

**\*\*Under CMS Review\*\***

## ACTHAR

### Products Affected

- HP ACTHAR

<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>	None
<b>Required Medical Information</b>	Diagnosis of multiple sclerosis AND patient is currently on a disease modifying drug (interferon beta 1a, peginterferon beta1a, interferon beta1b, glatiramer, natalizumab, mitoxatrone, dimethyl fumarate, teriflunomide, alemtuzumab) to control disease progression, OR has tried and failed, contraindicated or intolerant to all DMDs AND the patient has failed corticosteroid therapy within the last 30 days or has an FDA labeled contraindication to corticosteroid therapy.
<b>Age Restrictions</b>	Infantile spasms patient must be less than 24 months of age
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## ADEMPAS

### Products Affected

- ADEMPAS

<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>	Concomitant administration with nitrates or nitric oxide donors (such as amyl nitrate) in any form. Concomitant administration with phosphodiesterase inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline). Pregnancy.
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH .Chronic thromboembolic pulmonary hypertension (CTEPH) (Initial): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH. For all indications female patients are enrolled in the ADEMPAS REMS program.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Reauthorization: 12 months
<b>Other Criteria</b>	None

# AFINITOR

## Products Affected

- AFINITOR
- AFINITOR DISPERZ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of advanced metastatic renal cell carcinoma and patient has failed therapy (disease progressed) with Sutent or Nexavar OR Diagnosis of pancreatic neuroendocrine tumors (pNET) that are unresectable, locally advanced, or metastatic OR Diagnosis of renal angiomyolipoma with tuberous sclerosis complex (TSC) and patient does not require immediate surgery OR Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer and patient is a postmenopausal woman and patient has failed treatment with Femara or Arimidex and the medication will be used in combination with Aromasin OR Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with TSC that requires therapeutic intervention but is not a candidate for curative surgical resection OR diagnosis of adult patients with progressive, well-differentiated, non-functional, neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin with unresectable, locally advanced, or metastatic disease OR diagnosis of tuberous sclerosis complex (TSC) associated partial seizures.
<b>Age Restrictions</b>	18 years of age and older for RCC, pNET, and renal angiomyolipoma with TSC. 1 year of age and older for SEGA. 2 years of age and older for TSC associated partial seizures.
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or neurologist

Formularies: ID 19482 V.8, ID 19485 V.8, ID 19487 V.8.  
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HealthSun Health Plans  
2019 Prior Authorization Criteria

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## ALECENSA

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### Products Affected

- ALECENSA

<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>	None
<b>Required Medical Information</b>	Diagnosis of metastatic anaplastic lymphoma kinase(ALK) positive non-small cell lung cancer detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility AND a history of failure, contraindication, intolerance, or progressed on XALKORI (crizotinib)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## ALUNBRIG

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### Products Affected

- ALUNBRIG

<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>	None
<b>Required Medical Information</b>	Diagnosis of metastatic, ALK positive non-small cell lung cancer and have progressed or are intolerant to Xalkori (crizotinib)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## AMPYRA

### Products Affected

- AMPYRA
- *dalfampridine er*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	History of seizure. Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute).
<b>Required Medical Information</b>	Diagnosis of multiple sclerosis. Patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting Ampyra and patient is currently on a disease modifying drug (interferon beta 1a, peginterferon beta 1a, interferon beta 1b, or glatiramer) to control disease progression, or has documented treatment failure, intolerance, or contraindication to any one of the following: interferon beta 1a, peginterferon beta 1a, interferon beta 1b, or glatiramer.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	Initial: 3 months, Reauthorization: 12 months
<b>Other Criteria</b>	None

## AUBAGIO

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### Products Affected

- AUBAGIO

<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>	Severe hepatic impairment. Current treatment with leflunomide. Patients who are pregnant or women of childbearing potential not using reliable contraception.
<b>Required Medical Information</b>	Diagnosis of relapsing forms of multiple sclerosis (e.g., relapsing-remitting MS or progressive-relapsing MS) OR patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis AND Patient has tried and had an insufficient response to at least one other formulary MS disease modifying therapy ( e.g., Avonex, Betaseron, Copaxone, Gilenya, Tecfidera)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For renewal, patient has experienced an objective response to therapy (i.e. no or slowed progression of disease)



## AURYXIA

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### Products Affected

- AURYXIA

<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>	None
<b>Required Medical Information</b>	For the management of hyperphosphatemia in patients with chronic kidney disease on dialysis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## BEXAROTENE

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### Products Affected

- *bexarotene*

<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>	None
<b>Required Medical Information</b>	Patient must meet one of following criteria: received prior systemic therapy for CTCL OR advanced-stage MF (stage IIB, III or IV) or SS OR early-stage MF (stage IA, IB or IIA) with folliculotropic/large cell transformation OR early-stage MF (stage IA, IB or IIA) refractory to skin directed therapy.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Definite diagnosis of cutaneous T-cell lymphoma (CTCL) AND refractory to any prior systemic therapy (such as methotrexate)

## BOSULIF

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### Products Affected

- BOSULIF

<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>	None
<b>Required Medical Information</b>	Diagnosis of Philadelphia chromosome-positive (Ph+) CML with resistance, relapse, or inadequate response to prior therapy with one of the following tyrosine kinase inhibitors (TKI): Gleevec [imatinib] OR Tasigna [nilotinib] OR newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph + CML)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## BRIVIACT

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### Products Affected

- BRIVIACT ORAL

<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>	None
<b>Required Medical Information</b>	Diagnosis of partial-onset seizures, member must have history of inadequate response, contraindication, or intolerance to levetiracetam prior to approval.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## CABOMETYX

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### Products Affected

- CABOMETYX

<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>	Patients who have or are at risk for severe hemorrhage and/or patients with a recent history of bleeding or hemoptysis.
<b>Required Medical Information</b>	Diagnosis of advanced renal cell carcinoma
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## CALQUENCE

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### Products Affected

- CALQUENCE

<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>	None
<b>Required Medical Information</b>	MANTLE CELL LYMPHOMA (MCL) (1) Patient must have a diagnosis of MCL AND (2) Patient has tried one other therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## CAPRELSA

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### Products Affected

- CAPRELSA

<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>	Congenital long QT syndrome
<b>Required Medical Information</b>	Diagnosis of medullary thyroid cancer (MTC), and disease is one of the following: A) unresectable, locally advanced, or B) metastatic AND one of the following: patient has symptomatic disease or patient has progressive disease.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## CARIMUNE

### Products Affected

- CARIMUNE NF INTRAVENOUS SOLUTION RECONSTITUTED 6 GM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<p>Diagnosis of a primary humoral immunodeficiency disorder such as: primary immunoglobulin deficiency syndrome X-linked immunodeficiency with hyperimmunoglobulin etc). Documented hypogammaglobulinemia (IgG less than 600mg/dl) Idiopathic/Immune Thrombocytopenia Purpura. Diagnosis of Acute ITP with any of the following:            Management of acute bleeding due to severe thrombocytopenia (platelets less than 30 000/mcL). To increase platelet counts prior major surgical procedures. Severe thrombocytopenia (platelets less than 20 000/mcL) at risk for intracerebral hemorrhage. Diagnosis of Chronic ITP and ALL of the following are met: Prior treatment has included corticosteroids and splenectomy Duration of illness less than 6 months, no concurrent illness explaining thrombocytopenia, platelets persistently at or below 20 000/mcL. Chronic Lymphocytic Leukemia (CLL B-cell) with either of the following present: Hypogammaglobulinemia ( IgG less than 600mg/dL) or Recurrent bacterial infections associated with B-cell CLL. Kawasaki Disease-Diagnosed with Kawasaki Syndrome within ten days of onset of disease manifestations or is diagnosed after ten days of disease onset and continues to exhibit manifestations of inflammation or evolving coronary artery disease. IVIG is used in combination with high dose aspirin for the prevention of coronary artery aneurysms. Bone Marrow Transplant (BMT). Member is hypogammaglobinemic (IgG</p>

