

**Kalos Health Gold Plus
2020 Formulary - Prior Authorization Criteria**

ACITRETIN

Products Affected

- *acitretin*

PA Criteria	Criteria Details
Exclusion Criteria	Severely impaired liver or kidney function. Chronic abnormally elevated blood lipid values. Concomitant use of methotrexate or tetracyclines. Pregnancy. Females of child-bearing potential who intend to become pregnant during therapy or at any time for at least 3 years after discontinuing therapy. Females of child-bearing potential who will not use reliable contraception while undergoing treatment and for at least 3 years following discontinuation. Females of child-bearing potential who drink alcohol during treatment or for two months after cessation of therapy
Required Medical Information	Diagnosis for severe, recalcitrant psoriasis (including plaque, guttate, erythrodermic palmar- plantar and pustular) AND patient must have tried and failed, contraindication or intolerance to one formulary first line agent (e.g., Topical Corticosteroids (betamethasone, fluocinonide, desoximetasone), Topical Calcipotriene/Calcitriol, Topical Calcipotriene, OR Topical Tazarotene)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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 Last Updated: 11/30/2020
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ACTIMMUNE

Products Affected

- ACTIMMUNE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic granulomatous disease for use in reducing the frequency and severity of serious infections associated with chronic granulomatous disease, or B.) Severe, malignant osteopetrosis (SMO)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ADEMPAS

Products Affected

- ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant administration with nitrates or nitric oxide donors (such as amyl nitrate) in any form, B.) 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), C.) Pregnancy, or D.) Patients with pulmonary hypertension associated with idiopathic interstitial pneumonia
Required Medical Information	Diagnosis of one of the following A.) Pulmonary arterial hypertension (WHO group I) and diagnosis was confirmed by right heart catheterization, or B.) Chronic thromboembolic pulmonary hypertension (CTEPH, WHO group 4) and patient has persistent or recurrent disease after surgical treatment (e.g., pulmonary endarterectomy) or has CTEPH that is inoperable (Female patients must be enrolled in the ADEMPAS REMS program)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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AFINITOR

Products Affected

- AFINITOR DISPERZ
- AFINITOR ORAL TABLET 10 MG
- *everolimus oral tablet 2.5 mg, 5 mg, 7.5 mg*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Everolimus (Afinitor): Diagnosis of one of the following A.) Advanced metastatic renal cell carcinoma and patient has failed therapy (disease progressed) with Sutent or Nexavar, B.) Diagnosis of pancreatic neuroendocrine tumors (pNET) that are unresectable, locally advanced, or metastatic, C.) Diagnosis of renal angiomyolipoma with tuberous sclerosis complex (TSC) and patient does not require immediate surgery, D.) 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, E.) Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with TSC that requires therapeutic intervention but is not a candidate for curative surgical resection, or F.) 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. Afinitor Disperz: Diagnosis of one of the following A.) Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with TSC that requires therapeutic intervention but is not a candidate for curative surgical resection, or B.) Diagnosis of partial-onset seizures associated with tuberous sclerosis complex (TSC)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or neurologist
Coverage Duration	12 months

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PA Criteria	Criteria Details
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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ALECENSA

Products Affected

- ALECENSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic anaplastic lymphoma kinase positive non-small cell lung cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ALOSETRON

Products Affected

- *alosetron hcl*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Constipation, B.) History of Chronic or severe constipation or sequelae from constipation, C.) History of ischemic colitis, intestinal obstruction, stricture, toxic megacolon, GI perforation, adhesions, diverticulitis, Crohns disease, ulcerative colitis, D.) History of severe hepatic impairment, E.) History of impaired intestinal circulation, thrombophlebitis, or hypercoagulable state, F.) Coadministration with fluvoxamine
Required Medical Information	Diagnosis of irritable bowel syndrome, severe diarrhea-predominant
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ALPHA1-PROTEINASE INHIBITOR

Products Affected

- PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	Not covered for patients with IgA deficiency
Required Medical Information	Diagnosis of alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency in adult patients with emphysema
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ALUNBRIG

Products Affected

- ALUNBRIG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic, ALK positive non-small cell lung cancer and have progressed or are intolerant to Xalkori (crizotinib)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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AMBRISENTAN

Products Affected

- *ambrisentan*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Pregnancy, or B.) Idiopathic pulmonary fibrosis (IPF), including those with pulmonary hypertension
Required Medical Information	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
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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AMPYRA

Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) History of seizure. B.) Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute)
Required Medical Information	Diagnosis of multiple sclerosis and patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting dalfampridine
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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APOKYN

Products Affected

- APOKYN SUBCUTANEOUS SOLUTION CARTRIDGE

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with 5-HT(3) receptor antagonists (eg. ondansetron, granisetron, dolasetron, palonosetron, alosetron etc)
Required Medical Information	Diagnosis of Parkinson's disease (PD) and patient is experiencing acute intermittent hypomobility (defined as off episodes characterized by muscle stiffness, slow movements, or difficulty starting movements)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ARCALYST

Products Affected

- ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells Syndrome (MWS)
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ARIKAYCE

Products Affected

- ARIKAYCE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of pulmonary Mycobacterium avium complex (MAC) infection and used as part of a combination antibacterial regimen in treatment refractory patients
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist or pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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AURYXIA

Products Affected

- AURYXIA

PA Criteria	Criteria Details
Exclusion Criteria	Iron overload syndrome (e.g. hemochromatosis)
Required Medical Information	Diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or nephrologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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AUSTEDO

Products Affected

- AUSTEDO

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Suicidal ideation and/or untreated or inadequately treated depression. B.) Hepatic impairment. C. Taking MAOIs, reserpine, or tetrabenazine
Required Medical Information	Diagnosis of one of the following A.) Chorea associated with Huntington's disease (Huntington's chorea), or B.) Tardive dyskinesia
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist or neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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AYVAKIT

Products Affected

- AYVAKIT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of unresectable or metastatic gastrointestinal stromal tumor, with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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BALVERSA

Products Affected

- BALVERSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 or FGFR2 genetic alterations and patient has progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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BANZEL

Products Affected

- BANZEL

PA Criteria	Criteria Details
Exclusion Criteria	Familial Short QT Syndrome
Required Medical Information	Diagnosis of seizures associated with Lennox-Gastaut syndrome
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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BENLYSTA

Products Affected

- BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of active, autoantibody-positive, system lupus erythematosus (SLE)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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BEXAROTENE

Products Affected

- *bexarotene*
- TARGRETIN EXTERNAL

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cutaneous T-cell lymphoma (CTCL) and patient is not a candidate for or had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) for cutaneous manifestations of CTCL
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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BOSENTAN

Products Affected

- *bosentan*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Receiving concomitant cyclosporine A or glyburide therapy, B.) 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, or C.) Pregnancy
Required Medical Information	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 all of the following: A.) Patient has WHO Group I PAH, B.) Patient has New York Heart Association (NYHA) Functional Class II-IV, and C.) Female patients of reproductive potential must use two forms of reliable contraception
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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BOSULIF

Products Affected

- BOSULIF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) 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], Tasisna [nilotinib], Sprycel [dasatinib] , or B.) newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph + CML)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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BRAFTOVI

Products Affected

- BRAFTOVI ORAL CAPSULE 75 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) unresectable or metastatic melanoma with documented BRAF V600E or V600K mutation as detected by a FDA-approved test and used in combination with binimetinib, or B.) metastatic colorectal cancer with documented BRAF V600E mutation as detected by an FDA-approved test and patient has received prior therapy. Must be used in combination with cetuximab.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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BRUKINSA

Products Affected

- BRUKINSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of A.) Mantle Cell Lymphoma (MCL) and patient has tried one prior therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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CABLIVI

Products Affected

- CABLIVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) and used in combination with plasma exchange and immunosuppression therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	3 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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CABOMETYX

Products Affected

- CABOMETYX

PA Criteria	Criteria Details
Exclusion Criteria	Patients who have or are at risk for severe hemorrhage and/or patients with a recent history of bleeding or hemoptysis
Required Medical Information	Diagnosis of one of the following A.) Advanced renal cell carcinoma, or B.) Advanced hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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CALQUENCE

Products Affected

- CALQUENCE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) MANTLE CELL LYMPHOMA (MCL) and patient has tried one other therapy, B.) Chronic lymphocytic leukemia, or C.) Small lymphocytic lymphoma
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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CAPRELSA

Products Affected

- CAPRELSA

PA Criteria	Criteria Details
Exclusion Criteria	Congenital long QT syndrome
Required Medical Information	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.
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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CARBAGLU

Products Affected

- CARBAGLU

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of of one of the following A.) N-acetyl glutamate synthase (NAGS) deficiency AND patient has acute hyperammonemia, or B.) N-acetyl glutamate synthase (NAGS) deficiency AND patient has chronic hyperammonemia
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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CAYSTON

Products Affected

- CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	none
Required Medical Information	Diagnosis of cystic fibrosis is confirmed by appropriate diagnostic or genetic testing AND confirmation of P. aeruginosa in cultures of the airways
Age Restrictions	7 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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CINRYZE

Products Affected

- CINRYZE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Hereditary angioedema (HAE)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, immunologist, or allergist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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CLOBAZAM

Products Affected

- *clobazam*
- SYMPAZAN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of seizures associated with Lennox-Gastaut syndrome
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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CNS STIMULANTS

Products Affected

- armodafinil*
- modafinil*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Obstructive sleep apnea (OSA) confirmed by sleep lab evaluation, B.) Narcolepsy confirmed by sleep lab evaluation, or C.) Shift work disorder (SWD)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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COMETRIQ

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following a.) Gastrointestinal perforation, B.) Fistula, or C.) Severe hemorrhage
Required Medical Information	Diagnosis of Progressive, metastatic medullary thyroid cancer (MTC)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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COPIKTRA

