, the patient must have a trial with etanercept or adalimumab. Systemic-onset JIA, approve for patients who have tried one other systemic agent for SJIA (eg, a corticosteroid [oral, IV], a conventional synthetic DMARD [eg, MTX, leflunomide, sulfasalazine], or a biologic DMARD [eg, Kineret, a TNF inhibitor such as Enbrel, Humira or Remicade, or Ilaris (canakinumab for SC injection)], or a 1-month trial of a nonsteroidal anti-inflammatory drug [NSAID]).</p> <p>PJIA, approve if the patient has tried two of the following: etanercept, adalimumab, abatacept IV, or infliximab, unless the patient has CHF or a previously treated lymphoproliferative disease. If the patient has not tried two of these drugs, the patient must have a trial with etanercept or adalimumab. Cont tx - pt must have had a response (e.g., less joint pain, morning stiffness, or fatigue, improved function or ADLs, decreased soft tissue swelling in joints or tendon sheaths, improved lab values, reduced dosage of corticosteroids), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Actemra IV or SC.</p>

# ACTEMRA SQ

## Products Affected

- Actemra

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA - Prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	3 months initial, 3 years cont.
<b>Other Criteria</b>	RA - The pt had a trial with two of the following: certolizumab, etanercept, adalimumab, anakinra, abatacept IV, abatacept SC, golimumab IV, golimumab SC, infliximab, rituximab, unless the patient has CHF or lymphoproliferative disease. If the patient has not tried two of these drugs, the patient must have a trial with etanercept or adalimumab prior to approval. Cont tx - pt must have had a response (e.g., less joint pain, morning stiffness, or fatigue, improved function or ADLs, decreased soft tissue swelling in joints or tendon sheaths, improved lab values, reduced dosage of corticosteroids), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Actemra IV or SC.

# ADEMPAS

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## Products Affected

- Adempas

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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>	3 years
<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). Right heart catheterization is not required in pts who are currently receiving Adempas or another agent indicated for WHO group 1.

# AFINITOR

## Products Affected

- Afinitor Disperz

- Afinitor oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Afinitor for a Covered Use. Advanced, unresectable neuroendocrine tumors. Perivascular Epitheloid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangiomyomatosis, relapsed or refractory classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL).
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	HER2 status. Advanced HER2-negative breast cancer, 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>	Advanced HER2-negative breast cancer, approve if the patient is a postmenopausal woman and has HR+ disease and Afinitor will be used in combination with exemestane or tamoxifen and the patient has tried letrozole or anastrozole. Renal cell carcinoma (RCC), approve if patient meets one of the following: 1) patient has advanced RCC with predominant clear cell histology AND the patient has tried Inlyta, Votrient, Sutent, or Nexavar OR 2) patient has relapsed or medically unresectable RCC with non-clear cell histology. Tuberous sclerosis complex (TSC) for the treatment of subependymal giant cell astrocytoma (SEGA), approve if the patient requires therapeutic intervention but cannot be curatively resected. NET-approve. Renal angiomyolipoma with TSC-approve. WM/LPL - approve if 1. patient has progressive or relapsed disease OR 2. patient has not responded to primary therapy (e.g., Velcade+/- Rituxan, Velcade with dexamethasone +/-Rituxan, Kyprolis with Rituxan and dexamethasone, cyclophosp/doxorubicin/vincristine/pred/Rituxan, Imbruvica, Rituxan,

<b>PA Criteria</b>	<b>Criteria Details</b>
	Rituxan with cyclophosphamide and dexamethasone, Thalomid+/- Rituxan

# ALECENSA

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## Products Affected

- Alecensa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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 AND has either progressed on or is intolerant to Xalkori.

# AMPYRA

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## Products Affected

- Ampyra

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patient already started on dalfampridine extended-release for Multiple Sclerosis (MS).
<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 3 years.
<b>Other Criteria</b>	N/A



# ANABOLIC STEROIDS

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## Products Affected

- oxandrolone

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Girls 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.
<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

# ARCALYST

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## Products Affected

- Arcalyst

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patient already started on rilonacept for Muckle Wells Syndrome (MWS) or Familial Cold Autoinflammatory Syndrome (FCAS).
<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 they have had a response and are continuing therapy to maintain response/remission.

# BOSULIF

## Products Affected

- Bosulif oral tablet 100 mg, 500 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Bosulif for a Covered Use. Plus patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Bosulif is being used. For chronic myelogenous leukemia (CML), the Philadelphia chromosome (Ph) status of the leukemia must be reported. For CML, 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 and must have tried one other TKI indicated for use in CML (e.g., Gleevec, Sprycel, or Tassigna). For ALL, patient must have Ph-positive ALL and have tried two other tyrosine kinase inhibitors that are used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).

# BOTOX

## Products Affected

- Botox

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus Achalasia. Anal Fissure. BPH. Chronic facial pain/pain associated with TMJ dysfunction. Chronic low back pain. Headache (chronic tension HA, whiplash, chronic daily HA). Palmar hyperhidrosis. Myofascial pain. Salivary hypersecretion. Spasticity (eg, due to cerebral palsy, stroke, brain injury, spinal cord injury, MS, hemifacial spasm). Essential tremor. Dystonia other than cervical (eg, focal dystonias, tardive dystonia, anismus). Frey's syndrome (gustatory sweating). Ophthalmic disorders (eg, esotropia, exotropia, nystagmus, facial nerve paresis). Speech/voice disorders (eg, dysphonias). Tourette's syndrome.
<b>Exclusion Criteria</b>	Use in the management of cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, rejuvenation of the peri-orbital region), allergic rhinitis, gait freezing in Parkinsons disease, vaginismus, interstitial cystitis, trigeminal neuralgia, or Crocodile tears syndrome.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Headache and chronic migraine - if prescribed by, or after consultation with, a neurologist or HA specialist.
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	Primary axillary and Palmar hyperhidrosis after trial with at least 1 topical agent (eg, aluminum chloride). BPH after trial with at least 2 other therapies (eg, alpha1-blocker, 5 alpha-reductase inhibitor, TURP, transurethral microwave heat treatment, TUNA, interstitial laser therapy, stents, various forms of surgery). Chronic low back pain after trial with at least 2 other pharmacologic therapies (eg, NSAID, antispasmodics, muscle relaxants, opioids, antidepressants) and if being used as part of a multimodal therapeutic pain management program. Headache (eg, chronic tension headache, whiplash, chronic daily headache) after a trial with at least 2 other pharmacologic therapies (eg, anticonvulsants,

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>antidepressants, beta-blockers, calcium channel blockers, non-steroidal anti-inflammatory drugs). Essential tremor after a trial with at least 1 other pharmacologic therapy (eg, primidone, propranolol, benzodiazepines, gabapentin, topiramate). Tourette's syndrome if after a trial with at least 1 more commonly used pharmacologic therapy (eg, neuroleptics, clonidine, SSRIs, psychostimulants). Chronic migraine-must have 15 or more migraine headache days per month with headache lasting 4 hours per day or longer AND have tried at least two other prophylactic pharmacologic therapies, each from a different pharmacologic class (eg, beta-blocker, anticonvulsant, tricyclic antidepressant). OAB and urinary incontinence associated with a neurological condition (eg, spinal cord injury, multiple sclerosis), approve after a trial with at least one other pharmacologic therapy (eg, anticholinergic medication).</p>

# C1 ESTERASE INHIBITORS

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## Products Affected

- Cinryze

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on the prescribed drug for a covered use.
<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>	3 years
<b>Other Criteria</b>	N/A

# CABOMETYX

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## Products Affected

- Cabometyx

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients with Non-Small Cell Lung Cancer with RET Gene Rearrangements. Plus patients already taking Cabometyx for a Covered Use.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medication history, 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-Patients must meet both 1 AND 2-1. Patient has RCC with predominant clear-cell histology 2. Patient has tried one tyrosine kinase inhibitor therapy (e.g., Sutent [sunitinib malate capsules], Votrient [pazopanib tablets], Inlyta [axitinib tablets], Nexavar [sorafenib tosylate tablets]).

# CAPRELSA

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## Products Affected

- Caprelsa oral tablet 100 mg, 300 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma.
<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 - patient has symptomatic or progressive MTC AND has unresectable locally advanced or metastatic disease. DTC - clinically progressive or symptomatic metastatic disease AND has nonradioiodine-responsive tumors at sites other than central nervous system.



# CHENODAL

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## Products Affected

- Chenodal

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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.

# CHOLBAM

## Products Affected

- Cholbam oral capsule 250 mg, 50 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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. 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 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.

# CHORIONIC GONADOTROPINS (HCG)

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## Products Affected

- chorionic gonadotropin, human

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# CIALIS

## Products Affected

- Cialis oral tablet 2.5 mg, 5 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Indication for which tadalafil is being prescribed.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 mos.
<b>Other Criteria</b>	Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED).