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HealthSun Health Plans  
2019 Prior Authorization Criteria

<b>PA Criteria</b>	<b>Criteria Details</b>
	less than 400mg/dL). Hematopoietic Stem Cell Transplantation (HSCT). Is within first 100 days of allogenic hematopoietic stem cell transplantation. Is experiencing hypogammaglobulinemia (serum IgG level less than 400 mg/dL). AIDS/HIV- Has any of the following conditions: CD4+ T-cell counts greater than or equal 200/mm <sup>3</sup> , to prevent maternal transmission of HIV infection, IVIG is used in conjunction with zidovudine to prevent serious bacterial infections in HIV-infected members who have hypogammaglobulinemia (serum IgG less than 400 mg/dL).
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## COMETRIQ

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### Products Affected

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

<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>	Gastrointestinal perforation. Fistula. Severe hemorrhage.
<b>Required Medical Information</b>	Diagnosis of progressive, metastatic medullary thyroid cancer
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## COPAXONE

### Products Affected

- COPAXONE SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- *glatiramer acetate*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of relapsing-remitting multiple sclerosis OR diagnosis of first clinical episode with MRI features consistent with multiple sclerosis
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For renewal, patient does not have progressive disease and responding to therapy.

## COTELLIC

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### Products Affected

- COTELLIC

<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>	None
<b>Required Medical Information</b>	Diagnosis of unresectable OR metastatic malignant melanoma with BRAF V600E OR V600K mutation. Documentation of combination therapy with vemurafenib (Zelboraf)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## DICLOFENAC TOPICAL

### Products Affected

- *diclofenac sodium transdermal gel 1 %, 3 %*
- *diclofenac sodium transdermal solution*

<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>	None
<b>Required Medical Information</b>	Diclofenac 1% gel or 1.5% solution: Diagnosis of osteoarthritis, diclofenac 3% gel: Diagnosis of actinic keratosis
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## ENDARI

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### Products Affected

- ENDARI

<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>	None
<b>Required Medical Information</b>	Diagnosis of acute sickle cell disease AND Must have A) trial history of Hydroxyurea OR B) intolerance to Hydroxyurea OR C) contraindication to Hydroxyurea
<b>Age Restrictions</b>	5 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## ERLEADA

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### Products Affected

- ERLEADA

<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>	Pregnancy
<b>Required Medical Information</b>	Diagnosis of non-metastatic, castration-resistant prostate cancer
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## ESBRIET

### Products Affected

- ESBRIET

<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>	None
<b>Required Medical Information</b>	1)Diagnosis of Idiopathic pulmonary fibrosis (IPF) as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF, AND 2) not used in combination with Ofev (nintedanib).
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Pulmonologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None



## ESRD THERAPY

### Products Affected

- PROCRIT

<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>	Epoetin alfa therapy is not considered medically necessary for members with the following concomitant conditions: Concomitant use of another Recombinant Erythropoietin Product, anemia in cancer not related to chemotherapy OR anemia associated only with radiotherapy (without chemo). ESAs are not indicated in cancer patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure (ESAs remain indicated when myelosuppressive chemotherapy is intended for palliation).
<b>Required Medical Information</b>	Pretreatment hemoglobin levels of less than 10g/dL. Dose reduction or interruption if hemoglobin exceeds 10 g/dL (CKD not on dialysis-adult, cancer), 11 g/dL (CKD on dialysis), 12 g/dL (pediatric CKD) in addition to supporting statement of diagnosis from physician.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	None

## FARYDAK

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### Products Affected

- FARYDAK

<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>	None
<b>Required Medical Information</b>	Diagnosis of Multiple Myeloma (MM) Used in combination with both of the following: Velcade (bortezomib) and dexamethasone. Patient has received at least two prior treatment regimens which included both of the following: Velcade (bortezomib) and an immunomodulatory agent [eg, Revlimid (lenalidomide), Thalomid (thalidomide)].
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist/hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## FENTORA

### Products Affected

- FENTORA BUCCAL TABLET 100 MCG
- LAZANDA

<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>	None
<b>Required Medical Information</b>	Fentanyl Buccal Tablet (Fentora) may be considered medically necessary when the following criteria are met: The member is currently diagnosed with cancer, OTFC is required to manage break-through pain, member is currently taking opioid therapy and is opioid tolerant, and member has tried and failed generic Actiq (fentanyl citrate lozenge). Tolerance is defined as any of the following: greater than or equal to 60mg morphine/day for greater than or equal than 1 week or greater than or equal to 50 mcg transdermal fentanyl/hour for greater than or equal 1 week or an equi-analgesic dose of another opioid for greater than or equal 1 week.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## FORTEO

### Products Affected

- FORTEO SUBCUTANEOUS SOLUTION 600 MCG/2.4ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Patient has a diagnosis of one of the following: a) osteoporosis in a postmenopausal female, b) primary or hypogonadal osteoporosis in a male, or c) osteoporosis associated with sustained systemic glucocorticoid therapy AND patient is considered to be at high-risk for fracture by meeting one or more of the following: A) history of osteoporotic fracture, B) Low Bone Density less than 2.5 SD below normal, AND one or more of the following: i) failed one oral bisphosphonate and 1 injectable bisphosphonate, or ii) intolerant to one oral bisphosphonate and one injectable bisphosphonate. Patient has not received more than 2 years of therapy with Forteo.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve doses based on FDA labeling

## GILENYA

### Products Affected

- GILENYA ORAL CAPSULE 0.5 MG

<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>	Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. Baseline QTC interval greater than or equal to 500 milliseconds. Receiving concurrent treatment with Class Ia or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol).
<b>Required Medical Information</b>	Diagnosis of a relapsing form of multiple sclerosis or diagnosis of first clinical episode with MRI features consistent with MS AND Patient will be observed for signs and symptoms of bradycardia in a controlled setting for at least 6 hours after the first dose
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Reauthorization: 12 months
<b>Other Criteria</b>	For renewal, the patient has experienced no or slowed disease progression.

## GILOTRIF

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### Products Affected

- GILOTRIF

<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>	None
<b>Required Medical Information</b>	Supporting statement of diagnosis from the physician in patients with: 1) metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test or 2) metastatic squamous NSCLC, progressing after platinum-based chemotherapy.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## GOCOVRI

### Products Affected

- GOCOVRI

<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>	Patients with ESRD (CrCl below 15 ml/min/m <sup>2</sup> )
<b>Required Medical Information</b>	INITIAL: Diagnosis of Parkinsons disease AND (1) Patient is experiencing dyskinesia AND (2) Patient is receiving levodopa based therapy AND (3) Must have documented trial and failure to amantadine immediate release. RENEWAL: (1) must meet the initial criteria above AND (2) Documentation of positive clinical response to Gocovri (e.g., decreased off periods, decreased on time with troublesome dyskinesia)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## GROWTH HORMONE