Products Affected

- COPIKTRA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsed or refractory (with history of 2 prior therapies) of one of the following A) chronic lymphocytic leukemia, B) small lymphocytic lymphoma, or C) follicular lymphoma
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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CORLANOR

Products Affected

- CORLANOR

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Decompensated acute heart failure, B.) hypotension (i.e. blood pressure less than 90/50 mmHg), C.) sick sinus syndrome or sinoatrial block or 3rd degree AV block (unless a functioning demand pacemaker is present), D.) bradycardia (i.e., resting heart rate less than 60 bpm prior to treatment), or E.) Severe hepatic impairment (Child-Pugh C)
Required Medical Information	Diagnosis of one of the following A.) stable, symptomatic chronic heart failure with left ventricular ejection fraction 35% or less, who are in sinus rhythm with resting heart rate 70 beats per minute or more and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use, or B.) stable, symptomatic heart failure due to dilated cardiomyopathy in patients who are in sinus rhythm with an elevated heart rate
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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Kalos Health Gold Plus

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COSENTYX

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	<p>Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Failure, contraindication, or intolerance to Enbrel (etanercept) AND Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Non-radiographic axial spondyloarthritis: Diagnosis of non-radiographic axial spondyloarthritis. All indications (Initial, reauth): Patient is not receiving Cosentyx in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Cosentyx in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]. For a diagnosis of PsA or plaque psoriasis, Patient is not receiving Cosentyx in combination with a phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)].</p>
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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COTELLIC

Products Affected

- COTELLIC

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of unresectable or metastatic malignant melanoma with BRAF V600E OR V600K mutation, and documentation of combination therapy with vemurafenib (Zelboraf)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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CYSTARAN

Products Affected

- CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	Demonstrated cysteamine hypersensitivity or penicillamine hypersensitivity
Required Medical Information	Diagnosis of cystinosis and patient has corneal cystine crystal accumulation
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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DALIRESP

Products Affected

- DALIRESP

PA Criteria	Criteria Details
Exclusion Criteria	Moderate to severe liver impairment (Child-Pugh B or C)
Required Medical Information	Diagnosis of severe chronic obstructive pulmonary disease (COPD) (defined as FEV1 less than or equal to 50% of predicted and FEV1/forced vital capacity [FVC] less than 0.7) associated with chronic bronchitis and a history of COPD exacerbations
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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DAPTOMYCIN

Products Affected

- *daptomycin*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Staphylococcus aureus bacteremia, B.) complicated skin and skin structure infections, including infections caused by methicillin-resistant Staphylococcus aureus (MRSA), or C.) endocarditis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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DAURISMO

Products Affected

- DAURISMO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of newly diagnosed acute myeloid leukemia (AML) and used in combination with cytarabine in patients 75 years of age or older OR in patients that have comorbidities that preclude use of intensive induction chemotherapy
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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DEFERASIROX

Products Affected

- *deferasirox*
- *deferasirox granules*
- JADENU SPRINKLE

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Creatinine clearance less than 40 mL/min, B.) Poor performance status, C.) Platelet count less than 50 x 10 ⁹ /L, D.) Advanced malignancy, E.) High-risk myelodysplastic syndrome (MDS)
Required Medical Information	Diagnosis of one of the following A.) Chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes who have liver iron concentrations of at least 5 mg Fe/g dry weight AND serum ferritin level greater than 300 mcg/L, or B.) Chronic iron overload due to blood transfusions (transfusion hemosiderosis) as evidenced by transfusion of at least 100 mL/kg packed red blood cells AND serum ferritin level greater than 1000 mcg/L
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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DICLOFENAC TOPICAL

Products Affected

- *diclofenac sodium transdermal gel 3 %*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Actinic keratosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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DOJOLVI

Products Affected

- DOJOLVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Long-chain fatty acid oxidation disorder (LC-FAOD)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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DRONABINOL

Products Affected

- *dronabinol*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Anorexia associated to AIDS, or B.) Chemotherapy-induced nausea and vomiting
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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DUPIXENT

Products Affected

- DUPIXENT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe atopic dermatitis and patient has trial and failure, contraindication, or intolerance to two medium to high potency topical corticosteroids (e.g., mometasone, triamcinolone, fluocinolone, betamethasone, etc), or B.) Eosinophilic phenotype or oral corticosteroid- dependent moderate to severe asthma and used as an adjunct treatment, or C.) Chronic rhinosinusitis with nasal polyposis and used as an adjunct treatment
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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EMSAM

Products Affected

- EMSAM

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use with any of the following: SSRIs, SNRIs, clomipramine, imipramine, meperidine, tramadol, methadone, pentazocine, propoxyphene, dextromethorphan, carbamazepine, B.) Pheochromocytoma
Required Medical Information	Diagnosis of major depressive disorder
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ENBREL

Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, or E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy. Screening for latent tuberculosis infection is required prior to initiation of treatment.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ENDARI

Products Affected

- ENDARI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of acute sickle cell disease AND patient must have trial history of Hydroxyurea. Otherwise Endari requires documentation of (1) history of inadequate treatment with Hydroxyurea OR (2) history of adverse event with Hydroxyurea OR (3) Hydroxyurea is contraindicated.
Age Restrictions	5 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ENSPRYNG

Products Affected

- ENSPRYNG

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Active Hepatitis B infection, or B.) Active or untreated latent tuberculosis
Required Medical Information	Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, immunologist, or ophthalmologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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ENTRESTO

Products Affected

- ENTRESTO

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) History of angioedema related to previous ACE inhibitor or ARB therapy, B.) Concomitant use or use within 36 hours of ACE inhibitors, or C.) Concomitant use of aliskiren in patients with diabetes
Required Medical Information	Diagnosis of one of the following A.) Chronic heart failure, NYHA Class II to IV, or B.) Symptomatic heart failure with systemic left ventricular systolic dysfunction
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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EPIDIOLEX

Products Affected

- EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Lennox-Gastaut syndrome, or B.) Severe myoclonic epilepsy in infancy (Dravet syndrome), or C.) Seizures associated with tuberous sclerosis complex
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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ERIVEDGE

Products Affected

- ERIVEDGE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic basal cell carcinoma, or B.) Diagnosis of locally advanced basal cell carcinoma that has recurred following surgery or when the patient is not a candidate for surgery and radiation
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ERLEADA

Products Affected

- ERLEADA

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Nonmetastatic, castration-resistant prostate cancer, or B.) Metastatic, castration-sensitive prostate cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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ERLOTINIB

Products Affected

- *erlotinib hcl*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) locally advanced, unresectable, or metastatic pancreatic cancer and erlotinib (Tarceva) will be used in combination with gemcitabine, or B.) locally advanced or metastatic non-small cell lung cancer with one of the following: 1.) failure with at least one prior chemotherapy regimen, 2.) no evidence of disease progression after four cycles of first-line platinum-based chemotherapy and Tarceva will be used as maintenance treatment, or 3.) 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.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ESBRIET

Products Affected

- ESBRIET ORAL CAPSULE
- ESBRIET ORAL TABLET 801 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of idiopathic pulmonary fibrosis
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ESRD THERAPY

Products Affected

- EPOGEN INJECTION SOLUTION UNIT/ML, 3000 UNIT/ML, 4000
10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML
- RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	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.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	3 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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EVRYSDI

Products Affected

- EVRYSDI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of spinal muscular atrophy (SMA)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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FARYDAK

Products Affected

- FARYDAK ORAL CAPSULE 10 MG, 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	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)].
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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FASENRA

Products Affected

- FASENRA
- FASENRA PEN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of severe asthma with an eosinophilic phenotype
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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FEBUXOSTAT

Products Affected

- *febuxostat*

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use of azathioprine or mercaptopurine
Required Medical Information	Diagnosis of Gout and all of the following 1.) documented inadequate treatment response, adverse event, or contraindication to maximally titrated dose of Allopurinol, and 2.) patients with established cardiovascular disease, prescriber attests that benefit of treatment outweighs the risk of treatment
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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FENTANYL ORAL

Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Use in opioid non-tolerant patients
Required Medical Information	Must meet all of the following 1.) Diagnosis of cancer-related breakthrough pain, 2.) Patient is currently receiving/tolerant to around-the-clock opioid therapy for persistent cancer pain, and 3.) Patient and prescriber are enrolled in the TIRF REMS Access Program
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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FENTANYL TD

Products Affected

- *fentanyl*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Use in opioid non-tolerant patients
Required Medical Information	Must meet all of the following 1.) Patient is opioid tolerant (taking for one week or longer at least 60mg of morphine or equivalent daily), and 2.) Patient has tried one extended release oral opioids or is unable to take extended release oral opioids secondary to allergy, adverse events, swallowing difficulty, or uncontrollable nausea/vomiting
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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FERRIPROX

Products Affected

- *deferiprone*
- FERRIPROX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) Diagnosis of transfusional iron overload due to thalassemia syndromes, 2.) Patient has failed prior chelation therapy, and 3.) Patient has an absolute neutrophil count greater than $1.5 \times 10^9/L$
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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FINTEPLA

Products Affected

- FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
Required Medical Information	Diagnosis of Severe myoclonic epilepsy in infancy (Dravet syndrome)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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FIRDAPSE

Products Affected

- FIRDAPSE

PA Criteria	Criteria Details
Exclusion Criteria	History of seizures
Required Medical Information	Treatment of Lambert-Eaton myasthenic syndrome
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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FIRMAGON

Products Affected

- FIRMAGON (240 MG DOSE)
- FIRMAGON SUBCUTANEOUS SOLUTION RECONSTITUTED 80 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced or metastatic prostate cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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FORTEO

Products Affected

- FORTEO SUBCUTANEOUS SOLUTION PEN-INJECTOR
- *teriparatide (recombinant)*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following and trial of generic formulary bisphosphonate A.) Osteoporosis in postmenopausal female patient with high risk for fracture, B.) Primary or hypogonadal osteoporosis in male patient with high risk for fracture, or C.) Osteoporosis due to associated sustained systemic glucocorticoid therapy in patient with high risk for fracture
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 12 months, Renewal: 12 months, max treatment 24 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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FYCOMPA