# COMETRIQ

## Products Affected

- Cometriq

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D. Plus Renal Cell Carcinoma, Non-Small Cell Lung Cancer with RET Gene Rearrangements, and patients already started on Cometriq for a Covered Use.
<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 12 months.
<b>Other Criteria</b>	MTC - must have symptomatic or progressive MTC AND have unresectable locally advanced or metastatic disease. RCC - have relapsed or Stage IV and surgically unresectable, predominant clear-cell histology RCC AND has progressed on one of the first-line tyrosine kinase inhibitor therapies such as Sutent, Votrient, Inlyta, or Nexavar. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve.

# COPAXONE

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## Products Affected

- Copaxone subcutaneous syringe 40 mg/mL
- Glatopa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agent used for multiple sclerosis (ie, interferon beta-1a, interferon beta-1b, natalizumab, fingolimod, teriflunomide, dimethyl fumarate ER)
<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

# CORLANOR

## Products Affected

- Corlanor

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Previous use of a Beta-blocker, LVEF, sinus rhythm, and resting HR
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	HF in pts not currently receiving Corlanor - must all of the following 1. have LVEF of less than or equal 35 percent, 2. have sinus rhythm and a resting HR of greater than or equal to 70 BPM, AND 3. 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). HF in pts currently receiving Corlanor - had a LVEF of less than or equal to 35 percent prior to initiation of Corlanor therapy AND has tried or is currently receiving a Beta-blocker for HF unless the patient has a contraindication to the use of beta blocker therapy.

# COTELLIC

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## Products Affected

- Cotellic

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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 - being prescribed in combination with Zelboraf.



# CRINONE GEL

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## Products Affected

- Crinone vaginal gel 8 %

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus, secondary amenorrhea, support of an established pregnancy.
<b>Exclusion Criteria</b>	Use in patients to supplement or replace progesterone in the management of infertility.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Secondary amenorrhea, 12 months. Support of an established pregnancy, 9 months.
<b>Other Criteria</b>	N/A

# DALIRESP

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## Products Affected

- Daliresp

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D
<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 3 years.
<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 chronic bronchitis, 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, formoterol], long-acting anticholinergic (eg, tiotropium), inhaled corticosteroid (eg, fluticasone).

# ENBREL

## Products Affected

- Enbrel subcutaneous recon soln

- Enbrel subcutaneous syringe 25 mg/0.5mL (0.51), 50 mg/mL (0.98 mL)
- Enbrel SureClick

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D plus patient already on etanercept for a Covered Use. Graft versus host disease (GVHD). Behcet's disease. Mucous membrane pemphigoid [cicatrical pemphigoid]. Uveitis
<b>Exclusion Criteria</b>	Concurrent use with biologic therapy or targeted synthetic DMARD
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	For use in rheumatoid arthritis (RA), approve for adults.
<b>Prescriber Restrictions</b>	RA/Ankylosing spondylitis/JIA/JRA,prescribed by or in consult w/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist.Plaque psoriasis (PP)/Cic Pemphigoid, 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.
<b>Coverage Duration</b>	FDA approved indications - 3 months initial, 3 years cont, others 12 months.
<b>Other Criteria</b>	RA initial, Tried 1 DMARD for 3 mos or is also receiving MTX, has a contraindication or intolerance to MTX and leflunomide, or has early RA (defined as disease duration of less than 6 months) with at least one of the following features of poor prognosis: functional limitation, extraarticular disease such as rheumatoid nodules, RA vasculitis, or Felty's syndrome, positive rheumatoid factor or anti-CCP antibodies, or bony erosions by radiograph. JIA/JRA, approve if the pt has aggressive disease 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,

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide. Plaque psoriasis (PP) initial. Approve if the patient has tried at least one of the following agents for at least 3 months for plaque psoriasis: an oral therapy for psoriasis (eg, MTX, cyclosporine, Soriatane), oral methoxsalen plus PUVA, or a biologic agent OR the patient had intolerance to a trial of at least one oral or biologic therapy for plaque psoriasis OR 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 SC, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Have not responded to at least 1 conventional tx (eg, CS, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Cic Pemp Tried 2 conventional txs (eg, systemic corticosteroids, azathioprine, cyclophosphamide, dapsone, MTX, cyclosporine, mycophenolate mofetil). RA/AS/JIA/PP/PsA Cont - must have a response to tx.</p>

# ENTRESTO

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## Products Affected

- Entresto

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Combination therapy with an ACE inhibitor/ACE inhibitor containing product, an ARB/ARB containing product, or Tekturna (aliskiren tablets) or a Tekturna-Containing Product in patients with diabetes
<b>Required Medical Information</b>	Must have LVEF less than or equal to 40 percent prior to initiation with Entresto
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with, a cardiologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A

# EPCLUSA

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## Products Affected

- Epclusa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Epclusa for a Covered Use.
<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>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

# EPOETIN/PROCRIT

## 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>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia, . Plus anemia in patients with HIV who are receiving zidovudine. Anemic patients (Hb of 13.0 g/dL or less) at high risk for perioperative transfusions (secondary to significant, anticipated blood loss and are scheduled to undergo elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions). Additional off-label coverage is provided for Anemia due to myelodysplastic syndrome (MDS), Anemia associated with use of ribavirin therapy for hepatitis C (in combination with interferon or pegylated interferon alfa 2a/2b products with or without the direct-acting antiviral agents Victrelis or Incivek), and Anemia in HIV-infected patients.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pt is currently receiving iron therapy or confirmation of adequate iron stores (eg, prescribing information recommends supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%).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 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 munits/mL or less at tx start.Previously on EA approve if Hb is 12.0 g/dL or less.Anemia due to ribavirin for Hep C, pt is receiving tx for HepC (e.g. RBV in combo with INF, PegINF, with or w/o direct acting antiviral agents and Hb is 10.0 g/dL or less at tx start. Previously on EA

<b>PA Criteria</b>	<b>Criteria Details</b>
	or Aranesp 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/HepC anemia = 18 years of age and older
<b>Prescriber Restrictions</b>	MDS anemia, prescribed by or in consultation with, a hematologist or oncologist. Hep C anemia, prescribed by or in consultation with hepatologist, gastroenterologist or infectious disease physician who specializes in the management of hepatitis C.
<b>Coverage Duration</b>	Anemia w/myelosuppressive = 4 mos. Transfus=1 mo. Other=6mo. HIV + zidovudine = 4 mo
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.



# ERIVEDGE

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## Products Affected

- Erivedge

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus, patient already started on Erivedge for a covered use.
<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>	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.

# ESBRIET

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## Products Affected

- Esbriet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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>	3 years
<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.

# FARYDAK

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## Products Affected

- Farydak oral capsule 10 mg, 15 mg, 20 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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>	MM - must be used in combination with Velcade and dexamethasone AND previously tried Velcade and one immunomodulatory drug (i.e., Thalomid, Revlimid, or Pomalyst).

# FIRAZYR

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## Products Affected

- Firazyr

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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 3 years.
<b>Other Criteria</b>	N/A

# FLECTOR

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## Products Affected

- Flector

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 mos.
<b>Other Criteria</b>	Patients must try a generic oral NSAID or Voltaren gel.

# FORTEO

## Products Affected

- Forteo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Miacalcin, Fortical]), 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 2 years.
<b>Other Criteria</b>	Treatment of PMO, approve if pt has tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt 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 an IV bisphosphonate (ibandronate or zoledronic acid), OR pt has severe renal impairment (creatinine clearance less than 35 mL/min) or CKD or pt has had multiple osteoporotic fractures. Increase bone mass in men with primary or hypogonadal osteoporosis/Treatment of men and women with 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 multiple osteoporotic fractures.

# GILOTRIF

## Products Affected

- Gilotrif oral tablet 20 mg, 30 mg, 40 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Additional coverage is provide fro NSCLC - squamous cell carcinoma and NSCLC - HER2 positive.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For NSCLC - EGFR exon deletions or mutations HER2 status, 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 epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. NSCLC squamous cell must have disease progression with first line treatment with platinum based chemotherapy. NSCLC HER2 pos - if HER2 positive NSCLC approve.

# GLEEVEC

## Products Affected

- Gleevec oral tablet 100 mg, 400 mg

- imatinib oral tablet 100 mg, 400 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus chordoma, advanced or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. Plus patients already started on Gleevec for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For ALL/CML, new patient must have Ph-positive for approval of Gleevec.



# GRASTEK

## Products Affected

- Grastek

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	The patient is NOT currently receiving SC allergen immunotherapy
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	5 years through 65 years of age
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	The diagnosis of grass pollen-induced AR must be confirmed by either 1. positive skin test response to a grass pollen from the Pooideae subfamily of grasses (this includes, but is not limited to sweet vernal, Kentucky blue grass, Timothy grass, orchard, or perennial rye grass), or 2. positive in vitro test (i.e., a blood test for allergen-specific IgE antibodies) for a grass in the Pooideae subfamily of grasses. Therapy must be initiated 12 weeks prior to the expected onset of the grass pollen season or therapy is being dosed daily continuously for consecutive grass pollen seasons.