### Products Affected

- NORDITROPIN FLEXPRO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure. Active malignancy. Active proliferative or severe non-proliferative diabetic retinopathy. For PWS only: severe obesity, history of upper airway obstruction or sleep apnea, or severe respiratory impairment.
<b>Required Medical Information</b>	Diagnosis of pediatric indication: A) GHD and bone age at least 1 year or 2 standard deviations (SD) delayed compared with chronological age and 2 stim tests with peak GH secretion below 10 ng/mL or IGF-1/IGFBP3 level more than 2 SDS below mean if CNS pathology, h/o irradiation, or proven genetic cause, B) SGA and birth weight or length 2 or more SDS below mean for gestational age and fails to manifest catch up growth by age 2 (height 2 or more SDS below mean for age and gender), C) CRI and nutritional status has been optimized, metabolic abnormalities have been corrected, and patient has not had renal transplant D) SHOX deficiency or Noonan syndrome E) PWS confirmed by genetic testing, F) Turner Syndrome confirmed by chromosome analysis. For GHD, CRI, SHOX deficiency, Noonan syndrome, and PWS one of the following: height more than 3 SDS below mean for age and gender, or height more than 2 SDS below mean with GV more than 1 SDS below mean, or GV over 1 year 2 SDS below mean. OR Diagnosis of an adult indication: A) childhood- or adult-onset GHD confirmed by 2 standard GH stim tests (provide assay): 1 test must be insulin tolerance test (ITT) with blood glucose nadir less than 40 mg/dL (2.2 mmol/L). If

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HealthSun Health Plans  
2019 Prior Authorization Criteria

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>contraindicated, use a standardized stim test (i.e. arginine plus GH releasing hormone [preferred], glucagon, arginine), B) GHD with at least 1 other pituitary hormone deficiency and failed at least 1 GH stim test (ITT preferred), C) GHD with panhypopituitarism (3 or more pituitary hormone deficiencies), D) GHD with irreversible hypothalamic-pituitary structural lesions due to tumors, surgery or radiation of pituitary or hypothalamus region AND a subnormal IGF-1 (after at least 1 month off GH therapy) AND Objective evidence of GHD complications, such as: low bone density, increased visceral fat mass, or cardiovascular complications AND Completed linear growth (GV less than 2 cm/year) AND GH has been discontinued for at least 1 month (if previously receiving GH).</p>
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## HEPATITIS B

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### Products Affected

- *adefovir dipivoxil*
- *entecavir*

<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>	Patients that have immune-tolerant chronic hepatitis B per AASLD guidelines
<b>Required Medical Information</b>	Must submit documentation of immune-active chronic hepatitis B per AASLD guidelines.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	Duration of approval per AASLD Guidelines
<b>Other Criteria</b>	None

## HEPATITIS C

### Products Affected

- MAVYRET
- VOSEVI

<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>	None
<b>Required Medical Information</b>	Must submit documentation of chronic hepatitis C genotype (confirmed by HCV RNA level within the last 6 months). Must submit laboratory results within 6 weeks of initiating therapy including: 1) CBC w Platelets, 2) AST/ALT, 3) Total Bilirubin, 4) Serum Albumin, 5) PT/INR, 6) Serum Creatinine, and 7) GFR. FOR all GENOTYPES-Trial/failure, contraindication to, or intolerance to Mavyret required prior to the approval of Vosevi.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist
<b>Coverage Duration</b>	Duration of approval per AASLD Guidelines
<b>Other Criteria</b>	None

## HETLIOZ

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### Products Affected

- HETLIOZ

<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>	None
<b>Required Medical Information</b>	Diagnosis of Non-24-hour-sleep-wake disorder (Non-24) AND patient has documented blindness
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Reauthorization: 12 months
<b>Other Criteria</b>	For renewal, patient experienced an objective improvement (e.g., improvement in timing of nighttime sleep, improvement in duration of nighttime sleep, or reduction in daytime sleep).

## HRM

### Products Affected

- *guanfacine hcl er*
- *methylphenidate hcl er (cd) oral capsule extended release 10 mg, 20 mg, 40 mg, 50 mg, 60 mg*
- *methylphenidate hcl er oral tablet extended release 20 mg*
- *methylphenidate hcl er oral tablet extended release 24 hour*
- *methylphenidate hcl oral*

<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>	None
<b>Required Medical Information</b>	Physician has documented the indication for the continued use of the HRM (high risk med) with an explanation of the specific benefit established with the medication and how that benefit outweighs the potential risk. AND The physician must document on progress notes that patient counseling has and will continue to take place outlining the risks and potential side effects of the medication.
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## HRM-ANALGESICS

### Products Affected

- ASCOMP-CODEINE
- *butalbital-acetaminophen oral tablet 50-325 mg*
- *butalbital-apap-caff-cod*
- *butalbital-apap-caffeine oral capsule*
- *butalbital-apap-caffeine oral tablet 50-325-40 mg*
- *butalbital-asa-caff-codeine*
- *indomethacin er*
- *indomethacin oral*
- *ketorolac tromethamine oral*
- *meperidine hcl injection solution 100 mg/ml, 25 mg/ml, 50 mg/ml*
- *meperidine hcl oral*
- *pentazocine-naloxone hcl*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the patient has tried at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Mild pain: codeine. Moderate to severe pain: short-term NSAIDs, tramadol, tramadol/APAP, morphine sulfate, hydrocodone/APAP, oxycodone, oxycodone/APAP, fentanyl.

## HRM-ANTI-ARRHYTHMICS

### Products Affected

- DIGITEK ORAL TABLET 250 MCG
- DIGOX ORAL TABLET 250 MCG
- *digoxin oral solution*
- *digoxin oral tablet 250 mcg*
- *disopyramide phosphate oral*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## HRM-ANTIEMETIC DRUGS

### Products Affected

- *promethazine hcl oral syrup*
- *promethazine hcl oral tablet*
- *promethazine hcl rectal*

<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>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None



## HRM-ANTI-HISTAMINES

### Products Affected

- *carbinoxamine maleate oral solution*
- *clemastine fumarate oral tablet 2.68 mg*
- *cyproheptadine hcl oral solution*
- *promethazine vc plain oral solution*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the patient has tried at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	cetirizine, fexofenadine, loratadine, desloratadine, levocetirizine

## HRM-ANTIHYPERTENSIVE AGENTS

### Products Affected

- *methyldopa oral*
- *methyldopa-hydrochlorothiazide*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## HRM-ANTIPARKINSON AGENTS

### Products Affected

- *benztropine mesylate oral*
- *trihexyphenidyl hcl*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the patient has tried at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For the treatment of Parkinsonism, a trial of at least 1 formulary drug that is not an HRM in elderly (e.g., carbidopa/levodopa, pramipexole, ropinirole, bromocriptine, selegiline, rasagiline, entacapone, amantadine, etc.) or other type of clinical justification will be required in members 65 years of age and older. For the treatment of medication-induced movement disorder - extrapyramidal disease, a trial of at least 1 formulary drug that is not an HRM in elderly (e.g., amantadine, etc.) or other type of clinical justification will be required in members 65 years of age and older.

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## HRM-CALCIUM CHANNEL BLOCKERS, DIHYDROPYRIDINE

### Products Affected

- *nifedipine oral*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the patient has tried at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	extended-release nifedipine, nicardipine, amlodipine

## HRM-MEGESTROL

### Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives for diagnosis of cachexia secondary to chronic illness (dronabinol, oxandrolone) considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to at least 2 of the alternative(s) AND the prescribing physician attests to the medical necessity for using this high risk medication, AND anticipated treatment course/duration. For treatment of cancer related diagnosis or endometrial hyperplasia, or endometriosis, requests will be automatically approved.
<b>Age Restrictions</b>	PA applies to patients 65 years and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## HRM-ORAL AND TRANSDERMAL ESTROGENS AND PROGESTINS

### Products Affected

- CLIMARA PRO
- *estradiol oral*
- *estropipate oral tablet 0.75 mg*
- MENEST ORAL TABLET 0.3 MG, 0.625 MG, 1.25 MG
- PREMARIN ORAL
- PREMPRO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the patient has tried at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Bone Density: alendronate, risedronate, ibandronate, raloxifene (zoledronic acid for bed-bound patients or for post-hip fracture). Vaginal Symptoms: vaginal estrogen cream

## HRM-PLATELET INHIBITORS

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### Products Affected

- *dipyridamole oral*

<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>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the patient has tried at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	clopidogrel, aggrenox