Products Affected

- FYCOMPA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Partial-onset seizures with or without secondary generalization, or B.) Primary generalized tonic-clonic seizure disorder
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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GAVRETO

Products Affected

- GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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GILENYA

Products Affected

- GILENYA ORAL CAPSULE 0.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) 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, B.) History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker, C.) Baseline QTC interval greater than or equal to 500 milliseconds, D.) Receiving concurrent treatment with Class Ia or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol)
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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GILOTRIF

Products Affected

- GILOTRIF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) 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 B.) Metastatic squamous NSCLC, progressing after platinum-based chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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GLATIRAMER

Products Affected

- *glatiramer acetate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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GLEOSTINE

Products Affected

- GLEOSTINE ORAL CAPSULE 10 MG, 100 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Secondary therapy of Hodgkin's disease in combination with other agents and who have relapsed during or failed to respond to primary therapy, B.) Intracranial tumor primary and metastatic who have already received surgical or radiotherapeutic procedures, C.) Carcinoma of the breast, D.) Colorectal cancer, E.) Lung cancer, F.) Malignant melanoma, G.) Malignant tumor of the thymus, H.) Multiple myeloma, I.) Non-Hodgkin's lymphoma, or J.) Small cell carcinoma of lung AND monitoring of blood counts for evidence of Bone Marrow Suppression (thrombocytopenia or leukopenia).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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GOCOVRI

Products Affected

- GOCOVRI

PA Criteria	Criteria Details
Exclusion Criteria	Patients with end-stage renal disease (ESRD, CrCl below 15 ml/min/m ²)
Required Medical Information	Diagnosis of one of the following A.) Parkinsons disease and patient is experiencing dyskinesia, receiving levodopa based therapy, and has documented trial and failure to amantadine immediate release, or B.) Extrapramidal disease and has documented trial and failure to amantadine immediate release
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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GROWTH HORMONE

Products Affected

- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) growth promotion in pediatric patients with closed epiphyses, B.) acute critical illness caused by complications following open-heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure, C.) active malignancy, D.) active proliferative or severe nonproliferative diabetic retinopathy
Required Medical Information	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 SD below mean if CNS pathology, h/o irradiation, or proven genetic cause, B.) SGA and birth weight or length 2 or more SD below mean for gestational age and fails to manifest catch up growth by age 2 (height 2 or more SD 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. Diagnosis of GHD, CRI, SHOX deficiency, Noonan syndrome, and PWS one of the following: 1.) height more than 3 SD below mean for age and gender, 2.) height more than 2 SD below mean with GV more than 1 SD below mean, or 3.) GV over 1 year 2 SD below mean. Diagnosis of 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 contraindicated, use a standardized stim test (i.e. arginine plus GH releasing hormone, 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, a subnormal IGF-1 (after at least 1 month off GH

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PA Criteria	Criteria Details
	therapy), objective evidence of GHD complications, such as: low bone density, increased visceral fat mass, or cardiovascular complications, completed linear growth (GV less than 2 cm/year), and GH has been discontinued for at least 1 month (if previously receiving GH).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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HEPATITIS B

Products Affected

- *adefovir dipivoxil*
- BARACLUDE ORAL SOLUTION
- *entecavir*
- VEMLIDY

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of chronic hepatitis B and all of the following: 1.) Patient has evidence of viral replication, 2.) Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) or histologically active disease, and 3.) Patient is receiving anti-retroviral therapy if the patient has HIV co-infection
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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HEPATITIS C

Products Affected

- *sofosbuvir-velpatasvir*
- VOSEVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of HCV genotype, subtype and quantitative HCV RNA (viral load) testing any time prior to therapy. Must document the following within 12 weeks of starting therapy: CBC, INR, hepatic function panel, and GFR. Must document cirrhosis status, prior treatment history (if any), and planned duration of treatment. All genotypes will require trial/failure, contraindication to, or intolerance to Sofosbuvir-Velpatasvir prior to the approval of Vosevi.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in conjunction with gastroenterologist, hepatologist, or infectious disease specialist
Coverage Duration	Duration of approval per AASLD Guidelines
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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HRM-ANALGESICS

Products Affected

- *meperidine hcl injection solution 100 mg/ml, 25 mg/ml, 50 mg/ml*
- *meperidine hcl oral tablet*
- *pentazocine-naloxone hcl*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	High risk medication. Automatically approved for beneficiaries less than or equal to 64 years. Attestation that risk outweighs benefit as to the medical necessity for using this high risk medication and anticipated treatment course/duration, and if formulary alternatives 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 alternative(s) - See OTHER criteria for alternatives.
Age Restrictions	Less than or equal to 64 years old, claim for target drug automatically pays. Greater than or equal to 65 years old, prior authorization exception request is required indicating medically accepted indication not otherwise excluded from Part D.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Analgesics: APAP/codeine,hydrocodone/APAP,hydrocodone/IBU,hydromorphone,met hadone,morphine sulfate,oxycodone,oxycodone/APAP,oxycodone/ASA,oxycodone/ibuprofe n,oxymorphone IR,tramadol, tramadol/APAP
Indications	N/A
Off-Label Uses	N/A

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HRM-SKELETAL MUSCLE RELAXANTS

Products Affected

- *chlorzoxazone oral tablet 375 mg, 500 mg, 750 mg*
- *cyclobenzaprine hcl oral tablet 10 mg, 5 mg*
- *orphenadrine citrate er*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	High risk medication. Automatically approved for beneficiaries less than or equal to 64 years. Attestation that risk outweighs benefit as to the medical necessity for using this high risk medication and anticipated treatment course/duration.
Age Restrictions	Less than or equal to 64 years old, claim for target drug automatically pays. Greater than or equal to 65 years old, prior authorization exception request is required indicating medically accepted indication not otherwise excluded from Part D.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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HUMIRA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Non-infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa. Screening for latent tuberculosis infection is required prior to initiation of treatment.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A

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PA Criteria	Criteria Details
Off-Label Uses	N/A

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IBRANCE

Products Affected

- IBRANCE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy, or B) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer used in combination with an aromatase inhibitor AND One of the following 1) patient is a postmenopausal woman, 3) patient is a man, or 3) 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)].
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ICLUSIG

Products Affected

- ICLUSIG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated, or B.) Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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IDHIFA

Products Affected

- IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase 2 mutation as detected by an FDA approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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IMATINIB

Products Affected

- *imatinib mesylate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), B.) Ph+ acute lymphoblastic leukemia (ALL), C.) Gastrointestinal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy, D.) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, E.) hypereosinophilic syndrome or chronic eosinophilic leukemia, F.) myelodysplastic syndrome or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements, or G.) aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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IMBRUVICA

Products Affected

- IMBRUVICA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) who have received at least one prior therapy, B.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL), C.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion, D.) Waldenstrom's macroglobulinemia (WM), E.) Marginal zone lymphoma who require systemic therapy and have received at least one prior anti-CD20-based therapy, or F.) Graft vs host disease after failure of a least one first-line corticosteroid therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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INCRELEX

Products Affected

- INCRELEX

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) active or suspected malignancy, B.) use for growth promotion in patients with closed epiphyses, C.) Intravenous administration
Required Medical Information	Diagnosis of one of the following A.) growth failure in children with severe primary IGF-1 deficiency, or B.) growth hormone (GH) gene deletion in children who have developed neutralizing antibodies to GH
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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INHALED TOBRAMYCIN

Products Affected

- *tobramycin inhalation nebulization solution 300 mg/5ml*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Must meet all of the following 1.) Diagnosis of cystic fibrosis and 2.) Patient has evidence of P. aeruginosa in the lungs
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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INLYTA

Products Affected

- INLYTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) advanced renal cell carcinoma and patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens), or B.) advanced renal cell carcinoma and used as first-line therapy in combination with avelumab or pembrolizumab
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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INQOVI

Products Affected

- INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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INREBIC

Products Affected

- INREBIC

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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INTRAROSA

Products Affected

- INTRAROSA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Vaginal bleeding or dysfunctional uterine bleeding of an undetermined origin, B.) Known or suspected estrogen-dependent neoplasia
Required Medical Information	Diagnosis of one of the following A.) Moderate to severe dyspareunia due to menopause, or B.) Atrophic vaginitis due to menopause.
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 3 months, Renewal: 12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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INTRON A

Products Affected

- INTRON A

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Autoimmune hepatitis, or B.) Decompensated liver disease
Required Medical Information	Diagnosis of one of the following A.) Hairy cell leukemia, B.) Diagnosis of condylomata acuminata involving external surfaces to the genital or perianal areas, C.) Diagnosis of AIDS-related Kaposi's sarcoma, D.) Clinically aggressive follicular lymphoma and the medication will be used concurrently with anthracycline-containing chemotherapy or is not a candidate for anthracycline-containing chemotherapy, E.) Malignant melanoma and the request for coverage is within 56 days of surgery and the patient is at high risk of disease recurrence, F.) Diagnosis of chronic hepatitis B with compensated liver disease and patient has evidence of hepatitis B viral replication and patient has been serum hepatitis B surface antigen-positive for at least 6 months, or G.) Diagnosis of chronic hepatitis C with compensated liver disease and is receiving combination therapy with ribavirin, unless ribavirin is contraindicated, and the medication will not be used as part of triple therapy with a protease inhibitor and patient has a clinical reason for not using peginterferon
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Condylomata: 3 mos, HBV: E antigen pos: 16 wks, E antigen neg: 48 wks, KS: 16 wks, Other: 12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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IRESSA

Products Affected

- IRESSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic Non-small cell lung cancer (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
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ISTURISA

Products Affected

- ISTURISA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Cushing's disease in patients for whom pituitary surgery is not an option or has not been curative
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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ITRACONAZOLE