# 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)
- Omnitrope subcutaneous cartridge 5 mg/1.5 mL (3.3 mg/mL)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Somatropin products are all covered for Growth hormone deficiency (GHD), idiopathic short stature (ISS), Chronic Kidney disease (CKD) in children or adolescents, Noonan Syndrome in children/adolescents, Prader-Willi Syndrome (PW), SHOX deficiency in children/adolescents, Children born small for gestational age (SGA), Turner's Syndrome (TS) in girls, and Short Bowel Syndrome (SBS).
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	GHD in children/adoles initial must meet ONE of the following - 1. had hypophysectomy, 2. has congenital hypopituitarism AND had growth hormone response to one preferred GH test of less than 10 ng/mL (preferred tests are levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon), 3. has panhypopituitarism AND had growth hormone response to one preferred GH test of less than 10 ng/mL, has 3 or more pituitary hormone deficiencies (ACTH, TSH, LH/FSH, or prolactin), or pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior "bright spot" on MRI or CT, 4. pt had brain radiation, had growth hormone response to one preferred GH test of less than 10 ng/mL, AND meets one of these a. pretreatment growth rate (GR) is less than 7 cm/yr in children younger than 3 or b. GR is less than 4 cm/yr in 3 y/o or older, c. or if 18 y/o or younger with growth velocity that is less than 10th percentile for age/gender on last 6 months of data, OR 5. had growth hormone response to one preferred GH test of less than 10 ng/mL, ht less than the 10th percentile for age/gender, AND meets one of these a. pretreatment growth rate (GR) is less than 7 cm/yr in children younger than 3 or b. GR is less than 4 cm/yr in 3 y/o or older, c. or if 18 y/o or younger with growth velocity that is less than 10th percentile for age/gender on last 6 months of data. Cont 12 yr and younger ht increase 4 or more cm/yr. Additionally, pts older than 12 must also have open epiphyses and pts older than 18 must also not attained midparental ht.
<b>Age Restrictions</b>	ISS 5 y/o or older, SGA 2 y/o or older, SBS and HIV wasting/cachexia 18 y/o or older

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 4 weeks, others 12 mos
<b>Other Criteria</b>	<p>GHD initial in adults and adoles 1. endocrin 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, if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, GHRH plus arginine peak of less than or equal to 11 mcg/L if BMI is less than 25, peak less than 8 mcg/L if BMI is more than 25 but less than 30, or peak less than 4 mcg/L if BMI is more than 30) AND if a transitional adoles must be off tx for at least one month before retesting. Cont tx - endocrin must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 3rd percentile 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 older than 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - 1. 5 y/o old or older doubled annualized GR or 2. ht increase by 4 or more cm/yr. Additionally, pts older than 12 must also have open epiphyses and pts older than 18 must also have not attained midparental height. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolesents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. 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). Cont tx - ht increase by 4 or more cm/yr. Additionally, pts older</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>than 12 must also have open epiphyses and pts older than 18 must also have not attained midparental height. Cont Tx for CKD, Noonan, PW in child/adoles, SHOX, and TS in girls - ht increased by 2.5 cm/yr or more and epiphyses open. SBS initial pt receiving specialized nutritional support. Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support.</p>

# HARVONI

## Products Affected

- Harvoni

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients with recurrent HCV post-liver transplant. Plus patients started on Harvoni for a covered use
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin.
<b>Required Medical Information</b>	Genotype 1 - a. approve for 12 weeks if treatment naive OR pt does not have cirrhosis and is treatment experienced, b. as per Harvoni product labeling, approve for 24 weeks if treatment experienced in pts with compensated cirrhosis. Recurrent HCV Post-Liver Transplantation genotypes 1 and 4 - a. approve for 12 weeks if pt does not have cirrhosis or has compensated cirrhosis and will be taken with RBV, OR b. approve for 24 weeks if pt is RBV intolerant or ineligible and has compensated cirrhosis. Genotypes 4, 5 or 6 - as per labeling and AASLD guidelines, approve for 12 weeks. HCV RNA (pre-treatment).
<b>Age Restrictions</b>	18 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>	24wks or 12 wks see "REQ_MEDINFO" for details due to space limitations
<b>Other Criteria</b>	N/A

# HETLIOZ

## Products Affected

- HetlioZ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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 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 performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month. Cont - Approve if pt has received at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with HetlioZ under the guidance of a physician who specializes in the treatment of sleep disorders AND 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).

# HIGH RISK MEDICATIONS - BENZODIAZEPINES

## Products Affected

- Alprazolam Intensol
- clonazepam
- clorazepate dipotassium
- Diazepam Intensol
- diazepam oral solution 5 mg/5 mL (1 mg/mL)
- diazepam oral tablet
- diazepam rectal
- Lorazepam Intensol
- lorazepam oral tablet
- Onfi oral suspension
- Onfi oral tablet 10 mg, 20 mg
- oxazepam
- temazepam

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
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	Procedure-related sedation = 1mo. All other conditions = 12 months.
Other Criteria	All medically accepted indications other than Restless Leg Syndrome and insomnia, authorize use. Restless Leg Syndrome, approve clonazepam if the patient has tried one other agent for this condition (eg, ropinirole, pramipexole, carbidopa-levodopa [immediate-release or extended-release]). Insomnia, approve lorazepam, oxazepam, or temazepam if the patient has had a trial with two of the following: ramelteon, trazodone, 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.

# HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

## Products Affected

- diphenhydramine HCl oral elixir
- hydroxyzine HCl oral solution 10 mg/5 mL
- hydroxyzine HCl oral tablet
- promethazine oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
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 promethazine, authorize use without a previous drug trial for all FDA-approved indications other than emesis, including cancer/chemo-related emesis. For diphenhydramine, authorize use without a previous drug trial for all FDA-approved indications other than insomnia. For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. For the treatment of non-cancer/chemo related emesis, approve promethazine hydrochloride if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant) for the current condition. Approve diphenhydramine if the patient has tried at least two other FDA-approved products for the management of insomnia. 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.



# HIGH RISK MEDICATIONS - TERTIARY TRICYCLIC ANTIDEPRESSANTS

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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 (brand or generic): citalopram, escitalopram, fluoxetine, paroxetine, sertraline, venlafaxine, desvenlafaxine, duloxetine, bupropion, mirtazapine, nortriptyline, desipramine, or trazodone. For the treatment of pain, may approve amitriptyline (single-entity only, not amitriptyline combination products) or imipramine (brand or generic) if the patient has tried at least two of the following agents: duloxetine, pregabalin, gabapentin, venlafaxine, venlafaxine Er, desipramine, or nortriptyline. For the management of insomnia, may approve amitriptyline (single-entity only, not amitriptyline combination products), doxepin greater than 6 mg, or imipramine (brand or generic) if the patient has tried at least two of the following medications: ramelteon, trazodone, or doxepin 3 mg or 6 mg. For the treatment of obsessive compulsive disorder (OCD), may approve clomipramine (brand or generic) if the patient has tried at least two of the following medications: fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram, or

<b>PA Criteria</b>	<b>Criteria Details</b>
	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.

# HUMIRA

## Products Affected

- Humira Pediatric Crohn's Start subcutaneous syringe kit 40 mg/0.8 mL, 40 mg/0.8 mL (6 pack)
- Humira Pen
- Humira Pen Crohn's-UC-HS Start
- Humira Pen Psoriasis-Uveitis
- Humira subcutaneous syringe kit 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D plus patients already started on adalimumab for a Covered Use. Hidradenitis Suppurativa
<b>Exclusion Criteria</b>	Concurrent use with another biologic DMARD or targeted synthetic DMARD
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Crohn's disease (CD), 6 or older. 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
<b>Coverage Duration</b>	FDA indication initial 3 months, cont tx 3 years, others 12 months.
<b>Other Criteria</b>	RA initial, Tried 1 DMARD (brand or generic, oral or injectable) for 3 mos (this includes patients who have tried other biologic DMARDs for 3 mos), or pt is concurrently receiving methotrexate (MTX), or pt has a contraindication or intolerance to MTX and leflunomide, as determined by prescribing physician, or pt has early RA (defined as disease duration of less than 6 months) with at least one of the following features of poor prognosis: functional limitation, extraarticular disease such as rheumatoid nodules, RA vasculitis, or Felty's syndrome, positive rheumatoid factor or anti-cyclic citrullinated protein antibodies, or bony erosions by radiograph. 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

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>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. Pt has tried a systemic therapy (eg, MTX, CSA, acritretin, etanercept, infliximab, or ustekinumab) for 3 mos or PUVA) for 3 months , or pt experienced an intolerance to a trial of at least one systemic therapy (oral or biologic therapy), or pt has a contraindication to one oral agent for psoriasis such as 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, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, or a corticosteroid such as prednisone or methylprednisolone) for 2 months 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)</p>

# IBRANCE

## Products Affected

- Ibrance

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
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) ER positive disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal woman and Ibrance will be used as first line therapy in combination with anastrozole, ememestane, or letrozole 2, pt is premonopausal or perimenopausal woman and is receiving ovarian suppression/abaltation with LHRH agonists, surgical bilateral oophorectomy, or ovarian irradiation AND it will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole, 3. pt is a man who is receiving LHRH agonist AND Ibrance with be used as first line endocrine therapy in combination with anastrozole, exemestane or letrozole, 4. Pt is postmenopausal and has relapsed or progressed during endocrine therapy (e.g. anastrozole, exemestance, letrozole, tamoxifen) AND has not previously taken Ibrance in combination with letrozole, anastrozole, or exemestance AND will be used in combination with Faslodex, 5. Pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with LHRH agonist, surgical bilateral oophorectomy, or ovarian irradiation, relapsed or progressed on prior endocrine therapy, has not previously taken Ibrance in combination with letrozole, anastrozole, or exemestane AND will be used in combination with Faslodex.