## HRM-SEDATIVE HYPNOTIC AGENTS

### Products Affected

- *zaleplon*
- *zolpidem tartrate er*
- *zolpidem tartrate oral*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives, Silenor (less than or equal to 6mg/d) considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to the alternative(s) AND the prescribing physician attests to the medical necessity for using this high risk medication, AND Monitoring plan for adverse side effects, AND anticipated treatment course/duration.
<b>Age Restrictions</b>	PA applies to patients 65 years and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Non-HRM alternatives, must inadequate response, intolerable side effect, or contraindication to both: Rozerem (8 mg/d), Silenor (less than or equal to 6mg/d)



## HRM-SKELETAL MUSCLE RELAXANTS

### Products Affected

- *carisoprodol oral*
- *carisoprodol-aspirin*
- *carisoprodol-aspirin-codeine*
- *chlorzoxazone oral tablet 500 mg*
- *cyclobenzaprine hcl oral*
- *methocarbamol oral*
- *orphenadrine citrate er*

<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>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## HRM-SULFONYLUREAS

### Products Affected

- *chlorpropamide*
- *glyburide oral*
- *glyburide micronized*
- *glyburide-metformin*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND the patient has tried at least one non-HRM alternative (listed in OTHER CRITERIA) AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	glimepiride, glipizide

## HRM-UTI ANTIBACTERIALS

### Products Affected

- *nitrofurantoin macrocrystal oral*
- *nitrofurantoin monohyd macro*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The drug is being prescribed for an FDA-approved indication AND If formulary non HRM alternatives (Non-HRM alternatives: sulfamethoxazole/trimethoprim) considered safe and effective in the elderly are available, then the member had an inadequate response, intolerable side effect, or contraindication to the alternative AND the prescribing physician attests to the medical necessity for using this high risk medication and intent to monitor for side effects, AND anticipated treatment course/duration
<b>Age Restrictions</b>	PA applies to patients 65 years or older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## IBRANCE

### Products Affected

- IBRANCE

<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>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND One of the following: 1) Used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy OR 2) Used in combination with an aromatase inhibitor AND One of the following: 1) patient is a postmenopausal woman OR 2) both of the following: patient is a premenopausal or perimenopausal woman and patient is receiving a luteinizing hormone-releasing hormone (LHRH) agonist [eg, Zoladex (goserelin)].
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## ICLUSIG

### Products Affected

- ICLUSIG

<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>	None
<b>Required Medical Information</b>	Diagnosis of chronic myelogenous leukemia (CML) AND One of the following: A) History of failure, resistance, relapse, contraindication, or intolerance to at least TWO other tyrosine kinase inhibitors (SPRYCEL, TASIGNA, and BOSULIF), or B) Patient has the T315I mutation. OR Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) AND One of the following: A) History of failure, resistance relapse, contraindication, or intolerance to at least TWO other FDA-approved tyrosine kinase inhibitors (SPRYCEL, TASIGNA, BOSULIF), or B) Patient has the T315I mutation.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## IDHIFA

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### Products Affected

- IDHIFA

<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>	None
<b>Required Medical Information</b>	Diagnosis of relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase 2 mutation as detected by an FDA approved test.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## IMBRUVICA

### Products Affected

- IMBRUVICA

<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>	None
<b>Required Medical Information</b>	Diagnosis of mantle cell lymphoma (MCL) who have received at least one prior therapy OR chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) OR chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion OR Waldenstrom's macroglobulinemia (WM) OR marginal zone lymphoma who require systemic therapy and have received at least one prior anti-CD20-based therapy OR graft vs host disease after failure of a least one first-line corticosteroid therapy
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## INLYTA

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### Products Affected

- INLYTA

<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>	None
<b>Required Medical Information</b>	Diagnosis of advanced renal cell carcinoma AND patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens)
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only



## INTRAROSA

### Products Affected

- INTRAROSA

<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>	Vaginal bleeding or dysfunctional uterine bleeding of an undetermined origin, known or suspected estrogen-dependent neoplasia.
<b>Required Medical Information</b>	Diagnosis of moderate to severe dyspareunia or atrophic vaginitis AND A) Patient must be female, B) Patient must be menopausal or postmenopausal, C) Patient has tried and failed, has a contraindication or intolerance to a low dose vaginal estrogen preparation (e.g. Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem), D) Patient does not have renal or hepatic impairment.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 3 months, Reauthorization: 12 months
<b>Other Criteria</b>	None

## INVANZ

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### Products Affected

- INVANZ INJECTION

<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>	Invanz (ertapenem sodium) is contraindicated in patients with a hypersensitivity to ertapenem or other drugs of the same class, in patients with a prior anaphylactic reaction to beta-lactams and in patients with a hypersensitivity to amide-type anesthetics.
<b>Required Medical Information</b>	Labs with culture and sensitivity information.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## IRESSA

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### Products Affected

- IRESSA

<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>	None
<b>Required Medical Information</b>	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## JAKAFI

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### Products Affected

- JAKAFI

<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>	None
<b>Required Medical Information</b>	Myelofibrosis: Diagnosis of primary myelofibrosis, OR post-polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND history of failure, contraindication, or intolerance to hydroxyurea.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	This criteria applies to new starts only

## JUXTAPID

### Products Affected

- JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 5 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests. Pregnancy. Concomitant use with strong or moderate CYP3A4 inhibitors.
<b>Required Medical Information</b>	Diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient has been receiving at least 12 consecutive weeks of ONE LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. History of failure after 12 consecutive weeks or intolerance to PCSK9 inhibitor therapy. One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: LDL-C greater than or equal to 100 mg/dL with ASCVD OR LDL-C greater than or equal to 130 mg/dL without ASCVD. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic impairment (Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (ie. clarithromycin).

HealthSun Health Plans  
2019 Prior Authorization Criteria

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Reauthorization: 12 months
<b>Other Criteria</b>	None

## KALYDECO

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### Products Affected

- KALYDECO

<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>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis AND the patient has 1 mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data.
<b>Age Restrictions</b>	Oral granules: 2 years of age and older. Oral tablets: 6 years of age and older.
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

# KISQALI

## Products Affected

- KISQALI 200 DOSE
- KISQALI 400 DOSE
- KISQALI 600 DOSE
- KISQALI FEMARA 200 DOSE
- KISQALI FEMARA 400 DOSE
- KISQALI FEMARA 600 DOSE

<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>	None
<b>Required Medical Information</b>	Diagnosis of metastatic or advanced, HER-2 negative, hormone receptor-positive, postmenopausal women in combination with fulvestrant as initial endocrine based therapy or following disease progression on endocrine therapy OR Diagnosis metastatic or advanced, HER-2 negative, hormone receptor-positive, premenopausal, perimenopausal, or postmenopausal women, in combination with an aromatase inhibitor for initial endocrine-based treatment
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or gastroenterologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only



## KORLYM

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### Products Affected

- KORLYM

<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>	Pregnancy
<b>Required Medical Information</b>	Supporting statement of diagnosis and relevant medical information from physician
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## KYNAMRO

### Products Affected

- KYNAMRO SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests.
<b>Required Medical Information</b>	Diagnosis of homozygous familial hypercholesterolemia as evidenced by one of the following: A) genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or autosomal recessive hypercholesterolemia (ARH) adaptor protein gene locus OR B) untreated/pre-treatment LDL greater than 500 mg/dL with at least one of the following: cutaneous or tendonous xanthoma before age 10 years, history of early vascular disease (men younger than 55 years, women younger than 60 years) on both sides of the family if parenteral LDL levels are unknown, elevated LDL cholesterol levels before lipid-lowering therapy consistent with heterozygous FH in both parents AND Patient has tried and had an inadequate response to the maximum tolerated dose of a high potency statin (e.g., atorvastatin, rosuvastatin), unless all statins are contraindicated.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Reauthorization: 12 months

HealthSun Health Plans  
2019 Prior Authorization Criteria

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	For renewal, patient has responded to therapy with a decrease in LDL levels from baseline AND patient does not have contraindications to therapy.