Products Affected

- *itraconazole oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF), B.) Concurrent therapy with a CYP3A4 substrate (e.g., methadone, lovastatin, simvastatin, etc.)
Required Medical Information	Diagnosis of one of the following A.) Systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), B.) Onychomycosis confirmed by one of the following: positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy, or C.) Candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole (ORAL SOLUTION ONLY)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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IVIG

Products Affected

- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1 GM/10ML
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 2 GM/20ML

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Acute corn or maltose hypersensitivity, B.) Hereditary fructose intolerance, C.) Hyperprolinemia, D.) IgA deficiency with antibody formation and a history of hypersensitivity, E.) History of anaphylaxis or severe systemic reaction to human immune globulin
Required Medical Information	Supporting statement of diagnosis from the physician
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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JAKAFI

Products Affected

- JAKAFI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Intermediate or high-risk myelofibrosis, or B.) Polycythemia vera: Diagnosis of polycythemia vera, AND history of failure, contraindication, or intolerance to hydroxyurea, or C.) Acute Graft Versus Host Disease (GVHD): Diagnosis of Acute GVHD, AND disease is refractory to steroid therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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JYNARQUE

Products Affected

- JYNARQUE ORAL TABLET THERAPY
PACK

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) use in patients unable to sense or respond to thirst, B.) anuria, C.) history, signs, or symptoms of significant liver impairment or injury, D.) uncorrected abnormal blood sodium concentrations, E.) uncorrected urinary outflow obstruction
Required Medical Information	Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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KALYDECO

Products Affected

- KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	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.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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KESIMPTA

Products Affected

- KESIMPTA

PA Criteria	Criteria Details
Exclusion Criteria	Active Hepatitis B infection
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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KISQALI

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	KISQALI: Breast Cancer: Diagnosis of one of the following A.) 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 B.) 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. KISQALI FEMARA: Diagnosis of HER-2 negative, hormone receptor-positive, advanced or metastatic breast cancer in premenopausal, perimenopausal, or postmenopausal women, as initial endocrine based therapy.
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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KORLYM

Products Affected

- KORLYM

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) pregnancy, B.) coadministration with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, C.) concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses, D.) history of unexplained vaginal bleeding, E.) endometrial hyperplasia with atypia or endometrial carcinoma
Required Medical Information	Diagnosis of endogenous Cushing syndrome in patients with type 2 diabetes mellitus or glucose intolerance and one of the following A.) Used to control hyperglycemia secondary to hypercortisolism and patient has failed surgery, or B.) Used to control hyperglycemia secondary to hypercortisolism and patient is not a candidate for surgery
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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KOSELUGO

Products Affected

- KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of neurofibromatosis type 1 (NF1) in a patient who has symptomatic, inoperable plexiform neurofibromas (PN)
Age Restrictions	2 years of age to 17 years of age
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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KUVAN

Products Affected

- KUVAN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hyperphenylalaninemia (HPA) caused by tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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LENVIMA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, B.) Advanced renal cell carcinoma following one prior anti-angiogenic therapy in combination with everolimus, C.) Unresectable liver carcinoma, or D.) Advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, in a patient which has disease progression following prior systemic therapy and is not a candidate for curative surgery or radiation
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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LEUKINE

Products Affected

- LEUKINE INJECTION SOLUTION RECONSTITUTED

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with myelosuppressive chemotherapy or radiation or excessive (greater than or equal to 10%) leukemic myeloid blasts in bone marrow or peripheral blood
Required Medical Information	Diagnosis of one of the following A.) Patient has undergone allogeneic or autologous bone marrow transplant (BMT) and engraftment is delayed or failed, B.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, C.) Medication will be used for myeloid reconstitution after an autologous or allogeneic BMT, D.) Patient has acute myeloid leukemia and administration will be after completion of induction chemotherapy, or E.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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LEUPROLIDE

Products Affected

- ELIGARD
- *leuprolide acetate injection*
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)
- LUPRON DEPOT (6-MONTH)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) advanced or metastatic prostate cancer and patient with have trial of/contraindication to Eligard prior to approval of Lupron, B.) Diagnosis of central precocious puberty and patient had early onset of secondary sexual characteristics (male: earlier than 9 years of age. female: earlier than 8 years of age) and advanced bone age of at least one year compared with chronological age and has undergone gonadotropin-releasing hormone agonist (GnRHa) testing with peak luteinizing hormone (LH) level above pre-pubertal range or random LH level in pubertal range and Patient had the following diagnostic evaluations to rule out tumors, when suspected: diagnostic imaging of the brain (MRI or CT scan), Pelvic/testicular/adrenal ultrasound, Human chorionic gonadotropin levels, Adrenal steroids to rule out congenital adrenal hyperplasia, C.) the medication will be used for stimulation testing to confirm the diagnosis of central precocious puberty, D.) management of endometriosis, or E.) anemia caused by uterina leiomyomata
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A

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PA Criteria	Criteria Details
Off-Label Uses	N/A

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LIDOCAINE EXT

Products Affected

- *lidocaine external ointment*
- *lidocaine hcl external solution*
- *lidocaine hcl urethral/mucosal external gel*
- *lidocaine-prilocaine external cream*

PA Criteria	Criteria Details
Exclusion Criteria	Amide hypersensitivity
Required Medical Information	For topical anesthesia of skin and mucous membranes
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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LIDOCAINE PATCH

Products Affected

- *lidocaine external patch 5 %*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) pain associated with diabetic neuropathy, B.) pain associated with cancer-related neuropathy, C.) post-herpetic neuralgia, D.) Back pain, or E.) Osteoarthritis of the knee or hip
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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LINEZOLID

Products Affected

- *linezolid intravenous solution 600 mg/300ml*
- *linezolid oral*

PA Criteria	Criteria Details
Exclusion Criteria	Linezolid should not be used concurrently or within 14 days of MAOI therapy.
Required Medical Information	Supporting statement of diagnosis from the physician OR susceptibility testing shows drug activity for infection being treated
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	VRE: 4 weeks. Nosocomial and community acquired pneumonia: 3 weeks. All other indications: 2 weeks
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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LONSURF

Products Affected

- LONSURF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic colorectal cancer, previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based regimens, an anti-VEGF therapy, and if RAS wild-type, an anti-EGFR therapy, or B.) Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy if appropriate
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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LORBRENA

Products Affected

- LORBRENA

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with strong CYP3A4 inducers
Required Medical Information	Diagnosis of metastatic, anaplastic lymphoma kinase (ALK) positive non-small cell lung cancer with disease progression on either alectinib or ceritinib as the first ALK inhibitor for metastatic disease, or disease progression on crizotinib and at least one other ALK inhibitor for metastatic disease
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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LYNPARZA

Products Affected

- LYNPARZA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	<p>Diagnosis of one of the following A.) HER2- negative, deleterious or suspected deleterious germline BRCA mutated metastatic breast cancer AND patient has been previously treated with chemotherapy in neoadjuvant, adjuvant, or metastatic setting, B.) Advanced ovarian cancer with known or suspected BRCA mutation as detected by an FDA-approved test AND patient has trial and failure, contraindication, or intolerance to 3 or more prior lines of chemotherapy, C.) Recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer AND used for maintenance treatment in patients who are in complete or partial response to platinum-based chemotherapy (e.g. cisplatin, carboplatin), D.) Deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients with complete or partial response to first-line platinum-based chemotherapy, E.) Deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma and disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen, F.) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA-mutation, and/or genomic instability. Used in combination with bevacizumab for maintenance treatment, or G.) Deleterious or suspected deleterious germline or somatic homologous recombination repair gene mutated metastatic castration-resistant prostate cancer in patients who have progressed following prior treatment with enzalutamide or abiraterone.</p>
Age Restrictions	None

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PA Criteria	Criteria Details
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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MATULANE

Products Affected

- MATULANE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Hodgkin's Disease, Stages III and IV in combination with other anticancer drugs, B.)Malignant intracranial tumor including but not limited to medulloblastoma, C.) Multiple myeloma, D.) Non-Hodgkin's lymphona, or E.) Malignant glioma
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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MAYZENT

Products Affected

- MAYZENT

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) CYP2C9*3/*3 genotype, B.) In the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III-IV heart failure, or C.) Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker
Required Medical Information	Diagnosis of relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease and the following A.) Patients with relapsing forms of multiple sclerosis have history of/or contraindication to Avonex, Betaseron, Copaxone, or Gilenya
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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MEKINIST

Products Affected

- MEKINIST

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and used in combination with dabrafenib and no locoregional treatment options, B.) Malignant melanoma with lymph node involvement and following complete resection with BRAF V600E or V600K mutations and used in combination with dabrafenib, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutations and used in combination with dabrafenib or as monotherapy , or D.) Metastatic non-small cell lung cancer, with BRAF V600E mutation, in combination with dabrafenib.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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MEKTOVI

Products Affected

- MEKTOVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of unresectable or metastatic malignant melanoma with documented BRAF V600E or V600K mutation as detected by an FDA approved test AND used in combination with encorafenib
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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METHOTREXATE SC

Products Affected

- OTREXUP SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.4ML, 12.5 MG/0.4ML, 15 MG/0.4ML, 17.5 MG/0.4ML, 20 MG/0.4ML, 22.5 MG/0.4ML, 25 MG/0.4ML
- RASUVO SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.2ML, 12.5 MG/0.25ML, 15 MG/0.3ML, 17.5 MG/0.35ML, 20 MG/0.4ML, 22.5 MG/0.45ML, 25 MG/0.5ML, 30 MG/0.6ML, 7.5 MG/0.15ML

PA Criteria	Criteria Details
Exclusion Criteria	A.) Pregnancy, B.) Breastfeeding, C.) Alcoholism or liver disease, D.) Immunodeficiency syndromes, E.) Preexisting blood dyscrasias
Required Medical Information	Diagnosis of one of the following: A.) Severe rheumatoid arthritis in patients who are intolerant of or had an inadequate response to first-line therapy, B.) Polyarticular juvenile idiopathic arthritis in patients who are intolerant of or had an inadequate response to first-line therapy, C.) Severe, recalcitrant, disabling psoriasis in patients who are not adequately responsive to other forms of therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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METHOXSALEN

