ACTEMRA SQ

MEDICATION(S)
ACTEMRA 162 MG/0.9ML SOLN PRSYR, ACTEMRA ACTPEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous drugs tried.

AGE RESTRICTION
Interstitial lung disease-18 years and older (initial and continuation)

PRESCRIBER RESTRICTION
RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont)

COVERAGE DURATION
1 year

OTHER CRITERIA
RA initial - approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz], Orencia, Rinvoq or Xeljanz/XR (Note: if the patient does not meet this requirement, previous trial(s) with the following drugs will be counted towards meeting the try TWO requirement: Cimzia, infliximab, golimumab SC/IV, Amjevita (NDCs starting with 72511-) or another non-preferred adalimumab product will also count. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product., OR B) patient has heart failure or a previously treated lymphoproliferative disorder. PJIA, initial-approve if the patient meets one of the following (A or B): A) patient has tried TWO of the following drugs in the past: Enbrel, Orencia, Xeljanz or an adalimumab

product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz]. (Note: if the patient does not meet this requirement, a previous trial with the drug infliximab or a non-preferred adalimumab product will be counted towards meeting the try TWO requirement. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product), OR B) patient has heart failure or a previously treated lymphoproliferative disorder. Cont tx, RA/PJIA - approve if the pt had a response as determined by the prescriber. Interstitial lung disease associated with systemic sclerosis initial-approve if the patient has elevated acute phase reactants AND the diagnosis is confirmed by high-resolution computed tomography. Interstitial lung disease assoc with systemic sclerosis, Cont tx-approve if the patient had adequate efficacy.

PART B PREREQUISITE

N/A

ACYCLOVIR (TOPICAL)

MEDICATION(S)
ACYCLOVIR 5 % OINTMENT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ADALIMUMAB OTHER

MEDICATION(S)
ADALIMUMAB-ADAZ, CYLTEZO, CYLTEZO-CD/UC/HS STARTER, CYLTEZO-PSORIASIS STARTER, HYRIMOZ 10 MG/0.1 ML SOLN PRSYR, HYRIMOZ 20 MG/0.2ML SOLN PRSYR, HYRIMOZ 40 MG/0.4ML SOLN A-INJ, HYRIMOZ 40 MG/0.4ML SOLN PRSYR, HYRIMOZ 80 MG/0.8ML SOLN A-INJ, HYRIMOZ-CROHNS/UC STARTER PACK, HYRIMOZ-PED CROHNS STARTER, HYRIMOZ-PLAQUE PSORIASIS START

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with another biologic DMARD or targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous therapies tried

AGE RESTRICTION
CD, 6 or older (initial). UC, 5 or older (initial). PP-18 years and older (initial)

PRESCRIBER RESTRICTION
Init tx only-RA/JIA/JRA/Ankylosing spondylitis, prescr/consult w/rheum. PsA, prescr/consult w/rheum or derm. PP, prescr/consult w/derm. UC/ CD, prescr/consult w/gastro. HS, presc/consult w/derm. UV, prescr/consult w/ophthalmologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide.

Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. Plaque psoriasis (PP) initial. approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). cont tx - must respond to tx as determined by prescriber.

PART B PREREQUISITE

N/A

ADBRY

MEDICATION(S)
ADBRY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with another monoclonal antibody therapy

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years of age and older (initial therapy)

PRESCRIBER RESTRICTION
Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)

COVERAGE DURATION
Initial-Atopic Dermatitis-4 months, Continuation-1 year

OTHER CRITERIA
Atopic Dermatitis, initial-patient has atopic dermatitis involvement estimated to be greater than or equal to 10 percent of the body surface area and patient meets a and b: a. Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid AND b. Inadequate efficacy was demonstrated with the previously tried topical corticosteroid therapy.Continuation- Approve if the patient has been receiving Adbry for at least 4 months and patient has responded to therapy. Note: A patient who has received less than 4 months of therapy or who is restarting therapy with Adbry should be considered under initial therapy.

PART B PREREQUISITE
N/A

ADEMPAS

MEDICATION(S)
ADEMPAS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1).