## LENVIMA

### Products Affected

- LENVIMA 10 MG DAILY DOSE
- LENVIMA 14 MG DAILY DOSE
- LENVIMA 18 MG DAILY DOSE
- LENVIMA 20 MG DAILY DOSE
- LENVIMA 24 MG DAILY DOSE
- LENVIMA 8 MG DAILY DOSE

<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>	None
<b>Required Medical Information</b>	Diagnosis of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer OR advanced renal cell carcinoma following one prior anti-angiogenic therapy in combination with everolimus
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## LETAIRIS

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### Products Affected

- LETAIRIS

<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>	None
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension that was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) AND Patient has WHO Group I PAH AND pregnancy must be excluded prior to the start of therapy and will be prevented thereafter with two forms of reliable contraception in female patients of reproductive potential.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Reauthorization: 12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## LIDOCAINE PATCH

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### Products Affected

- *lidocaine external patch 5 %*

<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>	None
<b>Required Medical Information</b>	Diagnosis of pain associated with diabetic neuropathy OR pain associated with cancer-related neuropathy OR post-herpetic neuralgia.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## LONSURF

### Products Affected

- LONSURF

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic colorectal cancer, previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based regimens, an anti-VEGF therapy, and if RAS wild-type, an anti-EGFR therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For initial treatment: Absolute neutrophil count 1,500/mm <sup>3</sup> or greater or febrile neutropenia resolved, platelet count 75,000/mm <sup>3</sup> or greater, and grade 3 or 4 nonhematological reactions resolved to grade 0 or 1

## LUPRON

### Products Affected

- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Pregnancy in patients with child-bearing potential. Breastfeeding. Undiagnosed abnormal vaginal bleeding.
<b>Required Medical Information</b>	Diagnosis of one of the following: A) advanced or metastatic prostate cancer (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), B) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only) and for initial, patient has had an inadequate pain control response or patient has an intolerance or contraindication to one of the following: Danazol OR Combination [estrogen/progesterone] Oral Contraceptives OR Progestins and for retreatment course, Patient is experiencing recurrence of symptoms after an initial course of therapy with leuprolide acetate and Norethindrone acetate 5 mg daily will be co-administered, or C) Anemia due to uterine Leiomyomata (Fibroids) (3.75 mg 1-month & 11.25 mg 3-month depots only) and Patient is preoperative
<b>Age Restrictions</b>	Uterine fibroids, endometriosis and prostate cancer: 18 years of age and older, CPP: age 2-11 female and 2-12 male
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Endometriosis- 6 months, Uterine fibroids -3 months, Prostate cancer, Precocious Puberty -12 months

Formularies: ID 19482 V.8, ID 19485 V.8, ID 19487 V.8.  
Last Updated: 10/09/2018  
Version: 8 - Effective: 01/01/2019



HealthSun Health Plans  
2019 Prior Authorization Criteria

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	For endometriosis and uterine fibroids, patient will be using nonhormonal contraception during and for 12 weeks after therapy.

## LYNPARZA

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### Products Affected

- LYNPARZA

<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>	None
<b>Required Medical Information</b>	Appropriate diagnosis and testing for BRCA mutation (deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA approved test) advanced ovarian cancer that has been treated with 3 or more prior lines of chemotherapy)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## MATULANE

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### Products Affected

- MATULANE

<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>	None
<b>Required Medical Information</b>	Treatment of Hodgkin's Lymphoma OR medulloblastoma in combination with nitrogen mustard, vincristine and prednisone OR high-grade malignant glioma in combination with lomustine and vincristine
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## MEKINIST

### Products Affected

- MEKINIST

<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>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced or metastatic anaplastic thyroid cancer with documented positive BRAF V600E or V600K mutation as detected by an FDA-approved test as single agent or used in combination with Tafinlar OR Diagnosis of metastatic or unresectable melanoma and metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test OR Diagnosis of BRAF V600K mutation-positive unresectable or metastatic melanoma or use as adjuvant treatment of BRAF V600K mutation-positive melanoma
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## MS INTERFERONS

### Products Affected

- AVONEX
- AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT
- AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT
- BETASERON SUBCUTANEOUS KIT
- PLEGRIDY
- PLEGRIDY STARTER PACK SUBCUTANEOUS SOLUTION PEN-INJECTOR

<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>	None
<b>Required Medical Information</b>	Diagnosis of relapsing form of multiple sclerosis OR diagnosis of first clinical episode and MRI features consistent with multiple sclerosis.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## NERLYNX

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### Products Affected

- NERLYNX

<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>	None
<b>Required Medical Information</b>	Diagnosis of early stage HER2- overexpressed breast cancer. Must be used after trastuzumab therapy.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## NEXAVAR

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### Products Affected

- NEXAVAR

<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>	Squamous cell lung cancer being treated with carboplatin and paclitaxel.
<b>Required Medical Information</b>	Diagnosis of unresectable hepatocellular carcinoma OR Diagnosis of advanced renal cell carcinoma OR Diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## NINLARO

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### Products Affected

- NINLARO

<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>	None
<b>Required Medical Information</b>	Diagnosis of multiple myeloma, documentation of combination therapy with lenalidomide and dexamethasone. History of 1 prior therapy.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only



## NORTHERA

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### Products Affected

- NORTHERA

<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>	None
<b>Required Medical Information</b>	Request will be approved for the following indication(s): orthostatic dizziness, light-headedness, or the feeling that you are about to black out in adults with neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (i.e., Parkinson disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy).
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## **NUEDEXTA**

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### **Products Affected**

- NUEDEXTA

<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>	None
<b>Required Medical Information</b>	Patient diagnosis of pseudobulbar affect.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## NUPLAZID

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### Products Affected

- NUPLAZID ORAL TABLET 17 MG

<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>	None
<b>Required Medical Information</b>	Diagnosis of Parkinson disease psychosis including hallucinations and/or delusions
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## OPSUMIT

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### Products Affected

- OPSUMIT

<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>	Pregnancy.
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension WHO group I AND diagnosis was confirmed by right heart catheterization AND female patients are enrolled in the OPSUMIT REMS program.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Reauthorization: 12 months
<b>Other Criteria</b>	None

## ORKAMBI

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### Products Affected

- ORKAMBI ORAL TABLET

<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>	None
<b>Required Medical Information</b>	Initial Therapy: Diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test AND if less than 18 years of age, baseline ophthalmological exam completed. Continuation of therapy: Documentation patient is tolerating and responding to medication (i.e. improved FEV1, weight gain, decreased exacerbations, etc.)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Must be prescribed by, or in conjunction with, a pulmonologist or is from a CF center accredited by the Cystic Fibrosis Foundation
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## OSPHERA

### Products Affected

- OSPHERA

<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>	Vaginal bleeding or dysfunctional uterine bleeding of an undetermined origin, known or suspected estrogen-dependent neoplasia, acute thromboembolism or a past history of thromboembolic disease (including patients with a history of DVT, pulmonary embolism, retinal vein thrombosis, stroke, or myocardial infarction, known or suspected pregnancy.
<b>Required Medical Information</b>	Diagnosis of moderate to severe dyspareunia or atrophic vaginitis AND A) Patient must be female, B) Patient must be menopausal or postmenopausal, C) Patient has tried and failed, has a contraindication or intolerance to a low dose vaginal estrogen preparation (Premarin vaginal cream, Estrace vaginal cream, Estring, Vagifem), D) Dose must not exceed 1 tablet per day, E) Patient does not have hepatic impairment.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