Products Affected

- *methoxsalen rapid*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Aphakia, B.) Melanoma or a history of melanoma, C.) Invasive squamous cell carcinomas, or D.) History of a light sensitive disease/skin photosensitivity disorder such systemic lupus erythematosus (SLE), porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum or albinism
Required Medical Information	Diagnosis of one of the following A.) Psoriasis, B.) Cutaneous T-cell lymphoma, or C.) Vitiligo
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, immunologist, or dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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MIGLUSTAT

Products Affected

- *miglustat*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of mild to moderate type 1 Gaucher disease and patient is not a candidate for enzyme replacement therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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MS INTERFERONS

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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MYTESI

Products Affected

- MYTESI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of non-infectious diarrhea associated with HIV/AIDS in patients receiving anti-retroviral therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist or gastroenterologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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NATPARA

Products Affected

- NATPARA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hypoparathyroidism and used to control hypocalcemia
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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NERLYNX

Products Affected

- NERLYNX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) early stage HER2-positive breast cancer and used after trastuzumab therapy, or B.) advanced or metastatic HER2-positive breast cancer and patient has received 2 or more prior anti-HER2-based regimens in the metastatic setting
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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NEXAVAR

Products Affected

- NEXAVAR

PA Criteria	Criteria Details
Exclusion Criteria	Squamous cell lung cancer being treated with carboplatin and paclitaxel
Required Medical Information	Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment, or C.) Diagnosis of unresectable hepatocellular carcinoma
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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NINLARO

Products Affected

- NINLARO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of multiple myeloma and documentation of combination therapy with lenalidomide and dexamethasone, used in patients with history of 1 prior therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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NORTHERA

Products Affected

- NORTHERA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (e.g., Parkinson disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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NOXAFIL

Products Affected

- NOXAFIL ORAL SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant treatment with sirolimus, B.) Concomitant use of CYP3A4 substrates that prolong QT interval (pimozide, quinidine), C.) Concomitant use of HMG-CoA Reductase inhibitors primarily metabolized through CYP3A4, or D.) Concomitant use of ergot alkaloids
Required Medical Information	Diagnosis of one of the following A.) Oropharyngeal candidiasis, or B.) Patient is severely immunocompromised and requires prophylaxis of invasive aspergillosis or candidiasis due to high risk of infection
Age Restrictions	13 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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NUBEQA

Products Affected

- NUBEQA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of non-metastatic, castration-resistant prostate cancer
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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Pending CMS Review

NUCALA

Products Affected

- NUCALA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Severe asthma with eosinophilic phenotype, B.) Eosinophilic granulomatosis with polyangiitis (EGPA), or C.) Hypereosinophilic syndrome and patient has had for at least 6 months without an identifiable non-hematologic secondary cause
Age Restrictions	6 years of age and older
Prescriber Restrictions	*Criteria Pending CMS Review* Prescribed by or in consultation with a pulmonologist, rheumatologist, or immunologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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NUEDEXTA

Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) History of prolonged QT interval, congenital long QT syndrome or Torsades de pointes, B.) Heart failure, C.) Complete AV block without an implanted pacemaker or high risk of complete AV block, D.) Concomitant use with quinidine, quinine, mefloquine, or drugs that prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), E.) Concomitant use with MAOIs or within 14 days of MAOI therapy
Required Medical Information	Diagnosis of pseudobulbar affect
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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OCTREOTIDE

Products Affected

- *octreotide acetate injection solution 100 mcg/ml, 1000 mcg/ml, 200 mcg/ml, 50 mcg/ml, 500 mcg/ml*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) acromegaly and patient has inadequate response to or is ineligible for surgery, radiation, or bromocriptine mesylate, B.) metastatic carcinoid syndrome, C.) vasoactive intestinal peptide-secreting tumors (VIPomas) with associated diarrhea
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ODOMZO

Products Affected

- ODOMZO

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of locally advanced basal cell carcinoma of the skin and one of the following A.) Cancer has recurred following surgery or radiation therapy, B.) Patient is not a candidate for surgery or radiation therapy.
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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OPSUMIT

Products Affected

- OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	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
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ORFADIN

Products Affected

- *nitisinone*
- ORFADIN ORAL CAPSULE 20 MG
- ORFADIN ORAL SUSPENSION

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of tyrosinemia type 1
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ORKAMBI

Products Affected

- ORKAMBI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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OSPHENA

Products Affected

- OSPHENA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) undiagnosed abnormal genital bleeding, B.) known or suspected estrogen-dependent neoplasia, C.) active or history of DVT, D.) active or history of pulmonary embolism, E.) active or history of arterial thromboembolic disease F.) pregnancy
Required Medical Information	Diagnosis of one of the following A.) moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause, or B.) moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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OXANDROLONE

Products Affected

- *oxandrolone oral*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Breast or prostate cancer in men, B.) Breast cancer in women with hypercalcemia, C.) Pregnancy, D.) Nephrosis or nephrotic phase of nephritis, E.) Hypercalcemia
Required Medical Information	Diagnosis one of the following and receiving treatment as an adjunct therapy to promote weight gain A.) Extensive surgery, B.) Chronic infections, C.) Severe trauma, or D.) Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons, E.) Chronic corticosteroid administration, F.) Bone pain associated with osteoporosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	3 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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PANRETIN

Products Affected

- PANRETIN

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Kaposi sarcoma cutaneous lesions in patient with AIDS-related Kaposi sarcoma (KS)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or HIV specialist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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PCSK9 INHIBITOR

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	<p>PRALUENT: Must meet criteria #1, #2 or #3. REPATHA: Must meet criteria #1, #2, #3 or #4. 1.) Diagnosis of primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH). 2.) Myocardial infarction prophylaxis, stroke prophylaxis, and to reduce risk of coronary revascularization in pts with established CVD. 3.) Diagnosis of clinical atherosclerotic cardiovascular disease (CVD) 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 (TIA), g. peripheral arterial disease presumed to be atherosclerotic region. 4.) Primary hyperlipidemia 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. REQUIRED DOCUMENTATION FOR INITIAL THERAPY: A.) Baseline and current LDL-C, LDL-C greater than or equal to 70 mg/dL, AND used in combination with maximally tolerated high-intensity statin OR patient is statin intolerant and LDL-C greater than or equal to 70 mg/dL. FOR CONTINUING THERAPY: Will continue to be used in combination with maximally tolerated statin (unless statin intolerant).</p>
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist
Coverage Duration	Initial: 8 weeks, Renewal: 12 months

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PA Criteria	Criteria Details
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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PEGYLATED INTERFERON

Products Affected

- PEGASYS PROCLICK
SUBCUTANEOUS SOLUTION 180
MCG/0.5ML
- PEGASYS SUBCUTANEOUS
SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Autoimmune hepatitis or other autoimmune condition known to be exacerbated by interferon, B.) Uncontrolled depression
Required Medical Information	Diagnosis of one of the following A.) Chronic hepatitis B infection, or B.) Chronic hepatitis C and required criteria will be applied consistent with current AASLD-IDSA guidance with compensated liver disease
Age Restrictions	Hepatitis B: 3 years of age and older. Hepatitis C: 5 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
Coverage Duration	HBV: 12 months, HCV: based on current AASLD guidelines
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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PEMAZYRE

Products Affected

- PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, gastroenterologist, or hepatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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PENICILLAMINE

Products Affected

- *penicillamine oral tablet*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Breastfeeding, B.) During Pregnancy (except for treatment of Wilson's disease), C.) Hypersensitivity to penicillamine products, D.) Penicillamine-related aplastic anemia/agranulocytosis, E.) Rheumatoid arthritis patients with history or evidence of renal insufficiency
Required Medical Information	Diagnosis of one of the following A.) Cystinuria, B.) Rheumatoid arthritis, or C.) Wilson's disease
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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PIQRAY

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of hormone receptor (HR) positive, HER2-negative, PIK3CA-mutated, advanced or metastatic breast cancer and used in combination with fulvestrant for postmenopausal women, and men following progression on or after endocrine- based regimen.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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POMALYST

Products Affected

- POMALYST

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Must meet all of the following 1.) Disease has progressed on or 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 2 forms of reliable contraception before, during, and 1 month after discontinuing 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), and 5.) Registered and certified to be compliant with Pomalyst REMS program
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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POSACONAZOLE

Products Affected

- *posaconazole*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant treatment with sirolimus, B.) Concomitant use of CYP3A4 substrates that prolong QT interval (pimozide, quinidine), C.) Concomitant use of HMG-CoA Reductase inhibitors primarily metabolized through CYP3A4, or D.) Concomitant use of ergot alkaloids
Required Medical Information	Diagnosis of one of the following A.) Oropharyngeal candidiasis, or B.) Patient is severely immunocompromised and requires prophylaxis of invasive aspergillosis or candidiasis due to high risk of infection
Age Restrictions	13 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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PROMACTA

Products Affected

- PROMACTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic idiopathic thrombocytopenic purpura (ITP), B.) Chronic hepatitis C infection associated thrombocytopenia, or C.) Severe aplastic anemia with insufficient response to immunosuppressive therapy or in combination with standard immunosuppressive therapy
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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PULMONARY FIBROSIS

Products Affected

- OFEV

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Idiopathic pulmonary fibrosis (IPF), B.) Systemic sclerosis-associated interstitial lung disease (ILD), or C.) Chronic fibrosing interstitial lung disease with a progressive phenotype
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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QINLOCK

Products Affected

- QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced gastrointestinal stromal tumor (GIST) and patient has received prior treatment with 3 or more kinase inhibitors, including imatinib
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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QUININE SULFATE