# ICLUSIG

## Products Affected

- Iclusig oral tablet 15 mg, 45 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Iclusig for a Covered Use.
<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.)

# ILARIS

## Products Affected

- Ilaris (PF)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	When used in combination with concurrent biologic therapy (e.g. TNF antagonists, etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or riloncept.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	CAPS-4 years of age and older. SJIA-2 years of age and older.
<b>Prescriber Restrictions</b>	CAPS/MWS/FCAS initial- Prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist. SJIA initial- prescribed by or in consultation with a rheumatologist
<b>Coverage Duration</b>	3 mos initial, 3 years cont
<b>Other Criteria</b>	For renewal of CAPS/MWS/FCAS - after pt had been started on Ilaris, approve if the pt had a response to therapy as determined by prescribing physician and the pt is continuing therapy to maintain a response/remission. For treatment of SJIA, initial therapy approve if the pt meets one of the following 1. has tried at least 2 other biologics for SJIA (tocilizumab, abatacept, TNF antagonists (e.g. etanercept, adalimumab, infliximab) OR 2. pt has features of poor prognosis (e.g. arthritis of the hip, radiographic damage, 6-month duration of significant active systemic disease, defined by fever, elevated inflammatory markers, or requirement for treatment with systemic glucocorticoids AND tried Actemra or Kineret. SJIA renewal approve if it patient was already started on Ilaris and the pt had a response (e.g. resolution of fever, improvement in limitations of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or ADLs, reduced dosage of CS) and the pt is continuing therapy to maintain response/remission.

# IMBRUVICA

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## Products Affected

- Imbruvica

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Imbruvica for a Covered Use.
<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



# INLYTA

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## Products Affected

- Inlyta oral tablet 1 mg, 5 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Plus, patients already started on Inlyta for a Covered Use.
<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 has clinically progressive or symptomatic metastatic disease AND has nonradioiodine-responsive tumors at sites other than central nervous system.

# IRESSA

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## Products Affected

- Iressa

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D.
<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.

# IVIG

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## Products Affected

- Privigen

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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.

# JAKAFI

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## Products Affected

- Jakafi oral tablet 10 mg, 15 mg, 20 mg, 25 mg, 5 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus, patients already started on Jakafi for a Covered Use.
<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

# KALYDECO

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## Products Affected

- Kalydeco oral granules in packet
- Kalydeco oral tablet

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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>	CF - must have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, G1349D, OR R117H AND must NOT be Homozygous for the F508del Mutation in the CFTR Gene or have unknown CFTR gene mutations.

# LENVIMA

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## Products Affected

- Lenvima

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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>	DTC - must be locally recurrent or metastatic, progressive refractory to radioactive iodine treatment for approval.

# LETAIRIS/TRACLEER

## Products Affected

- Letairis

- Tracleer

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Chronic thromboembolic pulmonary hypertension (CTEPH) (Tracleer).
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) WHO Group 1 patients not currently on Letairis or Tracleer or another agent indicated for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently on Letairis or Tracleer or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For treatment of pulmonary arterial hypertension, must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH - prescribed by or in consultation with a cardiologist or pulmonologist
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	CTEPH - pt must have tried Adempas, has a contraindication to Adepmas, or is currently receiving Tracleer for CTEPH.

# LEUPROLIDE (LONG ACTING)

## Products Affected

- Lupron Depot
- Lupron Depot (3 Month)
- Lupron Depot (4 month)
- Lupron Depot (6 Month)
- Lupron Depot-Ped intramuscular kit 11.25 mg, 15 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D but specific to the following drugs as follows: Prostate cancer (Lupron Depot), Endometriosis (Lupron Depot), Uterine leiomyomata (Lupron Depot), Treatment of central precocious puberty (Lupron Depot Ped). Ovarian cancer (Lupron Depot, Lupron Depot Ped). Breast cancer (Lupron Depot, Lupron Depot Ped). Prophylaxis or treatment of uterine bleeding in premenopausal women with hematologic malignancy or prior to bone marrow/stem cell transplantation (BMT/SCT) (Lupron Depot, Lupron Depot Ped). Abnormal uterine bleeding (Lupron Depot, Lupron Depot Ped).
<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>	For abnormal uterine bleeding, uterine leiomyomata, endometriosis 6 mo. All other=12 mo
<b>Other Criteria</b>	N/A



# LIDODERM

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## Products Affected

- lidocaine topical adhesive patch,medicated

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus diabetic neuropathic pain.
<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

# LONSURF

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## Products Affected

- Lonsurf

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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>	Metastatic CRC - As per labeling, the patient has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-FU) AND oxaliplatin AND irinotecan AND if the tumor or metastases are wild-type KRAS and/or NRAS (that is, the tumors or metastases are KRAS and/or NRAS mutation negative) Erbitux or Vectibix has been tried.

# LYNPARZA

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## Products Affected

- Lynparza

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Lynparza.
<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 cancer approve if the patient has a germline BRCA mutation AND as per product labeling, has progressed on three or more prior lines of chemotherapy.

# MEKINIST

## Products Affected

- Mekinist oral tablet 0.5 mg, 2 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients with Non-Small Cell Lung Cancer (NSCLC) and patients already started on Mekinist for a Covered Use.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Mekinist is being used. For unresectable or metastatic melanoma 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>	For unresectable or metastatic melanoma must be used in patients with BRAF V600 mutation, not being used in combination with Zelboraf, and either 1. be used in combination with Tafinlar per product labeling or 2. be used as monotherapy in a patient who has not experienced disease progression on a BRAF Inhibitor for Melanoma (i.e., Tafinlar or Zelboraf). For NSCLC requires BRAF V600E Mutation and use in combination with Tafinlar.

# MYALEPT

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## Products Affected

- Myalept

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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

# NAMENDA

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## Products Affected

- memantine
- memantine titration pak
- Namenda
- Namenda Titration Pak
- Namenda XR
- Namzaric oral capsule, sprinkle, ER 24hr 14-10 mg, 28-10 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D. Plus patients with mild to moderate vascular dementia.
<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

# NATPARA

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## Products Affected

- Natpara

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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>	12 months
<b>Other Criteria</b>	Chronic hypoparathyroidism - Before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician AND as per product labeling, patient cannot be well-controlled on calcium supplements and active forms of vitamin D alone

# NEULASTA

## Products Affected

- Neulasta subcutaneous syringe

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D but worded more broadly as cancer patients receiving myelosuppressive chemotherapy. Plus patients undergoing PBPC collection and therapy
<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
<b>Coverage Duration</b>	Cancer pts receiving chemo -Authorization will be for 6 months. PBPC - 1 month
<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, older patient [aged greater than or equal to 65 years]), history of previous chemotherapy or radiation therapy, pre-existing neutropenia, open wounds or active infection, poor performance status, 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.



# NEUPOGEN

## Products Affected

- Neupogen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D worded more broadly as cancer patients receiving myelosuppressive chemotherapy, patients with acute myeloid leukemia (AML) receiving chemotherapy, cancer patients receiving bone marrow transplantation (BMT), patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy, and patients with severe chronic neutropenia [SCN] (e.g., congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). 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).
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	AML, HIV/AIDS, MDS - adults. Other uses - no age requirements.
<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 mo.MDS-3 mo.PBPC,Drug induce A/N,AA,ALL,BMT-1 mo.All other=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, older patient [aged greater than or

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>equal to 65 years], history of previous chemotherapy or radiation therapy, pre-existing neutropenia, open wounds or active infection, poor performance status), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, Neulasta, Neupogen) 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 account less than 100 cells/mm<sup>3</sup>], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).</p>

# NEXAVAR

## Products Affected

- Nexavar

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus , patients already started on Nexavar for a covered use, osteosarcoma, angiosarcoma, advanced or unresectable desmoids tumors, gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia.
<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 has locally recurrent or metastatic, progressive DTC and the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has disseminated symptomatic disease and the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). AML - Approve if the patient has relapsed or refractory disease AND FLT3-ITD mutation positive disease AND Nexavar will be used in combination with azacitidine injection (intravenous or subcutaneous) or decitabine IV injection.