PART B PREREQUISITE
N/A

AIMOVIG

MEDICATION(S)
AIMOVIG

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Combination therapy with Ajovy, Vyepti or Emgality

REQUIRED MEDICAL INFORMATION
Diagnosis, number of migraine headaches per month, prior therapies tried

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least one standard prophylactic pharmacologic therapy (e.g., anticonvulsant, beta-blocker), and has had inadequate response or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try a standard prophylactic pharmacologic therapy.

PART B PREREQUISITE
N/A

ALECENSA

MEDICATION(S)
ALECENSA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Anaplastic large cell lymphoma, Erdheim Chester disease

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Non-small cell lung cancer-approve if the patient has metastatic disease and anaplastic lymphoma kinase (ALK)-positive non-small cell lung disease. Anaplastic large cell lymphoma-approve if the patient has ALK-positive disease. Erdheim-Chester disease-approve if the patient has ALK rearrangement/fusion-positive disease.

PART B PREREQUISITE
N/A

ALPHA 1 PROTEINASE INHIBITORS

MEDICATION(S)
PROLASTIN-C

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Alpha1-Antitrypsin Deficiency with Emphysema (or Chronic Obstructive Pulmonary Disease)-approve if the patient has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L.

PART B PREREQUISITE
N/A

ALUNBRIG

MEDICATION(S)
ALUNBRIG

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
ALK status

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has IMT with ALK translocation. Metastatic NSCLC, must be ALK-positive, as detected by an approved test.

PART B PREREQUISITE
N/A

AMJEVITA

MEDICATION(S)
AMJEVITA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with another biologic DMARD or targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous therapies tried

AGE RESTRICTION
Crohn's disease (CD), 6 or older (initial therapy only). Ulcerative colitis (UC), 5 or older (initial therapy only). PP-18 years and older (initial therapy only).

PRESCRIBER RESTRICTION
RA/JIA/JRA/Ankylosing spondylitis, prescribed/consult w/rheumatologist (initial therapy only). Psoriatic arthritis (PsA), prescribed/consult w/a rheumatologist or dermatologist (initial therapy only). Plaque psoriasis (PP), prescribed/consult w/a dermatologist (initial therapy only). UC/ CD, prescribed/consult w/gastroenterologist (initial therapy only). HS, prescr/consult w/dermatologist (initial therapy only). UV, presc/consult w/ophthalmologist (initial therapy only).

COVERAGE DURATION
1 year

OTHER CRITERIA
RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried one other systemic therapy for this condition (e.g MTX, sulfasalazine, leflunomide, NSAID) or biologic (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or

leflunomide or if pt has aggressive disease. Plaque psoriasis (PP) initial. approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. CD initial. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). FDA approve indications cont tx - must respond to tx as determined by prescriber.

PART B PREREQUISITE

N/A

ANTIBIOTICS (IV)

MEDICATION(S)