Formularies: ID 19482 V.8, ID 19485 V.8, ID 19487 V.8.  
Last Updated: 10/09/2018  
Version: 8 - Effective: 01/01/2019

## PCSK9 INHIBITOR

### Products Affected

- PRALUENT SUBCUTANEOUS SOLUTION PEN-INJECTOR
- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	<p>For PRALUENT: MUST MEET CRITERIA #1 OR #3. For REPATHA: MUST MEET CRITERIA #1, #2, OR #3. 1. Diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by genotyping OR Simon Broome criteria: Total cholesterol greater than 290mg/dL or LDL cholesterol greater than 190mg/dL, PLUS ONE OF THE FOLLOWING: Tendon xanthomas in patient or 1st degree relative (parent, sibling, child) or 2nd degree relative (grandparent, uncle, aunt) OR DNA-based evidence of LDL receptor mutation, familial defective apo B-100, or PCSK9 mutation. 2a. Myocardial infarction prophylaxis, stroke prophylaxis, and to reduce risk of coronary revascularization in patients with established CVD OR 2b. Diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by genotyping OR diagnosis based on the following: a. History of untreated LDL-C greater than 500 mg/dL AND xanthoma before 10 years of age OR b. Documentation of HeFH in both parents. 3. Diagnosis of clinical atherosclerotic cardiovascular disease as defined as one of the following: a. acute coronary syndrome, b. history of myocardial infarction, c. stable/unstable angina, d. coronary or other arterial revascularization, e. stroke, f. transient ischemic stroke, g. peripheral arterial disease presumed to be atherosclerotic region AND MEETS CRITERIA #4, #5, and #6. 4. Provide baseline and current LDL-C. 5. LDL-C greater than or equal to 70mg/dL. 6. Used</p>

Formularies: ID 19482 V.8, ID 19485 V.8, ID 19487 V.8.  
Last Updated: 10/09/2018  
Version: 8 - Effective: 01/01/2019

HealthSun Health Plans  
2019 Prior Authorization Criteria

<b>PA Criteria</b>	<b>Criteria Details</b>
	in combination with maximally tolerated high-intensity statin OR MEETS CRITERIA #7 AND #8. 7. Statin intolerant 8. LDL-C greater than or equal to 70mg/dL. CONTINUING THERAPY: 1. Documented response to Praluent or Repatha, defined as ONE of the following: a. The patient is tolerating medication b. Will continue to be used in combination with maximally tolerated statin (unless statin intolerant).
<b>Age Restrictions</b>	Repatha: 13 years of age and older for diagnosis HoFM, Diagnosis CVD and HeFH AND Praluent and Repatha : 18 years of age and older
<b>Prescriber Restrictions</b>	Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or lipid specialist
<b>Coverage Duration</b>	Initial approval: 8 weeks, Renewal approval: 12 months
<b>Other Criteria</b>	None



## POMALYST

### Products Affected

- POMALYST

<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>	None
<b>Required Medical Information</b>	Documentation of ALL of the following: 1. Disease has progressed within 60 days of completion of the last therapy 2. If female of reproductive potential ALL of the below: Two negative pregnancy tests obtained prior to initiating therapy with Pomalyst, monthly negative pregnancy tests during therapy 3. Patient has been counseled about the use of reliable contraception before, during, and 1 month after initiation of therapy with Pomalyst 4. Patient assessment to determine if prophylactic aspirin or antithrombic treatment (warfarin, clopidogrel) will need to be taken to reduce the risk of VTE (embolism, stroke) 5. Registered and certified to be compliant with Pomalyst REMS (Risk Evaluation and Mitigation Strategy) program
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Oncologist or hematologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	A documented diagnosis of multiple myeloma and received at least two prior therapies including lenalidomide (Revlimid) and bortezomib (Velcade)

Formularies: ID 19482 V.8, ID 19485 V.8, ID 19487 V.8.  
Last Updated: 10/09/2018  
Version: 8 - Effective: 01/01/2019

## PROVIGIL

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### Products Affected

- *modafinil*

<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>	None
<b>Required Medical Information</b>	Supporting statement of diagnosis from the physician
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## REGANEX

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### Products Affected

- REGANEX

<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>	None
<b>Required Medical Information</b>	Diabetic Neuropathic Ulcers: Diabetic patient with ulcer wound. Treatment will be given in combination with ulcer wound care (debridement, infection control, and/or pressure relief).
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Diabetic Neuropathic Ulcers: Maximum 5 months.
<b>Other Criteria</b>	None

## RUBRACA

### Products Affected

- RUBRACA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer and all of the following criteria: 1. BRCA mutation detected by an approved FDA laboratory test, 2. Previous trial/failure with two or more chemotherapy regimens, 3. Used as monotherapy, 4. Agreement of provider to perform a complete blood count (CBC) at baseline and monthly thereafter, 5. Women of reproductive potential must use an effective method of contraception during therapy and for 6 months after the last dose OR Diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and all of the following: 1. Complete or partial response to platinum-based chemotherapy 2. Used as monotherapy 3. Agreement of provider to perform a complete blood count (CBC) at baseline and monthly thereafter, 4. Women of reproductive potential must use an effective method of contraception during therapy and for 6 months after the last dose.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Hematologist or Oncologist
<b>Coverage Duration</b>	12 months

Formularies: ID 19482 V.8, ID 19485 V.8, ID 19487 V.8.  
Last Updated: 10/09/2018  
Version: 8 - Effective: 01/01/2019

HealthSun Health Plans  
2019 Prior Authorization Criteria

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	This criteria applies to new starts only

## RYDAPT

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### Products Affected

- RYDAPT

<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>	Angioedema
<b>Required Medical Information</b>	Diagnosis of treatment naive FLT3 mutation-positive acute myelogenous leukemia (AML) and must be used in combination with standard cytarabine and daunorubicin induction and consolidation therapy or diagnosis of systemic mastocytosis.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## SAMSCA

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### Products Affected

- SAMSCA

<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>	None
<b>Required Medical Information</b>	Supporting statement of diagnosis from the physician
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## SILDENAFIL

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### Products Affected

- *sildenafil citrate oral tablet 20 mg*

<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>	None
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None



## SPRYCEL

### Products Affected

- SPRYCEL

<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>	None
<b>Required Medical Information</b>	Diagnosis of Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) that is newly diagnosed in the chronic phase OR Ph+ CML with resistance or intolerance to prior therapy, including imatinib OR Diagnosis of Ph+ acute lymphoblastic leukemia with resistance or intolerance to prior therapy OR Gastrointestinal stromal tumors (GIST) after disease progression on imatinib or Sutent (sunitinib)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## STIVARGA

### Products Affected

- STIVARGA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of metastatic colorectal cancer AND documentation of prior therapy with ALL of the following per the indication: 1. fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy 2. bevacizumab (Avastin) 3. panitumumab (Vectibix) OR cetuximab (Erbix) (for KRAS mutation-negative patients only) OR a documented diagnosis of locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate (Gleevec) and sunitinib malate (Sutent) OR a documented diagnosis of hepatocellular carcinoma in patients previously treated with sorafenib (Nexavar).
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## SUTENT

### Products Affected

- SUTENT

<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>	None
<b>Required Medical Information</b>	Diagnosis of advanced/metastatic renal cell carcinoma OR Diagnosis of gastrointestinal stromal tumors after disease progression on or intolerance to Gleevec OR Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease OR Diagnosis of high risk recurrent renal cell carcinoma following nephrectomy, used as adjuvant therapy.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## SYLATRON

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### Products Affected

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

<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>	Autoimmune hepatitis. Hepatic decompensation (Child-Pugh score greater than 6 [Class B or C])
<b>Required Medical Information</b>	Melanoma: Diagnosis of melanoma with microscopic or gross nodal involvement AND The prescribed medication will be used as adjuvant therapy within 84 days of definitive surgical resection, including complete lymphadenectomy.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## **SYMDEKO**