# NINLARO

## Products Affected

- Ninlaro oral capsule 2.3 mg, 3 mg, 4 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus , patients already started on Ninlaro.
<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., Velcade, Kyprolis, Thalomid, Revlimid, Pomalyst, Alkeran, dexamethasone, prednisone).

# NUCALA

## Products Affected

- Nucala

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent use with Xolair
<b>Required Medical Information</b>	N/A
<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>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 Nucala) AND Patient has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following A. inhaled LABA, B. inhaled long-acting muscarinic antagonist, C. Leukotriene receptor antagonist, or D. Theophylline. Patient's asthma continues to be uncontrolled as defined by ONE of the following - patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, patient has a FEV1 less than 80 percent predicted, Patient has an FEV1/FVC less than 0.80, or Patient's asthma worsens upon tapering of oral corticosteroid therapy. Continuation - The patient has responded to Nucala 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 BOTH an inhaled corticosteroid AND one of the following inhaled LABA, inhaled long-acting muscarinic antagonist, leukotriene receptor antagonist, or Theophylline.</p>

# NUVIGIL/PROVIGIL

## Products Affected

- modafinil

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Fatigue associated with multiple sclerosis (MS) - modafinil only. Excessive daytime sleepiness (EDS) due to myotonic dystrophy - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only. Idiopathic hypersomnolence - modafinil only
<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. Idiopathic hypersomnolence is covered diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center).

# OCALIVA

## Products Affected

- Ocaliva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Ocaliva for a covered use.
Exclusion Criteria	N/A
Required Medical Information	Prescriber specialty, lab values, prior medications used for diagnosis and length of trials
Age Restrictions	18 years and older (initial and continuation therapy)
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial and continuation therapy)
Coverage Duration	6 months initial, 3 years cont.
Other Criteria	<p>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</p> <p>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)).</p>

# ODOMZO

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## Products Affected

- Odomzo

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus metastatic BCC.
<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.



# OFEV

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## Products Affected

- Ofev

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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>	3 years
<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.

# ORENCIA

## Products Affected

- Orenzia
- Orenzia (with maltose)
- Orenzia ClickJect

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients who have already been started on abatacept for a covered use.
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA and JIA/JRA prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	3 mos initial, 3 years cont
<b>Other Criteria</b>	RA Initial, approve if the patient has tried one of the following drugs: etanercept, adalimumab, certolizumab, infliximab, golimumab SC, golimumab IV unless the patient has CHF, lymphoproliferative disease, or a previous severe infection. If the patient has not tried one of these drugs, the patient must have a trial with etanercept or adalimumab. Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)] initial, approve Orenzia IV only if the patient has tried adalimumab or etanercept (Orenzia SC is not FDA-approved for the treatment of JIA/JRA). Cont x - responded to therapy as per the prescriber.

# ORKAMBI

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## Products Affected

- Orkambi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Combination use with Kalydeco
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	12 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)

# OTEZLA

## Products Affected

- Otezla

- Otezla Starter oral tablets, dose pack 10 mg (4)-20 mg (4)-30 mg (47)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Must not be used combination in with a biologic DMARD or targeted synthetic DMARD.
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist.
Coverage Duration	4 months initial, 1 year cont
Other Criteria	PsA initial, must have tried ONE biologic DMARD (eg, Cimzia, Humira, Enbrel, Simponi, Remicade, or Stelara) for at least 3 months or cannot take a TNF because of hepatitis B, hepatitis C, demyelinating disease, or malignancy, congestive heart failure (CHF), being on chronic systemic corticosteroid therapy (e.g., prednisone, dexamethasone), chronic infection or is at high risk of infection (e.g., HIV, malignancy, neutropenia, DM), as determined by the prescribing physician, OR history of recurrent infections, as determined by the prescribing physician. PP initial- approve if pt has meets one of the following a. tried ONE biologic (e.g., Cosentyx, Humira, Enbrel, Remicade, or Stelara) for at least 3 months, unless intolerant, OR b. cannot take a TNF because of the reasons listed above. PsA/PP initial - If the patient has not tried one of these drugs, the patient must have a trial with etanercept or adalimumab. PsA/PP cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician.

# PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

## Products Affected

- sildenafil oral

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) WHO Group 1, patients not currently taking an agent indication for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently receiving an agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	N/A

# PRALUENT

## Products Affected

- Praluent Pen subcutaneous pen injector 150 mg/mL, 75 mg/mL
- Praluent Syringe subcutaneous syringe 150 mg/mL, 75 mg/mL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent use of Juxtapid or Kynamro.
<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>	18 years of age 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>	Authorization will be for 12 months.
<b>Other Criteria</b>	Hyperlipidemia in patients with HeFH without ASCVD -approve if meets all of the following 1. Pt has been diagnosed with 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 3. LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. Hyperlipidemia Pt with Clinical ASCVD with or without HeFH -approve if meets all of the following has an LDL-C greater than or equal to 70 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 therapy), AND 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 tried ONE high intensity statin (as defined above) AND LDL-C remains greater than or equal to 70 mg/dL unless the pt is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and

<b>PA Criteria</b>	<b>Criteria Details</b>
	during both trials the skeletal-related symptoms resolved during d/c.

# PROLIA

## Products Affected

- Prolia

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Miacalcin, Fortical]), 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 3 years.
<b>Other Criteria</b>	Treatment of postmenopausal osteoporosis/Treatment of osteoporosis in men (to increase bone mass), approve if the patient has meets one 1. has had inadequate response after 12 months of therapy with an oral bisphosphonate, had osteoporotic fracture while receiving an oral bisphosphonate, or intolerability to an oral bisphosphonate, 2. OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), 3. OR the patient has severe renal impairment (eg, creatinine clearance less than 35 mL/min) or chronic kidney disease, or if the patient has multiple osteoporotic fractures. Treatment of bone loss in men 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).



# PROMACTA

## Products Affected

- Promacta oral tablet 12.5 mg, 25 mg, 50 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Thrombocytopenia due to hepatitis C virus (HCV)-related cirrhosis.
<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.
<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, either a gastroenterologist, a 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 corticosteroids or IVIG 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 (eg, Pegasys or PegIntron plus ribavirin, with or without direct-acting antiviral agents [boceprevir, telaprevir]). 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, Atgam)

# REBIF

## Products Affected

- Rebif (with albumin)
- Rebif Rebidose subcutaneous pen injector 22 mcg/0.5 mL, 44 mcg/0.5 mL, 8.8mcg/0.2mL-22 mcg/0.5mL (6)
- Rebif Titration Pack

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients who experienced an attack and are at risk for multiple sclerosis.
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agent used for multiple sclerosis (ie, interferon beta-1a, interferon beta-1b, glatiramer, natalizumab, fingolimod, terflunomide, dimethyl fumarate).
<b>Required Medical Information</b>	Diagnosis of MS includes the following patient types: patients with actual diagnosis of MS, patients who have experienced an MS attack, and patients who are at risk for developing 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

# RECLAST

## Products Affected

- zoledronic acid-mannitol-water intravenous solution

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent Use with Other Medications for Osteoporosis (e.g., other bisphosphonates, Prolia, Forteo, Evista, calcitonin nasal spray), 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>	Paget's 1 month. Others 12 months.
<b>Other Criteria</b>	<p>Treatment of osteoporosis in post menopausal women or osteoporosis in men, must meet ONE of the following patient had an inadequate response after a trial duration of 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or patient had an osteoporotic fracture while receiving therapy or patient experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt 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 IV Reclast. Treatment of PMO may have also tried IV Boniva for approval.</p> <p>Prevention or treatment of glucocorticoid induced osteoporosis (GIO), approve if: pt is initiating or continuing therapy with systemic glucocorticoids, AND has had an inadequate response after a trial duration of 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or patient had an osteoporotic fracture while receiving therapy or patient experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take an oral bisphosphonate because the pt cannot swallow</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt 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 has tried Reclast. Treatment of Paget's disease, approve if patient has elevations in serum alkaline phosphatase of two times higher than the upper limit of the age-specific normal reference range, OR patient is symptomatic (eg, bone pain, hearing loss, osteoarthritis), OR patient is at risk for complications from their disease (eg, immobilization, bone deformity, fractures, nerve compression syndrome). Preventions of PMO - meets one of the following had an inadequate response after a trial duration of 12 months (eg, ongoing and significant loss of BMD, lack of BMD increase) or patient had an osteoporotic fracture while receiving therapy or patient experienced intolerability (eg, severe GI-related adverse effects, severe musculoskeletal-related side effects, a femoral fracture), OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt 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 Reclast.</p>