AMIKACIN SULFATE 500 MG/2ML SOLUTION, AMPICILLIN SODIUM 1 GM RECON SOLN, AMPICILLIN SODIUM 10 GM RECON SOLN, AMPICILLIN SODIUM 125 MG RECON SOLN, AMPICILLIN-SULBACTAM SODIUM, AZITHROMYCIN 500 MG RECON SOLN, AZTREONAM, BICILLIN C-R, BICILLIN C-R 900/300, BICILLIN L-A, CEFOXITIN SODIUM, CEFTAZIDIME 1 GM RECON SOLN, CEFTAZIDIME 2 GM RECON SOLN, CEFTAZIDIME 6 GM RECON SOLN, CEFUROXIME SODIUM 1.5 GM RECON SOLN, CEFUROXIME SODIUM 750 MG RECON SOLN, CIPROFLOXACIN IN D5W 200 MG/100ML SOLUTION, CLINDAMYCIN PHOSPHATE 300 MG/2ML SOLUTION, CLINDAMYCIN PHOSPHATE 600 MG/4ML SOLUTION, CLINDAMYCIN PHOSPHATE 900 MG/6ML SOLUTION, CLINDAMYCIN PHOSPHATE IN D5W, COLISTIMETHATE SODIUM (CBA), DOXY 100, ERTAPENEM SODIUM, GENTAMICIN IN SALINE 0.8-0.9 MG/ML-% SOLUTION, GENTAMICIN IN SALINE 1-0.9 MG/ML-% SOLUTION, GENTAMICIN IN SALINE 1.2-0.9 MG/ML-% SOLUTION, GENTAMICIN IN SALINE 1.6-0.9 MG/ML-% SOLUTION, GENTAMICIN SULFATE 40 MG/ML SOLUTION, IMIPENEM-CILASTATIN, LEVOFLOXACIN IN D5W 500 MG/100ML SOLUTION, LEVOFLOXACIN IN D5W 750 MG/150ML SOLUTION, LINEZOLID 600 MG/300ML SOLUTION, MEROPENEM 1 GM RECON SOLN, MEROPENEM 500 MG RECON SOLN, METRONIDAZOLE 500 MG/100ML SOLUTION, MOXIFLOXACIN HCL 400 MG/250ML SOLUTION, MOXIFLOXACIN HCL IN NACL, NAFCILLIN SODIUM, OXACILLIN SODIUM, OXACILLIN SODIUM IN DEXTROSE, PENICILLIN G POT IN DEXTROSE 40000 UNIT/ML SOLUTION, PENICILLIN G POT IN DEXTROSE 60000 UNIT/ML SOLUTION, PENICILLIN G POTASSIUM, PENICILLIN G SODIUM, STREPTOMYCIN SULFATE 1 GM RECON SOLN, TAZICEF 1 GM RECON SOLN, TAZICEF 2 GM RECON SOLN, TAZICEF 6 GM RECON SOLN, TEFLARO, TIGECYCLINE, TOBRAMYCIN SULFATE 1.2 GM RECON SOLN, TOBRAMYCIN SULFATE 1.2 GM/30ML SOLUTION, TOBRAMYCIN SULFATE 10 MG/ML SOLUTION, TOBRAMYCIN SULFATE 80 MG/2ML SOLUTION, VANCOMYCIN HCL 1 GM RECON SOLN, VANCOMYCIN HCL 10 GM RECON SOLN, VANCOMYCIN HCL 500 MG RECON SOLN, VANCOMYCIN HCL 750 MG RECON SOLN

PA INDICATION INDICATOR

1 - All FDA-Approved Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ANTIFUNGALS (IV)

MEDICATION(S)
FLUCONAZOLE IN SODIUM CHLORIDE 200-0.9 MG/100ML-% SOLUTION, FLUCONAZOLE IN SODIUM CHLORIDE 400-0.9 MG/200ML-% SOLUTION, VORICONAZOLE 200 MG RECON SOLN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

APOKYN

MEDICATION(S)
APOKYN, APOMORPHINE HCL 30 MG/3ML SOLN CART

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a serotonin 5-HT3 Antagonist

REQUIRED MEDICAL INFORMATION
Diagnosis, other therapies

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Parkinson's disease (PD), new to therapy-approve if the patient meets the following criteria: 1. Patient has advanced PD, 2. patient is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, 3. Patient is currently receiving carbidopa/levodopa. Parkinson's disease (PD), patients currently receiving apokyn or apomorphine-approve if the patient meets the following criteria: 1. patient has advanced PD, 2. patient is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, 3. patient is currently receiving carbidopa/levodopa and 4.patient has previously tried one other treatment for off episodes and had significant intolerance or inadequate efficacy.

PART B PREREQUISITE
N/A

ARCALYST

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent biologic therapy

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age.

PRESCRIBER RESTRICTION
Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA initial-rheum, geneticist, derm, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum

COVERAGE DURATION
CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont

OTHER CRITERIA
CAPS renewal - approve if the patient has had a response as determined by the prescriber. DIRA initial-approve if the patient weighs at least 10 kg, genetic test confirms a mutation in the IL1RN gene and the patient has demonstrated a clinical benefit with anakinra subcutaneous injection. DIRA cont-approve if the patient has responded to therapy. Pericarditis initial-approve if the patient has recurrent pericarditis AND for the current episode, the patient is receiving standard treatment or standard treatment is contraindicated. Continuation-approve if the patient has had a clinical response.