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### **Products Affected**

- SYMDEKO

<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>	None
<b>Required Medical Information</b>	Diagnosis of cystic fibrosis and patient is homozygous for the F508del mutation OR have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor verified by an FDA-cleared CF mutation test
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Reauthorization: 12 months
<b>Other Criteria</b>	None

## SYNRIBO

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### Products Affected

- SYNRIPO

<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>	None
<b>Required Medical Information</b>	Diagnosis of chronic myelogenous leukemia AND patient has tried and failed or has a contraindication or intolerance to 2 tyrosine kinase inhibitors
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## SYPRINE

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### Products Affected

- *trientine hcl*

<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>	None
<b>Required Medical Information</b>	Diagnosis of Wilson's disease and intolerance to penicillamine
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## TAFINLAR

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### Products Affected

- TAFINLAR

<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>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced or metastatic anaplastic thyroid cancer with documented positive BRAF V600E or V600K mutation as detected by an FDA-approved test as single agent or used in combination with Mekinist OR Diagnosis of metastatic or unresectable melanoma and metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Tafinlar should not be used in patients with wild-type BRAF melanoma due to the potential risk of tumor promotion in these patients



## TAGRISSO

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### Products Affected

- TAGRISSO

<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>	None
<b>Required Medical Information</b>	Diagnosis of metastatic, non-small cell lung cancer with one of the following- confirmed presence of T790M EGFR tumor mutation OR confirmed presence of epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R tumor mutations, as detected by an FDA-approved test.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## TARCEVA

### Products Affected

- TARCEVA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer and Tarceva will be used in combination with gemcitabine OR Diagnosis of locally advanced or metastatic (stage III or IV) non-small cell lung cancer with one of the following: A) failure with at least one prior chemotherapy regimen and Tarceva will be used as monotherapy, or B) no evidence of disease progression after four cycles of first-line platinum-based chemotherapy and Tarceva will be used as maintenance treatment and Tarceva will be used as monotherapy, or C) Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

# TASIGNA

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## Products Affected

- TASIGNA

<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>	Long QT syndrome. Uncorrected hypokalemia. Uncorrected hypomagnesemia. Concomitant use with a drug known to prolong the QT interval or strong cytochrome P450 3A4 inhibitors
<b>Required Medical Information</b>	Diagnosis of newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in the chronic phase OR Diagnosis of Ph+ CML with resistance or intolerance to prior therapy that include imatinib.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## TECFIDERA

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### Products Affected

- TECFIDERA

<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>	None
<b>Required Medical Information</b>	Diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting MS or progressive-relapsing MS, or secondary-progressive MS) OR patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## TOBI

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### Products Affected

- TOBI PODHALER

<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>	None
<b>Required Medical Information</b>	This agent may be considered medically necessary when the following criteria are met: Cystic Fibrosis-The patient has a diagnosis of cystic fibrosis (CF). The patient is colonized with P. Aeruginosa.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## TRACLEER

### Products Affected

- TRACLEER

<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>	Receiving concomitant cyclosporine A or glyburide therapy. Aminotransferase elevations are accompanied by signs or symptoms of liver dysfunction or injury or increases in bilirubin at least 2 times the upper limit of normal.
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension that was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) AND Patient has WHO Group I PAH AND Patient has New York Heart Association (NYHA) Functional Class II-IV AND pregnancy must be excluded prior to the start of therapy and will be prevented thereafter with two forms of reliable contraception in female patients of reproductive potential.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 6 months, Reauthorization: 12 months
<b>Other Criteria</b>	Liver aminotransferases will be measured prior to initiation of treatment and then monthly.

## TRETINOIN

### Products Affected

- *tretinoin external cream*
- *tretinoin external gel 0.01 %, 0.025 %*

<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>	None
<b>Required Medical Information</b>	Approval will be given to all members using this agent for a medically necessary, FDA approved, non-cosmetic indication(s).
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## TYKERB

### Products Affected

- TYKERB

<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>	None
<b>Required Medical Information</b>	Diagnosis of breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND a) the medication will be used in combination with Xeloda in a patient with advanced or metastatic disease and the patient has received prior therapy including an anthracycline, a taxane, and trastuzumab or b) The medication will be used in combination with Femara for the treatment of a postmenopausal woman with hormone receptor-positive metastatic disease for whom hormonal therapy is indicated.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only



# TYMLOS

## Products Affected

- TYMLOS

<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>	Patients at increased risk of osteogenic sarcoma.
<b>Required Medical Information</b>	Diagnosis of osteoporosis in post-menopausal women at high risk for fracture. Member must have failed therapy with a bisphosphonate (defined by a fracture while on therapy or worsening bone density) unless such a trial is shown to be inappropriate or contraindicated (i.e., presence of severe osteoporosis [T-scores -3.0 or worse in lumbar spine, femoral neck, or total hip region], history of major osteoporotic fracture, presence of renal insufficiency, etc) AND member has at least one of the following: T-score equal to or worse than -2.5 in the lumbar spine, femoral neck, or total hip region OR a FRAX calculator based 10-year risk of at least 20% for a major osteoporotic fracture (spine, shoulder, hip, or wrist), or a 10-year risk of at least 3% for a hip fracture OR presence or history of osteoporotic fracture.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	Initial: 12 months, Renewal: Total duration not to exceed 24 months during patient's lifetime.
<b>Other Criteria</b>	None

Formularies: ID 19482 V.8, ID 19485 V.8, ID 19487 V.8.  
Last Updated: 10/09/2018  
Version: 8 - Effective: 01/01/2019

## UPTRAVI

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### Products Affected

- UPTRAVI

<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>	None
<b>Required Medical Information</b>	Diagnosis of pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization AND patient has tried and had an insufficient response to at least one other PAH agent (e.g., sildenafil) therapy and one other ERA agent (e.g. letairis, opsumit, tracleer).
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None

## VENCLEXTA

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### Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

<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>	None
<b>Required Medical Information</b>	Diagnosis of chronic lymphocytic leukemia (CLL) OR small lymphocytic lymphoma, with or without 17p deletion and patient has had at least 1 prior therapy
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## VERZENIO

### Products Affected

- VERZENIO

<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>	None
<b>Required Medical Information</b>	BREAST CANCER (1) Patient must have a diagnosis of advanced or metastatic breast cancer AND (2a) must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy OR (2b) used as monotherapy for treatment of disease progression following endocrine therapy and patient has already received at least one prior chemotherapy regimen of Ibrance or Kisqali OR (2c) used as initial endocrine-based treatment in combination with an aromatase inhibitor AND (3) disease is hormone receptor positive AND human epidermal growth factor 2 (HER2)- negative
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Approve for continuation of therapy

## VOTRIENT

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### Products Affected

- VOTRIENT

<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>	None
<b>Required Medical Information</b>	Diagnosis of advanced/metastatic renal cell carcinoma OR Diagnosis of advanced soft tissue sarcoma and patient received at least one prior chemotherapy (doxorubicin, dacarbazine, ifosfamide, epirubicin, docetaxel, or vinorelbine).
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## XALKORI

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### Products Affected

- XALKORI

<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>	None
<b>Required Medical Information</b>	Diagnosis of locally advanced or metastatic (stage III or IV) non-small cell lung cancer AND patient has non-squamous cell histology AND Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility or are ROS1-positive
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Must be prescribed by an oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## XTANDI

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### Products Affected

- XTANDI

<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>	None
<b>Required Medical Information</b>	Metastatic castration-resistant prostate cancer (mCRPC): Diagnosis of mCRPC. History of failure, contraindication or intolerance to Zytiga.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## XURIDEN