# REMICADE

## Products Affected

- Remicade

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D plus patients already started on infliximab for non-Crohn's disease covered uses. Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Undifferentiated spondylarthroplasty, Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Juvenile Idiopathic Arthritis (JIA). Sarcoidosis
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	CD and UC, Pts aged 6 years or more.
<b>Prescriber Restrictions</b>	Prescribed by or in consult w/:RA/AS/Still's/Undifferent spondyl/JIA-rheumatol.Plaque Psor/Pyoderma gangrenosum/HS-dermatol.Psoriatic Arthritis-rheumatol or dermatol.CD/UC-gastroenterol.Uveitis/-ophthalmol.GVHD-transplant center, oncol, or hematol.Behcet's-rheumatol, dermatol,ophthalmol, gastroenterol, or neurol.Sarc-pulm, ophthal, derm
<b>Coverage Duration</b>	FDA ind/JIA initial - 3 mos, cont 3 years, others 12 mo
<b>Other Criteria</b>	Approve for RA if pt will be taking Remicade in combination with MTX or one other traditional DMARD (eg, leflunomide, sulfasalazine, hydroxychloroquine) unless the pt has a contraindication or intolerance to MTX and leflunomide, AND pt has tried one of etanercept, adalimumab, certolizumab, or golimumab SC OR if the patient has not tried one of these drugs, the patient must have a trial with etanercept or adalimumab. Ankylosing Spondylitis and PsA. Pt has tried one of etanercept, adalimumab, certolizumab, or golimumab SC OR if the patient has not tried one of these drugs, the patient must have a trial with etanercept or adalimumab. CD in patients aged greater than 6 years but less than 18 years, approve if the pt has tried corticosteroid (CS) or if CSs contraindicated or if currently on CS or if the patient has tried one other agent for CD (eg, azathioprine, 6-MP, MTX, certolizumab, adalimumab,

PA Criteria	Criteria Details
	<p>Entyvio) OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had ileocolonic resection. CD in patients 18 years or more, approve if the patient has tried adalimumab or certolizumab. Plaque psoriasis (PP).Pt tried etanercept, adalimumab, or ustekinumab for 3 mos or or the pt experienced an intolerance.Ulcerative colitis (UC).Tried 2-mo trial of systemic CS, 6-MP, AZA, CSA or tacrolimus or was intolerant to one of these agents OR the patient has pouchitis AND has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Behcet's.Pt has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa), Enbrel or Humira OR has ophthalmic manifestations. SD.Tried CS AND 1 non-biologic DMARD (eg, MTX) for 2 mos, or was intolerant.UV.Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab.Sarc.Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide.Pyoderma gangrenosum (PG).Tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos. Hidradenitis suppurativa (HS).Tried 1 tx (eg, intralesional/oral CS, systemic antibiotic, isotretinoin).GVHD.Tried 1 tx (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.) or receiving IFB concurrently. JIA (regardless of type of onset) approve if Remicade started in combination with MTX or one other traditional DMARD (eg, leflunomide, sulfasalazine) AND the pt has tried 1 other agent for this condition (eg, MTX, sulfasalazine, or leflunomide, an NSAID, or one biologic DMARD [eg, Humira, Orencia, Enbrel, Kineret, Actemra]) or the pt has aggressive disease. FDA approved indications cont tx - approve if patient has had a response, as determined by the prescriber.</p>

# REMODULIN

## Products Affected

- Remodulin

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	PAH WHO group, right heart catheterization results, WHO functional status, previous drugs tried
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	PAH WHO Group 1, prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. PAH WHO Group 1, patients not currently on Remodulin pt required to have had a right-heart catheterization to confirm the diagnosis of PAH (mPAP greater than 25 mm Hg at rest, PCWP equal to or less than 15 mm Hg, and PVR greater than 3 Wood units) AND have Class II, III, or IV WHO functional status AND if the pt has idiopathic PAH, they must have one of the following: 1. had an acute response to vasodilator testing that occurred during the right heart cath (defined as decrease in mPAP of at least 10 mm Hg to an absolute mPAP of less than 40 mm Hg without a decrease in cardiac output) AND has tried an oral CCB or 2. pt did not have an acute response to vasodilator testing or 3. cannot undergo vasodilator test or cannot take CCB due to extreme right HF (e.g. hypotension, cardiac index less than 1.5, or right atrial pressure greater than 20, or 4. has tried a CCB without vasodilator testing. PAH WHO Group1, patients currently on Remodulin- pt must have had a right heart catheterization to confirm the diagnosis of PAH.

# REPATHA

## Products Affected

- Repatha Pushtronex

- Repatha SureClick
- Repatha Syringe

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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 - 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>	Authorization will be for 12 months.
<b>Other Criteria</b>	Hyperlipidemia in patients with HeFH without ASCVD -approve if meets all of the following 1. Pt has been diagnosed with 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 3. LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. Hyperlipidemia Pt with Clinical ASCVD with or without HeFH -approve if meets all of the following has an LDL-C greater than or equal to 70 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 therapy), AND 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 tried ONE high intensity statin (as defined above) AND LDL-C remains greater than or equal to 70 mg/dL unless the pt is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c.



<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>HoFH - approve if meets all of the following has one of the following genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR untreated LDL-C greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents), OR treated LDL-C greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha, Kynamro or Juxtapid), OR have clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND tried ONE high intensity statin (as defined above) for greater than or equal to 8 weeks and LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c.</p>

# REVLIMID

## Products Affected

- Revlimid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Revlimid for a Covered Use. Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Follicular Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis.
<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 (eg, Velcade, HyperCVAD [cyclophosphamide, vincristine, doxorubicin, and dexamethasone alternating with high-dose mefloretin and cytarabine] + Rituxan [rituximab injection], the NORDIC regimen [dose-intensified induction immunochemotherapy with Rituxan + cyclophosphamide, vincristine, doxorubicin, prednisone alternating with Rituxan and high-dose cytarabine], RCHOP/RICE [Rituxan, cyclophosphamide, doxorubicin, vincristine, prednisone]/[Rituxan, Ifex (ifosafamide injection), carboplatin, etoposide], Treanda (bendamustine injection) plus Rituxan, Velcade (bortezomib injection) +/- Rituxan, cladribine + Rituxan, FC (fludarabine, cyclophosphamide) +/- Rituxan, PCR [pentostatin, cyclophosphamide, Rituxan]), or Imbruvica (ibrutinib capsules), OR 2) Pt has tried one prior therapy or therapeutic regimen (examples listed above) 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,

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>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 (eg, RCHOP, dose-adjusted EPOCH [etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin] + Rituxan, RCEPP [Rituxan, cyclophosphamide, etoposide, prednisone, procarbazine], DHAP [dexamethasone, cisplatin, cytarabine] +/- Rituxan, ICE [Ifex, carboplatin, etoposide] +/- Rituxan, and Treanda +/- Rituxan). Myelofibrosis-approve if the pt has tried one other therapy (eg, Jakafi [ruxolitinib tablets], androgens [eg, nandrolone, oxymetholone], Epogen, Procrit, Aranesp, prednisone, danazol, Thalomid [thalidomide capsules], melphalan, Myleran [busulfan tablets], alpha interferons, and hydroxyurea).</p>

# RITUXAN

## Products Affected

- Rituxan

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically-accepted indications not otherwise excluded from Part D. Patients already started on Rituxan for a Covered Use.
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	RA (initial course). Prescribed by a rheumatologist or in consultation with a rheumatologist.
<b>Coverage Duration</b>	RA, 1mo. Othr=12 mo.
<b>Other Criteria</b>	RA (initial course), approve if 1. Rituxan is prescribed in combination with methotrexate or another traditional DMARD (eg, leflunomide or sulfasalazine) unless the patient has been shown to be intolerant or has a contraindication to one or more traditional DMARDs AND 2. the patient has tried one of certolizumab pegol, etanercept, adalimumab, infliximab, golimumab (ie, a TNF antagonist), unless the patient has CHF or a lymphoproliferative disease OR if the patient has not yet tried a TNF antagonist, the patient must have a trial with etanercept or adalimumab.

# SAMSCA

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## Products Affected

- Samsca

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<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.

# SOLARAZE

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## Products Affected

- diclofenac sodium topical gel 3 %

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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 6 months.
<b>Other Criteria</b>	N/A

# SOVALDI

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## Products Affected

- Sovaldi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Sovaldi for a covered use. Plus Recurrent HCV Post-Liver Transplantation genotypes 1, 2, 3, and 4 and CHC Genotype 5 or 6.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Will not be used in combination with telaprevir, boceprevir, Harvoni, or Viekira Pak
<b>Age Restrictions</b>	18 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>	12 wks, 16 wks, 24 wks, or 48 wks as specified in Other Criteria.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

# SPRYCEL

## Products Affected

- Sprycel oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D. Plus GIST and patients already started on Sprycel for a Covered Use.
<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 12 months.
<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.