PART B PREREQUISITE
N/A

ARIKAYCE

MEDICATION(S)
ARIKAYCE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Cystic fibrosis pseudomonas aeruginosa infection

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous medication history

AGE RESTRICTION
MAC-18 years and older (initial therapy)

PRESCRIBER RESTRICTION
MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections. Cystic fibrosis-prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis

COVERAGE DURATION
Initial-1 year Cont, negative culture approve up to 1yr total, positive culture-1 year

OTHER CRITERIA
MAC Lung disease, initial-approve if the patient has a positive sputum culture for mycobacterium avium complex and the culture was collected within the past 3 months and was collected after the patient has completed a background multidrug regimen, the Mycobacterium avium complex isolate is susceptible to amikacin with a minimum inhibitor concentration (MIC) of less than or equal to 64 microgram/mL AND Arikayce will be used in conjunction to a background multidrug regimen. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin). MAC Lung Disease, continuation-approve if Arikayce will be used in conjunction with a background multidrug regimen AND i. Patient meets ONE of the following criteria (a or b):a)patient has not achieved negative sputum cultures for Mycobacterium avium complex OR b)

patient has achieved negative sputum cultures for Mycobacterium avium complex for less than 12 months. Cystic fibrosis-patient has pseudomonas aeruginosa in culture of the airway.

PART B PREREQUISITE

N/A

AUBAGIO

MEDICATION(S)
AUBAGIO, TERIFLUNOMIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use of teriflunomide with other disease-modifying agents used for multiple sclerosis (MS)

REQUIRED MEDICAL INFORMATION
Relapsing form of MS, to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or MS specialist.

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
Initial treatment - approve if the patient has tried generic dimethyl fumarate. Note: Prior use of brand Tecfidera, Bafiertam, or Vumerity with inadequate efficacy or significant intolerance (according to the prescriber) also counts. Cont tx - approve if the patient has been established on teriflunomide.

PART B PREREQUISITE
N/A

AVONEX

MEDICATION(S)
AVONEX PEN, AVONEX PREFILLED

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use of other disease-modifying agent used for multiple sclerosis

REQUIRED MEDICAL INFORMATION
Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or after consultation with a neurologist or an MS specialist.

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
Cont tx-approve if the patient has been established on Avonex.

PART B PREREQUISITE
N/A

AYVAKIT

MEDICATION(S)
AYVAKIT

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Myeloid/Lymphoid neoplasms with Eosinophilia

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation or if the patient has tried two of the following: Gleevec (imatinib), Sutent (sunitinib), Sprycel (dasatinib), Stivarga (regorafenib) or Qinlock (ripretinib). Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for PDGFRA D842V mutation. Systemic mastocytosis-Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has either indolent systemic mastocytosis or one of the following subtypes of advanced systemic mastocytosis-aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm or mast cell leukemia.

PART B PREREQUISITE
N/A

BALVERSA

MEDICATION(S)
BALVERSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapies, test results

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy or checkpoint inhibitor therapy.

PART B PREREQUISITE
N/A

BENLYSTA

MEDICATION(S)
BENLYSTA 200 MG/ML SOLN A-INJ, BENLYSTA 200 MG/ML SOLN PRSYR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent Use with Other Biologics or Lupkynis

REQUIRED MEDICAL INFORMATION
Diagnosis, medications that will be used in combination, autoantibody status

AGE RESTRICTION
18 years and older (initial).

PRESCRIBER RESTRICTION
SLE-Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus Nephritis-nephrologist or rheum. (Initial/cont)

COVERAGE DURATION
SLE-Initial-4 months, cont-1 year. Lupus Nephritis-6 mo initial, 1 year cont

OTHER CRITERIA
Lupus Nephritis Initial-approve. Cont-approve if the patient has responded to the requested medication. SLE-Initial-The patient has autoantibody-positive SLE, defined as positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA] AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician. Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine,

mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician AND The patient has responded to Benlysta as determined by the prescriber.