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### Products Affected

- XURIDEN

<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>	None
<b>Required Medical Information</b>	Diagnosis of Hereditary orotic aciduria
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist that treats metabolic defects
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	None



## YONSA

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### Products Affected

- YONSA

<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>	None
<b>Required Medical Information</b>	Diagnosis of metastatic castration-resistant prostate cancer, and used in combination with methylprednisolone AND Documented history of trial with, inadequate treatment response, adverse event, or contraindication to Zytiga
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or urologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## ZEJULA

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### Products Affected

- ZEJULA

<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>	None
<b>Required Medical Information</b>	Diagnosis of recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer and patient had a complete or partial response to platinum-based chemotherapy.
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or gynecologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## ZELBORAF

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### Products Affected

- ZELBORAF

<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>	None
<b>Required Medical Information</b>	Diagnosis of unresectable or metastatic melanoma OR Erdheim-Chester disease. Patient has positive BRAF-V600E mutation documented by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Oncologist
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## ZOLINZA

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### Products Affected

- ZOLINZA

<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>	None
<b>Required Medical Information</b>	Diagnosis of cutaneous T-cell lymphoma AND progressive, persistent or recurrent disease or patient is not a candidate for or following 2 systemic therapies (bexarotene, romidepsin, etc.)
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## ZYDELIG

### Products Affected

- ZYDELIG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
<b>Required Medical Information</b>	The patient has one of the following diagnoses: A) chronic lymphocytic leukemia AND The medication will be used in combination with rituximab AND The patient has relapsed on at least one prior therapy (purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]) AND the patient does not have any co-morbidities that prevents the use of cytotoxic chemotherapy (severe neutropenia or thrombocytopenia, creatinine clearance less than 60 mL/minute), B) follicular lymphoma AND the patient has relapsed on at least two prior systemic therapies (rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicin], purine analogs [fludarabine]), or C) small lymphocytic lymphoma AND The patient has relapsed on at least two prior systemic therapies (rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicin], purine analogs [fludarabine]).
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months

Formularies: ID 19482 V.8, ID 19485 V.8, ID 19487 V.8.  
Last Updated: 10/09/2018  
Version: 8 - Effective: 01/01/2019

HealthSun Health Plans  
2019 Prior Authorization Criteria

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	This criteria applies to new starts only

## ZYKADIA

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### Products Affected

- ZYKADIA

<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>	None
<b>Required Medical Information</b>	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC).
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only

## ZYTIGA

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### Products Affected

- ZYTIGA

<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>	Pregnancy
<b>Required Medical Information</b>	Diagnosis of metastatic prostate cancer AND Patient has castration-resistant disease (defined by tumor growth/disease progression, risk in PSA levels, new metastases) OR high-risk castration-sensitive prostate cancer AND Zytiga will be used in combination with prednisone.
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	None
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	This criteria applies to new starts only



## PART B VERSUS PART D

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### Products Affected

- *acetylcysteine inhalation*
- *acyclovir sodium intravenous solution*
- *albuterol sulfate inhalation*
- AMBISOME
- *amikacin sulfate injection solution 500 mg/2ml*
- AMINOSYN II INTRAVENOUS SOLUTION 10 %, 8.5 %
- AMINOSYN II/ELECTROLYTES
- AMINOSYN/ELECTROLYTES
- AMINOSYN-HBC
- AMINOSYN-PF
- AMINOSYN-RF
- *amphotericin b injection*
- *ampicillin sodium injection solution reconstituted 1 gm, 125 mg*
- *ampicillin sodium intravenous solution reconstituted 10 gm*
- *ampicillin-sulbactam sodium injection*
- *aprepitant*
- ARCALYST
- ASTAGRAF XL
- AZACTAM INJECTION SOLUTION RECONSTITUTED 2 GM
- AZASAN
- *azathioprine oral*
- *azithromycin intravenous solution reconstituted 500 mg*
- BIVIGAM INTRAVENOUS SOLUTION 10 GM/100ML
- BROVANA
- *budesonide inhalation*
- *calcitonin (salmon)*
- *calcitriol oral*
- *casprofungin acetate*
- *cefazolin sodium injection solution reconstituted 1 gm, 10 gm, 500 mg*
- *cefepime hcl injection*
- *cefoxitin sodium*
- *ceftriaxone sodium injection solution reconstituted 1 gm, 2 gm, 250 mg, 500 mg*
- *ceftriaxone sodium intravenous solution reconstituted 10 gm*
- *cefuroxime sodium injection solution reconstituted 7.5 gm, 750 mg*
- *cefuroxime sodium intravenous solution reconstituted 1.5 gm*
- *chlorpromazine hcl oral*
- CINRYZE
- *ciprofloxacin in d5w intravenous solution 200 mg/100ml*
- *clindamycin phosphate injection solution 600 mg/4ml*
- CLINIMIX E/DEXTROSE (2.75/10)
- CLINIMIX E/DEXTROSE (2.75/5)
- CLINIMIX E/DEXTROSE (4.25/10)
- CLINIMIX E/DEXTROSE (4.25/25)
- CLINIMIX E/DEXTROSE (4.25/5)
- CLINIMIX E/DEXTROSE (5/15)
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- *cyclophosphamide oral capsule*
- *cyclosporine modified*
- *cyclosporine oral capsule*
- *daptomycin intravenous solution reconstituted 500 mg*
- DEPO-PROVERA INTRAMUSCULAR SUSPENSION 400 MG/ML
- *dextrose intravenous solution 10 %, 5 %*
- *dextrose-nacl intravenous solution 10-0.2 %, 10-0.45 %, 2.5-0.45 %, 5-0.2 %, 5-0.225 %, 5-0.33 %, 5-0.45 %, 5-0.9 %*
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- ERAXIS
- ERYTHROCIN LACTOBIONATE INTRAVENOUS SOLUTION RECONSTITUTED 500 MG
- FIRMAGON
- FLEBOGAMMA DIF INTRAVENOUS SOLUTION 5 GM/50ML
- *fluconazole in sodium chloride intravenous solution 200-0.9 mg/100ml-%, 400-0.9 mg/200ml-%*
- FREAMINE HBC
- *furosemide injection*
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- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML
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- *granisetron hcl oral*
- *heparin sodium (porcine) injection solution 1000 unit/ml, 10000 unit/ml, 20000 unit/ml, 5000 unit/ml*
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- *ipratropium-albuterol*
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- *levalbuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/0.5ml, 1.25 mg/3ml*
- *levocarnitine oral solution*
- *levocarnitine oral tablet*

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- *levofloxacin in d5w intravenous solution 500 mg/100ml, 750 mg/150ml*
- *levofloxacin intravenous*
- *linezolid intravenous solution 600 mg/300ml*
- *magnesium sulfate injection solution 50 %, 50 % (10ml syringe)*
- *meropenem*
- *methotrexate oral*
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
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- *metronidazole in nacl intravenous solution 500-0.79 mg/100ml-%*
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- NORMOSOL-R IN D5W
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- *octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml*
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- *ondansetron hcl oral*
- *paricalcitol oral*
- *penicillin g potassium injection solution reconstituted 20000000 unit*
- *penicillin g sodium*
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- *perphenazine oral tablet 4 mg, 8 mg*
- *piperacillin sod-tazobactam so intravenous solution reconstituted 2.25 (2-0.25) gm, 3.375 (3-0.375) gm, 4.5 (4-0.5) gm*
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- *potassium chloride in nacl intravenous solution 20-0.45 meq/l-%, 20-0.9 meq/l-%*
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- PROSOL
- PULMOZYME
- RABAVERT
- RAPAMUNE ORAL SOLUTION
- RECOMBIVAX HB
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- SENSIPAR
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- TREXALL
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- *vancomycin hcl intravenous solution reconstituted 10 gm, 1000 mg, 500 mg*
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- XATMEP
- 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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