# STIVARGA

## Products Affected

- Stivarga

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Stivarga for a Covered Use.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis for which Stivarga is being used. For metastatic colorectal cancer (CRC) and gastrointestinal stromal tumors (GIST), 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 metastatic CRC with KRAS and/or NRAS mutation, patient must have previously been treated with each of the following for approval: a fluoropyrimidine (eg, Xeloda, 5-FU), oxaliplatin, and irinotecan. For metastatic CRC with no detected KRAS and/or NRAS mutations (ie, KRAS/NRAS wild-type), patient must have previously been treated with each of the following for approval: a fluoropyrimidine (eg, Xeloda, 5-FU), oxaliplatin, irinotecan, anti-EGFR therapy (eg, Eribitux, Vectibix). For GIST, patient must have previously been treated with imatinib (Gleevec) and sunitinib (Sutent).

# SUTENT

## Products Affected

- Sutent oral capsule 12.5 mg, 25 mg, 37.5 mg, 50 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Sutent for a Covered Use. Advanced, unresectable neuroendocrine tumors, chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and Hurthle) thyroid carcinoma, medullary thyroid carcinoma, thymic carcinoma.
<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 previously tried imatinib (Gleevec). Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient has clinically progressive or symptomatic metastatic disease and the patient has nonradioiodine-responsive tumors at sites other than the central nervous system. Medullary thyroid carcinoma, approve if the patient has progressive disease or symptomatic distant metastases and the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). Thymic carcinoma - has tried chemotherapy (e.g., carboplatin/paclitaxel) or radiation therapy.

# SYMLIN

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## Products Affected

- SymlinPen 120
- SymlinPen 60

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D worded as patient has type 1 or 2 diabetes mellitus.
<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

# TAFINLAR

## Products Affected

- Tafinlar oral capsule 50 mg, 75 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus NSCLC in patients with BRAF V600 E mutation. Plus patients already started on Tafinlar for a Covered Use.
<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>	For unresectable or metastatic melanoma with BRAF V600 mutation AND used as monotherapy or in combination with Mekinist. For NSCLC with BRAF V600E mutation.

# TAGRISO

## Products Affected

- Tagrisso oral tablet 40 mg, 80 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	NSCLC - prior therapies and EGFR T790M mutation
<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 or after one of Tarceva, Iressa, or Gilotrif therapy.

# TARCEVA

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Tarceva for a Covered Use, renal cell carcinoma (RCC).
<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>	Advanced, recurrent, or metastatic NSCLC, approve if the patient has EGFR exon 19 deletion or exon 21 (L858R) substitution. Locally advanced or metastatic NSCLC, approve if the patient has failed at least one prior chemotherapy regimen or the patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy (switch-maintenance therapy). Pancreatic locally advanced, unresectable, or metastatic cancer, approve if Tarceva is being prescribed in combination with gemcitabine. RCC, approve if the patient has non-clear cell histology that is Stage IV OR relapsed disease.

# TASIGNA

## Products Affected

- Tasigna oral capsule 150 mg, 200 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tasigna for a Covered Use. Plus Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST).
<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 3 years.
<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 (Strivarga). For ALL, Approve if the patient has tried two other tyrosine kinase inhibitors that are used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).

# TAZORAC

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## Products Affected

- Tazorac

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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>	PP/acne vulgaris - 3 years, other - 12 months
<b>Other Criteria</b>	Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene).



# TECFIDERA

## Products Affected

- Tecfidera

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tecfidera for a Covered Use.
<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). MS, previous MS therapies tried.
<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 3 years.
<b>Other Criteria</b>	Relapsing form of MS initial, approve if patient meets one of the following: 1) Patient has tried Avonex, Rebif, Betaseron, Extavia, Copaxone/Glatopa, or Plegridy, OR 2) Patient is unable to administer injections due to dexterity issues or visual impairment.

# THALOMID

## Products Affected

- Thalomid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Thalomid for a Covered Use, 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.
<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>	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]). 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 if the patient has tried two other therapies (eg, azathioprine, capsaicin, psoralen plus ultraviolet A [PUVA] therapy, ultraviolet B [UVB] therapy). 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).

# TOPAMAX/ZONEGRAN

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# TOPICAL IMMUNOMODULATORS

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## Products Affected

- tacrolimus topical

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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) or generic tacrolimus 0.1 percent or 0.03 percent 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.

# TOPICAL RETINOID PRODUCTS

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## Products Affected

- adapalene topical cream
- adapalene topical gel
- Avita topical cream
- clindamycin-tretinoin
- tretinoin microspheres topical gel with pump
- tretinoin topical

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<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

# TOPICAL TESTOSTERONE PRODUCTS

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## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<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.
<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, approve if hypogonadism has been confirmed by a low for age serum testosterone (total or free) level defined by the normal laboratory reference values.

# TRANSMUCOSAL FENTANYL DRUGS

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## Products Affected

- fentanyl citrate buccal lozenge on a handle  
1,200 mcg, 1,600 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
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).

# TYKERB

## Products Affected

- Tykerb

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tykerb for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tykerb is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	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 or a postmenopausal woman and Tykerb will be used in combination with an aromatase inhibitor, that is letrozole (Femara), anastrozole, or elemestane. HER-2 positive early breast cancer, approve if Tykerb will be used in combination with Herceptin.



# TYSABRI

## Products Affected

- Tysabri

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tysabri for a Covered Use.
<b>Exclusion Criteria</b>	Concurrent use of another immunomodulator (eg, Rebif, Betaseron, Extavia, Copaxone or Avonex or Aubagio), Tecfidera, or fingolimod (Gilenya) or an immunosuppressant such as mitoxantrone, cyclophosphamide, rituximab (Rituxan), alemtuzumab (Campath), azathioprine, MTX, or mycophenolate mofetil in multiple sclerosis (MS) patients. Concurrent use with immunosuppressants (eg, 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) or tumor necrosis factor (TNF) alfa inhibitors (eg, infliximab, adalimumab, certolizumab pegol) in Crohn's disease (CD) patients. Per warning and precautions, coverage is not provided for immune compromised patients with MS or CD.
<b>Required Medical Information</b>	Adults with MS. Patient has a relapsing form of MS (relapsing forms of MS are relapsing remitting [RRMS], secondary progressive [SPMS] with relapses, and progressive relapsing [PRMS]). Adults with CD. Patient has moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein).
<b>Age Restrictions</b>	Adults
<b>Prescriber Restrictions</b>	MS. Prescribed by, or in consultation with , a neurologist or physician who specializes in the treatment of MS.CD. Prescribed by or in consultation with a gastroenterologist.
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	Adults with a relapsing form of MS. Patient has had an inadequate response to, or is unable to tolerate, therapy with at least one of the following MS medications: interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone/Glatopa), Plegridy, fingolimod (Gilenya), Tecfidera, Lemtrada, or Aubagio OR the patient has highly active or aggressive disease according to the prescribing physician. Adults with CD. Patient has moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein) and patient has tried two TNF antagonists for CD for at least 2 months

<b>PA Criteria</b>	<b>Criteria Details</b>
	each, adalimumab, certolizumab pegol, or infliximab, and had an inadequate response or was intolerant to the TNF antagonists.

# UPTRAVI

## Products Affected

- Upravi

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients currently taking Upravi.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Confirmation of right heart catheterization (select populations), 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>	3 years
<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). Right heart catheterization is NOT required in pts who are currently receiving Upravi or another agent indicated for PAH (WHO group 1). Patient must meet a) OR b): a) tried TWO or is currently taking TWO oral therapies for PAH (either alone or in combination) each for greater than or equal to 60 days: PDE5 inhibitor (eg, sildenafil, Adcirca, 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, Tyvaso, Ventavis, Remodulin, or epoprostenol injection).

# VENCLEXTA

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## Products Affected

- Venclexta

- Venclexta Starting Pack

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients currently taking Venclexta for a Covered Use.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, prior therapy, 17p deletion status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	CLL - approve if the patient has 17p deletion and has tried one prior therapy.

# VIEKIRA

## Products Affected

- Viekira Pak

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Viekira for a covered use
<b>Exclusion Criteria</b>	Previous failure of Viekira in patients with minimal liver disease. Combination use with other direct acting antivirals, excluding ribavirin
<b>Required Medical Information</b>	Genotype 1, Cirrhosis status and genotype 1 subtype
<b>Age Restrictions</b>	18 years or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD, Recurrent HVC post liver transplant - prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center, GI, hepatologist, ID, or a liver transplant physician
<b>Coverage Duration</b>	24 wks G1a w cirrh, Rec HCV Post-Liver Trans, 12 wks others
<b>Other Criteria</b>	Prescribed in combination with RBV for Genotype 1a, and Recurrent HCV post liver transplant.