Products Affected

- *quinine sulfate oral*

PA Criteria	Criteria Details
Exclusion Criteria	Prolongation of QT interval. Glucose-6-phosphate dehydrogenase deficiency. Myasthenia gravis. Known hypersensitivity to mefloquine or quinidine. Optic neuritis. Diagnosis of Blackwater fever
Required Medical Information	Diagnosis of one of the following A.) uncomplicated Plasmodium falciparum malaria, B.) uncomplicated Plasmodium vivax malaria, or C.) babesiosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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RAVICTI

Products Affected

- RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of urea cycle disorders
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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REGRANEX

Products Affected

- REGRANEX

PA Criteria	Criteria Details
Exclusion Criteria	Known neoplasm at the site of application
Required Medical Information	Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply
Age Restrictions	16 years of age and older
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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RETEVMO

Products Affected

- RETEVMO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in patients who require systemic therapy, B.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC), or C.) Advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and are refractory to radioactive iodine, if appropriate
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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REVLIMID

Products Affected

- REVLIMID

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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RILUTEK

Products Affected

- *riluzole*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of amyotrophic lateral sclerosis (ALS)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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RINVOQ

Products Affected

- RINVOQ

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of moderate to severe rheumatoid arthritis and patient has had an inadequate response or intolerance to methotrexate
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ROZLYTREK

Products Affected

- ROZLYTREK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following: A) ROS1-positive metastatic non-small cell lung cancer (NSCLC), OR B) Solid tumors that 1) have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, AND 2) are metastatic or where surgical resection is likely to result in severe morbidity, AND 3) have either progressed following treatment or have no satisfactory alternative therapy
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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RUBRACA

Products Affected

- RUBRACA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of 1. deleterious BRCA mutation (germline and/or somatic)-associated ovarian, fallopian tube, or primary peritoneal cancer and all of the following criteria (A-E): A.) BRCA mutation positive as detected by an approved FDA laboratory test, B.) Previous trial/failure with two or more chemotherapy regimens, C.) Used as monotherapy, D.) Agreement of provider to perform a complete blood count (CBC) at baseline and monthly thereafter, E.) Women of reproductive potential must use an effective method of contraception during therapy and for 6 months after the last dose. Diagnosis of 2. Diagnosis of recurrent ovarian, fallopian tube, or primary peritoneal cancer and all of the following (A-D): A.) Complete or partial response to platinum-based chemotherapy B.) Used as monotherapy C.) Agreement of provider to perform a complete blood count (CBC) at baseline and monthly thereafter, D.) Women of reproductive potential must use an effective method of contraception during therapy and for 6 months after the last dose. Renewal will be based on lack of disease progression or unacceptable toxicity. Diagnosis of 3. Deleterious BRCA mutation (germline and/or somatic) associated metastatic castration-resistant prostate cancer and patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None

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PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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RUCONEST

Products Affected

- RUCONEST

PA Criteria	Criteria Details
Exclusion Criteria	Known allergy to rabbits or rabbit-derived products (leporine protein hypersensitivity)
Required Medical Information	Diagnosis of Hereditary angioedema (HAE)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, immunologist, or allergist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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RYDAPT

Products Affected

- RYDAPT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) 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 B.) systemic mastocytosis or mast cell leukemia
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SAMSCA

Products Affected

- SAMSCA
- *tolvaptan oral tablet 30 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) use in patients unable to sense or respond to thirst, B.) anuria, C.) hypovolemic hyponatremia, D.) urgent need to raise serum sodium acutely
Required Medical Information	Diagnosis of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium less than 125 mEq/L or less marks hyponatremia that is symptomatic and has resisted correction with fluid restriction), including in patients with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SIGNIFOR

Products Affected

- SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Cushing disease and patient has inadequate response to or is not a candidate for surgery
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SILDENAFIL

Products Affected

- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
Exclusion Criteria	Nitrate therapy
Required Medical Information	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
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SKYRIZI

Products Affected

- SKYRIZI (150 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of moderate to severe plaque psoriasis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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SOLTAMOX

Products Affected

- SOLTAMOX

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant coumarin-type anticoagulant therapy, B.) history of thromboembolic disease such as DVT or PE
Required Medical Information	Diagnosis of breast cancer and documentation of inability to swallow tablet formulation
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SOMATULINE

Products Affected

- SOMATULINE DEPOT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) acromegaly in patient with inadequate response to or is ineligible for surgery or radiotherapy, B.) carcinoid syndrome, or C.) gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SOMAVERT

Products Affected

- SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of acromegaly and patient has inadequate response to or is ineligible for surgery or radiation therapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SPRYCEL

Products Affected

- SPRYCEL

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) that is newly diagnosed in the chronic phase, B.) Ph+ CML in chronic, accelerated, or lymphoid blast phase with resistance or intolerance to prior therapy, C.) Diagnosis of Ph+ acute lymphoblastic leukemia with resistance or intolerance to prior therapy, or D.) Newly diagnosed Ph+ acute lymphoblastic leukemia in combination with chemotherapy
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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STELARA

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) moderate to severely active Crohn disease and patient has trial and failure or intolerance or contraindication to Humira, B.) moderate to severe plaque psoriasis and patient has trial and failure or intolerance or contraindication to Humira and Enbrel, C.) active psoriatic arthritis and patient has trial and failure or intolerance or contraindication to Humira and Enbrel, or D.) moderate to severe active ulcerative colitis and patient has trial and failure or intolerance or contraindication to Humira
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or gastroenterologist or dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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STIVARGA

Products Affected

- STIVARGA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) metastatic colorectal cancer in patients previously treated with ALL of the following per the indication: 1. (fluoropyrimidine-, oxaliplatin-, and irinotecan)-based chemotherapy 2. anti-VEGF bevacizumab 3. anti-EGFR panitumumab OR cetuximab (for KRAS mutation-negative patients only), B.) liver carcinoma in patients previously treated with sorafenib, or C.) locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib and sunitinib
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SUNOSI

Products Affected

- SUNOSI

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI
Required Medical Information	Diagnosis of one of the following A.) narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to modafinil or armodafinil, or B.) obstructive sleep apnea (OSA) with excessive daytime drowsiness and has trial of/or contraindication to modafinil or armodafinil
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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SUTENT

Products Affected

- SUTENT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) gastrointestinal stromal tumor after disease progression on or intolerance to imatinib, B.) pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease, C.) advanced renal cell carcinoma, or D.) renal cell carcinoma and used as adjuvant therapy following nephrectomy in patients who are at high risk for recurrence
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SYMDEKO

Products Affected

- SYMDEKO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis and One of the following A.) Patient is homozygous for the F508del mutation, or B.) Patient has 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
Age Restrictions	6 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SYMLIN

Products Affected

- SYMLINPEN 120 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- SYMLINPEN 60 SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) confirmed diagnosis of gastroparesis, B.) hypoglycemia unawareness
Required Medical Information	Diagnosis of one of the following A.) type 1 diabetes mellitus and patient uses mealtime insulin therapy and has failed to achieve desired glucose control, or B.) type 2 diabetes mellitus and patient uses mealtime insulin therapy and has failed to achieve desired glucose control
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SYNAREL

Products Affected

- SYNAREL

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) pregnancy, B.) breastfeeding, C.) undiagnosed abnormal vaginal bleeding
Required Medical Information	Diagnosis of one of the following A.) central precocious puberty, or B.) endometriosis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SYNRIBO

Products Affected

- SYNRIPO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) and patient has tried and failed or has a contraindication or intolerance to 2 tyrosine kinase inhibitors
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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SYPRINE

Products Affected

- CLOVIQUE
- *trientine hcl*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of Wilson's disease in patients that are intolerant to penicillamine
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TABRECTA

Products Affected

- TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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TAFINLAR

Products Affected

- TAFINLAR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	A.) Diagnosis of locally advanced or metastatic anaplastic thyroid carcinoma with BRAF V600E mutation, in combination with trametinib and no satisfactory locoregional treatment options OR B.) Diagnosis of metastatic non-small cell lung cancer with BRAF V600E mutation, in combination with trametinib OR in patients previously treated as monotherapy OR C.) Diagnosis of unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutation AND 1) used as monotherapy OR 2) in combination with trametinib OR 3) used as adjuvant therapy following complete resection in patients with lymph node involvement AND used in combination with trametinib.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TAGRISSO

Products Affected

- TAGRISSO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) metastatic, non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R mutation and used as first line therapy, or B.) Metastatic, non-small cell lung cancer with confirmed presence of T790M EGFR mutation AND whose disease has progressed on or after EGFR tyrosine kinase inhibitor based therapy (Diagnosis should be confirmed by an FDA-approved test)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TALZENNA

Products Affected

- TALZENNA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), HER2-negative locally advanced or metastatic breast cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TASIGNA

Products Affected

- TASIGNA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia, or D.) Concomitant use with a drug known to prolong the QT interval or strong cytochrome P450 3A4 inhibitors
Required Medical Information	Diagnosis of one of the following A.) Newly diagnosed Philadelphia chromosome-positive chronic myelogenous leukemia (CML) in chronic phase, B.) Chronic-phase and accelerated-phase Philadelphia chromosome-positive CML in patients resistant or intolerant to prior therapy that include imatinib, or C.) Chronic phase Philadelphia chromosome-positive CML in patients with resistance or intolerance to prior tyrosine-kinase inhibitor therapy
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TAVALISSE

Products Affected

- TAVALISSE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of thrombocytopenia in patient with chronic idiopathic thrombocytopenic purpura (ITP) and an insufficient response to one previous treatment
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TAZORAC

Products Affected

- *tazarotene external*
- TAZORAC EXTERNAL GEL
- TAZORAC EXTERNAL CREAM 0.05 %

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) acne vulgaris and patient has trial with at least one generic topical acne product, or B.) stable moderate to severe plaque psoriasis with 20% or less body surface area involvement and patient has trial with at least one other topical psoriasis product (e.g., medium to high potency corticosteroid and/or vitamin D analogs)
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TAZVERIK