# VOTRIENT

## Products Affected

- Votrient

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus, patients already taking Votrient for a Covered Use. Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Dermatofibrosarcoma Protuberans (DFSP), Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST).
<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 (angiosarcoma, Pleomorphic rhabdomyosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive, soft tissue sarcoma of the extremity/superficial trunk, including synovial sarcoma, or other non-lipogenic (non-adipocytic) soft tissue sarcoma) - approve. Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient has clinically progressive or symptomatic metastatic disease and the patient has nonradioiodine-responsive tumors at sites other than the central nervous system. Uterine sarcoma, approve if the patient has advanced or metastatic disease. Advanced RCC - approve. DFSP - approve if the patient has metastasis. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - approve if the patient has received primary treatment with chemotherapy (e.g., carboplatin with paclitaxel) and/or surgery AND has complete clinical remission. GIST - approve if the patient has tried TWO of the following: Gleevec, Sutent, or Strivarga.

# XALKORI

## Products Affected

- Xalkori oral capsule 200 mg, 250 mg

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Additional coverage is provided for soft tissue sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation, NSCLC with ROS1 Rearrangement, and NSCLC with MET amplification. Plus patients already started on crizotinib for a Covered Use.
<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 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 MET amplification, or have ROS1 rearrangement for approval.

# XENAZINE

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## Products Affected

- tetrabenazine

- Xenazine

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.
<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, Xenazine and generic (tetrabenazine) must be prescribed by or after consultation with a neurologist. For TD, Xenazine and generic (tetrabenazine) must be prescribed by or after consultation with a neurologist or psychiatrist.
<b>Coverage Duration</b>	Authorization will be for 3 years.
<b>Other Criteria</b>	N/A



# XOLAIR

## Products Affected

- Xolair

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Seasonal or perennial allergic rhinitis (SAR or PAR).
Exclusion Criteria	N/A
Required Medical Information	Moderate to severe persistent asthma and SAR/PAR, baseline IgE level of at least 30 IU/mL. For asthma, patient has a 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 positive skin testing (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach) and/or 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, with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) AND must have tried therapy with a leukotriene modifier (e.g., montelukast) with a daily non-sedating H1 antihistamine
Age Restrictions	Moderate to severe persistent asthma-6 years and older. All other diagnoses-12 years and older.
Prescriber Restrictions	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.
Coverage Duration	Initial tx 4 months, continued tx 12 months
Other Criteria	Moderate to severe persistent asthma must meet all criteria patient's asthma symptoms have not been adequately controlled by concomitant use of at least 3 months of inhaled corticosteroid and a long-acting beta-agonist (LABA) or LABA alternative, if LABA contraindicated or pt has

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>intolerance then alternatives include sustained-release theophylline or a leukotriene modifier (eg, montelukast), AND inadequate control demonstrated by hospitalization for asthma, requirement for systemic corticosteroids to control asthma exacerbation(s), or increasing need (eg, more than 4 times a day) for short-acting inhaled beta2 agonists for symptoms (excluding preventative use for exercise-induced asthma). For continued Tx for asthma - must meet specialist criteria and patient has responded to therapy (e.g., decreased asthma symptoms or exacerbations, decreased hospitalizations, emergency room, urgent care, or physician visits due to asthma, decreased reliever/rescue medication use, increased lung function parameters (FEV1, PEF)), as determined by the prescribing physician. SAR/PAR must meet the following criteria - pt has tried concurrent therapy with at least one drug from 2 of the following classes, a non-sedating or low-sedating antihistamine/nasal antihistamine, a nasal corticosteroid, or montelukast or pt has tried at least one drug from all 3 of these classes during one allergy season AND pt has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy, AND for pts with allergies to animals, these animals must be removed from the patient's immediate environment (eg, work, home). For continued tx SAR/PAR - must meet specialist criteria and pt must have responded to therapy (e.g., decreased symptoms of sneezing, itchy nose, watery, red, or itchy eyes, itchy throat, nasal congestion) as determined by the prescribing physician. For CIU cont tx - must meet specialist criteria and have responded to therapy (e.g., decreases severity of itching, decreased number and/or size of hives) as determined by the prescribing physician.</p>

# XTANDI

## Products Affected

- Xtandi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Xtandi for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Xtandi is being used. For metastatic castration-resistant prostate cancer, prior therapies tried.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	For prostate cancer, patient must have metastatic, castration-resistant prostate cancer for approval. For metastatic, castration-resistant prostate cancer in patients who are not currently taking Xtandi, the patient must have had a trial with abiraterone (Zytiga) unless the patient is unable to try abiraterone due to a contraindication or severe intolerance (eg, difficulty achieving blood glucose control in patients with diabetes, psychiatric reactions) to prednisone OR the pt is chemotherapy treatment-naïve and has visceral metastases (e.g., metastases to lung, liver, or other organs except bone). Note- metastases to the bone is not visceral metastases.

# ZELBORAF

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## Products Affected

- Zelboraf

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus, patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, and patients already started on vemurafenib for a Covered Use.
<b>Exclusion Criteria</b>	Concurrent use with Mekinist.
<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 must not have experienced disease progression on Tafinlar. HCL - must have relapsed or refractory disease AND tried at least two therapies for hairy cell leukemia (e.g., cladribine, Nipent, cladribine or Nipent with or without Rituxan).

# ZYDELIG

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## Products Affected

- Zydelig

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Additional off-label coverage is provided for Marginal Zone Lymphoma and Lymphoplasmacytic Lymphoma (LPL) with or without Waldenstrom's Macroglobulinemia (WM).
<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

# ZYKADIA

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## Products Affected

- Zykadia

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Must have metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive.
<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>	The patient must have either been intolerant or progressed on therapy with Xalkori.

# ZYTIGA

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## Products Affected

- Zytiga

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All FDA-approved indications not otherwise excluded from Part D. Plus, patients already started on Zytiga for a Covered Use.
<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>	Metastatic castration-resistance prostate cancer, approve if Zytiga is being used in combination with prednisone.

## PART B VERSUS PART D

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### Products Affected

- Abelcet
- acetylcysteine
- 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 %), 5 mg/mL
- AmBisome
- amino acids 15 %
- Aminosyn 7 % with electrolytes
- Aminosyn 8.5 %-electrolytes
- Aminosyn II 10 %
- Aminosyn II 15 %
- Aminosyn II 7 %
- Aminosyn II 8.5 %
- Aminosyn II 8.5 %-electrolytes
- Aminosyn M 3.5 %
- Aminosyn-HBC 7%
- Aminosyn-PF 10 %
- Aminosyn-PF 7 % (sulfite-free)
- Aminosyn-RF 5.2 %
- amiodarone intravenous solution
- amphotericin B
- azathioprine
- azathioprine sodium
- budesonide inhalation
- Cancidas
- CellCept Intravenous
- cidofovir
- Clinimix 5%/D15W Sulfite Free
- Clinimix 5%/D25W sulfite-free
- Clinimix 2.75%/D5W Sulfite Free
- Clinimix 4.25%/D10W Sulf Free
- Clinimix 4.25%/D5W Sulfite Free
- Clinimix 4.25%-D20W sulf-free
- Clinimix 4.25%-D25W sulf-free
- Clinimix 5%-D20W(sulfite-free)
- cromolyn inhalation
- cyclophosphamide oral capsule
- cyclosporine intravenous
- cyclosporine modified
- cyclosporine oral capsule
- Cyramza
- dronabinol
- Emend oral
- Empliciti
- Engerix-B (PF) intramuscular syringe
- Engerix-B Pediatric (PF)
- Freamine HBC 6.9 %
- Gengraf
- granisetron HCl oral
- Hepatamine 8%
- Intralipid intravenous emulsion 20 %
- Intralipid intravenous emulsion 30 %
- ipratropium bromide inhalation
- Lioresal
- methotrexate sodium (PF)
- methotrexate sodium oral
- methylprednisolone oral tablet
- mycophenolate mofetil
- mycophenolate sodium
- Nebupent
- Neoral oral solution
- Nephramine 5.4 %
- nitroglycerin intravenous
- Nulojix
- ondansetron
- ondansetron HCl oral
- Perforomist
- prednisolone sodium phosphate oral tablet, disintegrating
- Prednisone Intensol
- prednisone oral tablet
- Premasol 10 %
- Premasol 6 %
- Prograf intravenous
- Pulmicort inhalation suspension for nebulization 1 mg/2 mL
- Pulmozyme
- Rapamune oral solution
- Recombivax HB (PF) intramuscular suspension 10 mcg/mL, 40 mcg/mL



- Recombivax HB (PF) intramuscular syringe
- Rheumatrex
- Simulect intravenous recon soln 20 mg
- sirolimus
- tacrolimus oral
- tobramycin in 0.225 % NaCl
- Travasol 10 %
- TrophAmine 10 %
- Trophamine 6%
- Tyvaso
- Vectibix intravenous solution 100 mg/5 mL (20 mg/mL)
- Zortress

## **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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