Products Affected

- TAZVERIK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Metastatic or locally advanced epithelioid sarcoma in patients not eligible for complete resection, B.) Relapsed or refractory follicular lymphoma in patients whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, or C.) Relapsed or refractory follicular lymphoma in patients who have no satisfactory alternative treatment options
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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Pending CMS Review

TECFIDERA

Products Affected

- *dimethyl fumarate oral*
- TECFIDERA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	*Criteria Pending CMS Review* Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TEFLARO

Products Affected

- TEFLARO

PA Criteria	Criteria Details
Exclusion Criteria	Known serious hypersensitivity to cephalosporin class
Required Medical Information	Diagnosis of one of the following A.) acute bacterial skin and skin structure infection and patient has documented culture and sensitivity to teflaro, or B.) community acquired pneumonia and patient has documented culture and sensitivity to teflaro
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	2 weeks
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TEGSEDI

Products Affected

- TEGSEDI

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Platelet count less than 100,000 per microliter, B.) urinary protein to creatinine ratio (UPCR) of 1000 mg/g or higher
Required Medical Information	Diagnosis of Polyneuropathy of hereditary transthyretin-mediated amyloidosis
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TESTOSTERONE

Products Affected

- *methyltestosterone oral*
- *testosterone cypionate intramuscular solution 100 mg/ml, 200 mg/ml, 200 mg/ml (1 ml)*
- *testosterone enanthate intramuscular solution*
- *testosterone transdermal gel 10 mg/act (2%), 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)*
- *testosterone transdermal solution*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Carcinoma of the breast (males only) or prostate, B.) Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, B.) Inoperable metastatic breast cancer in women who are postmenopausal, C.) Primary hypogonadism. Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value, or D.) Delayed puberty (testosterone enanthate)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TETRABENAZINE

Products Affected

- *tetrabenazine*

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Actively suicidal, B.) Untreated or inadequately treated depression, C.) Impaired hepatic function, D.) Concomitant use of monoamine oxidase inhibitors, E.) Concomitant use of reserpine or within 20 days of discontinuing reserpine
Required Medical Information	Diagnosis of chorea associated with Huntington's disease
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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THALOMID

Products Affected

- THALOMID

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of one of the following A.) Multiple myeloma that is newly diagnosed, or B.) Erythema nodosum leprosum (ENL)
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or infectious disease specialist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TIBSOVO

Products Affected

- TIBSOVO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Acute myeloid leukemia in relapsed or refractory patients, with susceptible isocitrate dehydrogenase-1 mutation, or B.) Acute myeloid leukemia in newly-diagnosed patients, with susceptible isocitrate dehydrogenase-1 mutation AND one of the following 1.) patient is 75 years or older , or 2.) patient has comorbidities that preclude intensive induction chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TIGLUTIK

Products Affected

- TIGLUTIK

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of amyotrophic lateral sclerosis (ALS)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TOPICAL RETINOIDS

Products Affected

- *adapalene external cream*
- *adapalene external gel*
- AVITA
- *tretinoin external*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of mild to moderate acne vulgaris
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TOREMIFENE

Products Affected

- *toremifene citrate*

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic breast cancer and patient must have previous inadequate response or intolerance to tamoxifen
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	6 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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TRACLEER

Products Affected

- TRACLEER ORAL TABLET SOLUBLE

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Receiving concomitant cyclosporine A or glyburide therapy, B.) 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, or C.) Pregnancy
Required Medical Information	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 all of the following: A.) Patient has WHO Group I PAH, B.) Patient has New York Heart Association (NYHA) Functional Class II-IV, and C.) Female patients of reproductive potential must use two forms of reliable contraception
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Initial: 6 months, Renewal: 12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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TRELSTAR

Products Affected

- TRELSTAR MIXJECT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced prostate cancer and used in palliative treatment
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TRIKAFTA

Products Affected

- TRIKAFTA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cystic fibrosis and patient has at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene verified by an FDA-cleared CF mutation test
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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Kalos Health Gold Plus

2020 Formulary - Prior Authorization Criteria

TUKYSA

Products Affected

- TUKYSA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced unresectable or metastatic HER2-positive breast cancer (including brain metastases) in patients who have received one or more prior anti-HER2-based regimens in the metastatic setting and drug is being used in combination with trastuzumab and capecitabine
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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TURALIO

Products Affected

- TURALIO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TYKERB

Products Affected

- TYKERB

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) and One of the following A.) used in combination with capecitabine in a patient who has received prior therapy including an anthracycline, a taxane and trastuzumab, or B.) used in combination with letrozole in postmenopausal women for whom hormonal therapy is indicated
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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TYMLOS

Products Affected

- TYMLOS

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of postmenopausal osteoporosis and one of the following A.) osteoporotic fracture or multiple risk factors for fracture, or B.) previous trial of/or contraindication to bisphosphonate
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Initial: 12 months, Renewal: 12 months, max treatment 24 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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UPTRAVI

Products Affected

- UPTRAVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	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
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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VALCHLOR

Products Affected

- VALCHLOR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of cutaneous T-cell lymphoma (stage IA and IB mycosis fungoides-type) and patient has received prior skin-directed therapy (e.g. Topical corticosteroids, phototherapy, or topical nitrogen mustard)
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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VARIZIG

Products Affected

- VARIZIG INTRAMUSCULAR SOLUTION

PA Criteria	Criteria Details
Exclusion Criteria	History of hypersensitivity (including anaphylaxis or severe systemic reaction) to immune globulin or any component of the preparation
Required Medical Information	Diagnosis of post-exposure varicella (chickenpox) infection prophylaxis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
2020 Formulary - Prior Authorization Criteria**

VENCLEXTA

Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant use with strong CYP3A inhibitor during the initial and titration phase in patients with CLL or SLL
Required Medical Information	Diagnosis of one of the following A.) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), or B.) Newly-diagnosed acute myeloid leukemia (AML) and used in combination with azacitidine, decitabine or low-dose cytarabine in patients 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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VERZENIO

Products Affected

- VERZENIO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of advanced or metastatic, HER2-negative, hormone receptor-positive breast cancer AND One of the following: A.) For postmenopausal women must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy and patient has trial and failure or contraindication to Ibrance or Kisqali, B). For premenopausal or perimenopausal women must be used in combination with fulvestrant for the treatment of disease progression following endocrine therapy and patient has trial and failure or contraindication to Ibrance, C.) 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, D.) For postmenopausal women used as initial endocrine- based treatment in combination with an aromatase inhibitor and patient has trial and failure or contraindication to Kisqali or Ibrance, or E.) For premenopausal or perimenopausal women used as initial endocrine- based treatment in combination with an aromatase inhibitor and patient has trial and failure or contraindication to Kisqali
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A

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PA Criteria	Criteria Details
Off-Label Uses	N/A

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VIGABATRIN

Products Affected

- *vigabatrin*
- VIGADRONE

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Infantile spasms, or B.) Refractory complex partial seizures and the drug is being used as adjunctive therapy in patients who have responded inadequately to several alternative treatments
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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VITRAKVI

Products Affected

- VITRAKVI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic or surgically unresectable neurotrophic receptor tyrosine kinase (NTRK) gene fusion-positive solid tumors and used in patients with unsatisfactory alternative treatments or who have progressed following treatment
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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VIZIMPRO

Products Affected

- VIZIMPRO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	First line treatment of metastatic non-small cell lung cancer with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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VOTRIENT

Products Affected

- VOTRIENT

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) advanced renal cell carcinoma, or B.) advanced soft tissue sarcoma and patient received at least one prior chemotherapy (e.g., doxorubicin, dacarbazine, ifosfamide, epirubicin, docetaxel, or vinorelbine)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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VYNDAMAX

Products Affected

- VYNDAMAX

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of wild type or hereditary transthyretin related familial amyloid cardiomyopathy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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XALKORI

Products Affected

- XALKORI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive or ROS1-positive as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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XELJANZ

Products Affected

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following: A.) Moderate to severe rheumatoid arthritis (RA), B.) Active psoriatic arthritis, or C.) Moderate to severe ulcerative colitis (UC).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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XGEVA

Products Affected

- XGEVA

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia (calcium less than 8.0 mg/dL)
Required Medical Information	Diagnosis of one of the following A.) bone metastases from a solid tumor, B.) giant cell tumor of the bone that is unresectable or where surgical resection is likely to result in severe morbidity, C.) hypercalcemia of malignancy refractory to bisphosphonate therapy, or D.) multiple myeloma used for the prevention of skeletal related events
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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XOLAIR

Products Affected

- XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic idiopathic urticaria in patients who remain symptomatic despite H1 antihistamine therapy, or B.) Moderate to severe persistent asthma in patients with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids
Age Restrictions	6 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or dermatologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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**Kalos Health Gold Plus
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XOSPATA

Products Affected

- XOSPATA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of relapsed or refractory acute myeloid leukemia, with presence of FLT3 mutation as detected by an FDA-approved test
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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XPOVIO

Products Affected

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

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Relapsed or refractory multiple myeloma used in combination with dexamethasone in a patient who has received at least 4 prior therapies and is refractory to at least 2 proteasome inhibitors, at least 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody, or B.) Relapsed or refractory diffuse large B-cell lymphoma (DLBCL, including from follicular lymphoma) in a patient who has received at least 2 lines of systemic therapy
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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XTANDI

Products Affected

- XTANDI

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) castration-resistant prostate cancer (CRPC), or B) metastatic castration-sensitive prostate cancer
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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XYREM

Products Affected

- XYREM

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Concomitant treatment with sedative hypnotic agents, B.) Succinic semialdehyde dehydrogenase deficiency
Required Medical Information	Diagnosis of cataplexy and excessive daytime sleepiness in patients with narcolepsy
Age Restrictions	7 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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YONSA

Products Affected

- YONSA

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following A.) Pregnancy, or B.) Patients with severe baseline hepatic impairment (Child-Pugh Class C)
Required Medical Information	Diagnosis of metastatic castration-resistant prostate cancer and All of the following 1.) used in combination with methylprednisolone, and 2.) documented history of trial with, inadequate treatment response, adverse event, or contraindication to Zytiga (Abiraterone)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ZARXIO

Products Affected

- ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	<p>Diagnosis of one of the following: A) congenital, cyclic, or idiopathic neutropenia, B) severe febrile neutropenia (FN) with the following: Has not received prophylactic pegfilgrastim and Used as adjunct to appropriate antibiotics in high-risk patients and any one of the following: 65 years or older, Uncontrolled primary disease, Pneumonia, Hypotension and multiorgan dysfunction (sepsis syndrome), Invasive fungal infection, Hospitalization when developed fever, Prior FN, Severe (ANC less than 100/mcL) or anticipated prolonged (more than 10 days) neutropenia, C) Autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, D) Undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, E) Acute myeloid leukemia and will be given after completion of induction or consolidation chemotherapy, F) Acute lymphoblastic leukemia and will be given after completion of the first few days of chemotherapy of the initial induction or first post-remission course, G) Myelodysplastic syndrome with severe neutropenia and recurrent infection, H) Receiving radiation therapy, not on chemotherapy, and expected to have prolonged delays in treatment due to neutropenia, I) Neutropenia associated with HIV infection and antiretroviral therapy, J) Aplastic anemia, K) Primary prophylaxis of FN in one of the following patients: 20% or higher risk of FN based on chemotherapy regimen OR Less than 20% risk of FN based on chemotherapy regimen with one of the following: 65 years or older, Poor performance status, Poor nutritional status, Previous FN, Extensive prior treatment including large radiation ports, Cytopenias due to bone marrow involvement by tumor, Administration of combined chemoradiotherapy, Presence of open wounds or active infections, Other serious comorbidities (including renal or liver dysfunction) or Receiving</p>

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PA Criteria	Criteria Details
	dose-dense chemotherapy regimen in breast or small cell lung cancer or non-Hodgkins lymphoma.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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Kalos Health Gold Plus
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ZEJULA

Products Affected

- ZEJULA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) advanced or recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer and used for maintenance therapy in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin), or B.) advanced ovarian, fallopian tube, or primary peritoneal cancer and patient has been treated with 3 or more prior chemotherapy regimens, and cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA mutation, or genomic instability, and disease has progressed more than 6 months after response to the last platinum-based chemotherapy
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or gynecologist
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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ZELBORAF

Products Affected

- ZELBORAF

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Unresectable or metastatic melanoma and patient has positive BRAF-V600E mutation documented by an FDA-approved test, or B.) Erdheim-Chester disease and patient has documented BRAF V600 mutation
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ZIEXTENZO

Products Affected

- ZIEXTENZO

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of chemotherapy induced febrile neutropenia (prophylaxis)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

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ZOLINZA

Products Affected

- ZOLINZA

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of primary cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease on or following two systemic therapies (e.g., bexarotene, romidepsin, etc)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ZYDELIG

Products Affected

- ZYDELIG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Chronic lymphocytic leukemia and all of the following: Used in combination with rituximab, patient has relapsed on at least one prior therapy (e.g., purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]), and patient does not have any co-morbidities that prevents the use of cytotoxic chemotherapy (i.e. severe neutropenia or thrombocytopenia, creatinine clearance less than 60 mL/minute), B.) Non-Hodgkins lymphoma (Follicular, B-Cell) and the patient has relapsed on at least two prior systemic therapies (e.g., 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(e.g., rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicin], purine analogs [fludarabine])
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ZYKADIA

Products Affected

- ZYKADIA ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC)
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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ZYTIGA

Products Affected

- *abiraterone acetate*
- ZYTIGA ORAL TABLET 500 MG

PA Criteria	Criteria Details
Exclusion Criteria	None
Required Medical Information	Diagnosis of one of the following A.) Castration-resistant metastatic prostate cancer and used in combination with prednisone, or B.) High risk, castration-sensitive metastatic prostate cancer and used in combination with prednisone
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None
Indications	N/A
Off-Label Uses	N/A

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PART B VERSUS PART D

Products Affected

- ABELCET INTRAVENOUS SUSPENSION 5 MG/ML
- *acetylcysteine inhalation solution 10 %, 20 %*
- *acyclovir sodium intravenous solution 50 mg/ml*
- *albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml*
- AMBISOME INTRAVENOUS SUSPENSION RECONSTITUTED 50 MG
- AMINOSYN II INTRAVENOUS SOLUTION 10 %
- AMINOSYN-PF INTRAVENOUS SOLUTION 7 %
- *amphotericin b intravenous solution reconstituted 50 mg*
- *aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg*
- AZASAN ORAL TABLET 100 MG, 75 MG
- *azathioprine oral tablet 50 mg*
- *budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml*
- *calcitonin (salmon) nasal solution 200 unit/act*
- *calcitriol oral capsule 0.25 mcg, 0.5 mcg*
- *calcitriol oral solution 1 mcg/ml*
- *cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg*
- CLINIMIX E/DEXTROSE (2.75/5) INTRAVENOUS SOLUTION 2.75 %
- CLINIMIX E/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX E/DEXTROSE (4.25/5) INTRAVENOUS SOLUTION 4.25 %
- CLINIMIX E/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX E/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (4.25/10) INTRAVENOUS SOLUTION 4.25 %
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- CLINIMIX/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %
- CLINIMIX/DEXTROSE (5/20) INTRAVENOUS SOLUTION 5 %
- CLINISOL SF INTRAVENOUS SOLUTION 15 %
- *cromolyn sodium inhalation nebulization solution 20 mg/2ml*
- *cyclophosphamide oral capsule 25 mg, 50 mg*
- *cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg*
- *cyclosporine modified oral solution 100 mg/ml*
- *cyclosporine oral capsule 100 mg, 25 mg*
- *diphtheria-tetanus toxoids dt intramuscular suspension 25-5 lfu/0.5ml*
- ENGERIX-B INJECTION SUSPENSION 10 MCG/0.5ML, 20 MCG/ML
- ENVARUS XR ORAL TABLET EXTENDED RELEASE 24 HOUR 0.75 MG, 1 MG, 4 MG
- *everolimus oral tablet 0.25 mg, 0.5 mg, 0.75 mg*
- FREAMINE HBC INTRAVENOUS SOLUTION 6.9 %
- GENGRAF ORAL CAPSULE 100 MG, 25 MG

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- GENGRAF ORAL SOLUTION 100 MG/ML
- *granisetron hcl oral tablet 1 mg*
- HEPATAMINE INTRAVENOUS SOLUTION 8 %
- IMOVAX RABIES INTRAMUSCULAR INJECTABLE 2.5 UNIT/ML
- INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %
- *ipratropium bromide inhalation solution 0.02 %*
- *ipratropium-albuterol inhalation solution 0.5-2.5 (3) mg/3ml*
- ISOLYTE-P IN D5W INTRAVENOUS SOLUTION
- ISOLYTE-S INTRAVENOUS SOLUTION
- *levalbuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/0.5ml, 1.25 mg/3ml*
- *methotrexate oral tablet 2.5 mg*
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
- *methotrexate sodium injection solution 50 mg/2ml*
- *mycophenolate mofetil oral capsule 250 mg*
- *mycophenolate mofetil oral suspension reconstituted 200 mg/ml*
- *mycophenolate mofetil oral tablet 500 mg*
- *mycophenolate sodium oral tablet delayed release 180 mg, 360 mg*
- NEPHRAMINE INTRAVENOUS SOLUTION 5.4 %
- NORMOSOL-M IN D5W INTRAVENOUS SOLUTION
- NUTRILIPID INTRAVENOUS EMULSION 20 %
- *ondansetron hcl oral solution 4 mg/5ml*
- *ondansetron hcl oral tablet 24 mg, 4 mg, 8 mg*
- *ondansetron oral tablet dispersible 4 mg, 8 mg*
- *paricalcitol oral capsule 1 mcg, 2 mcg, 4 mcg*
- *penicillin g sodium injection solution reconstituted 5000000 unit*
- *pentamidine isethionate inhalation solution reconstituted 300 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, 40.5 (36-4.5) gm*
- PLASMA-LYTE 148 INTRAVENOUS SOLUTION
- PLASMA-LYTE A INTRAVENOUS SOLUTION
- PLENAMINE INTRAVENOUS SOLUTION 15 %
- *potassium chloride intravenous solution 10 meq/100ml, 2 meq/ml, 2 meq/ml (20 ml), 20 meq/100ml, 40 meq/100ml*
- PREMASOL INTRAVENOUS SOLUTION 10 %
- PROCALAMINE INTRAVENOUS SOLUTION 3 %
- PROGRAF ORAL PACKET 0.2 MG, 1 MG
- PROSOL INTRAVENOUS SOLUTION 20 %
- PULMOZYME INHALATION SOLUTION 1 MG/ML
- RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED
- RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 10 MCG/ML (1ML SYRINGE), 40 MCG/ML, 5 MCG/0.5ML
- SANDIMMUNE ORAL SOLUTION 100 MG/ML
- *sirolimus oral solution 1 mg/ml*
- *sirolimus oral tablet 0.5 mg, 1 mg, 2 mg*

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- *sodium chloride intravenous solution 3 %, 5 %*
- *tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg*
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- TENIVAC INTRAMUSCULAR INJECTABLE 5-2 LFU
- TPN ELECTROLYTES INTRAVENOUS CONCENTRATE
- TRAVASOL INTRAVENOUS SOLUTION 10 %
- TREXALL ORAL TABLET 10 MG, 15 MG, 5 MG, 7.5 MG
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- XATMEP ORAL SOLUTION 2.5 MG/ML
- ZORTRESS ORAL TABLET 1 MG
- ZOSYN INTRAVENOUS SOLUTION 2-0.25 GM/50ML, 3-0.375 GM/50ML

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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