PART B PREREQUISITE

N/A

BESREMI

MEDICATION(S)
BESREMI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with other interferon products

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BETASERON/EXTAVIA

MEDICATION(S)
BETASERON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other disease-modifying agent used for multiple sclerosis

REQUIRED MEDICAL INFORMATION
Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or after consultation with a neurologist or an MS specialist.

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
For patients requesting Betaseron-Cont tx-approve if the patient has been established on Betaseron.

PART B PREREQUISITE
N/A

BEXAROTENE (ORAL)

MEDICATION(S)
BEXAROTENE 75 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)

COVERAGE DURATION
3 years

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

BOSENTAN/AMBRISENTAN

MEDICATION(S)
AMBRISENTAN, BOSENTAN

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Chronic thromboembolic pulmonary hypertension (CTEPH) (bosentan)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For treatment of pulmonary arterial hypertension, ambrisentan or bosentan must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH - prescribed by or in consultation with a cardiologist or pulmonologist

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment.

PART B PREREQUISITE
N/A

BOSULIF

MEDICATION(S)
BOSULIF

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis. For CML/ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies tried

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
For CML, patient must have Ph-positive CML For ALL, patient must have Ph-positive ALL and has tried ONE other tyrosine kinase inhibitors that are used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).

PART B PREREQUISITE
N/A

BRAFTOVI

MEDICATION(S)
BRAFTOVI 75 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, BRAF V600 status

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer. NSCLC- approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets).

PART B PREREQUISITE
N/A

BRUKINSA

MEDICATION(S)
BRUKINSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior therapies

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Mantle Cell Lymphoma - approve if the patient has tried at least one systemic regimen or patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail). Chronic lymphocytic leukemia/small lymphocytic lymphoma-approve. Marginal zone lymphoma-approve if the patient has tried at least one systemic regimen. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma-approve.

PART B PREREQUISITE
N/A

C1 ESTERASE INHIBITORS

MEDICATION(S)
CINRYZE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders

COVERAGE DURATION
1 year

OTHER CRITERIA
Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II], Prophylaxis, Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50 percent of normal) at baseline and lower than normal serum C4 levels at baseline. Patient is currently taking Cinryze for prophylaxis - approve if the patient meets the following criteria (i and ii): i) patient has a diagnosis of HAE type I or II, and ii) according to the prescriber, the patient has had a favorable clinical response since initiating Cinryze as prophylactic therapy compared with baseline. HAE Due to C1-INH Deficiency [Type I or Type II], Treatment of Acute Attacks, Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50 percent of normal) at baseline and lower than normal serum C4 levels at baseline. Patient who has treated previous acute HAE attacks with Cinryze: approve if the patient has a

diagnosis of HAE Type I or Type II and according to the prescriber, the patient has had a favorable clinical response.

PART B PREREQUISITE

N/A

CABLIVI

MEDICATION(S)
CABLIVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist

COVERAGE DURATION
Approve for 12 months

OTHER CRITERIA
aTTP-approve if the requested medication was initiated in the inpatient setting in combination with plasma exchange therapy AND patient is currently receiving at least one immunosuppressive therapy AND if the patient has previously received Cablivi, he/she has not had more than two recurrences of aTTP while on Cablivi.

PART B PREREQUISITE
N/A

CABOMETYX

MEDICATION(S)
CABOMETYX

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Patients with Non-Small Cell Lung Cancer, Gastrointestinal stromal tumors (GIST), Bone cancer, Endometrial Carcinoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, histology, RET gene rearrangement status

AGE RESTRICTION
Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried a vascular endothelial growth factor receptor (VEGFR)-targeted therapy. Endometrial carcinoma-approve if the patient has tried one systemic regimen. GIST-approve if the patient has tried two of the following-imatinib, Ayvakit, sunitinib, dasatinib, Stivarga or Qinlock. NSCLC-approve if the patient has RET rearrangement positive tumor.

PART B PREREQUISITE

N/A

CALQUENCE

MEDICATION(S)
CALQUENCE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CAPRELSA

MEDICATION(S)
CAPRELSA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Non-Small Cell Lung Cancer with RET Gene Rearrangements

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
MTC - approve. DTC - approve if refractory to radioactive iodine therapy.

PART B PREREQUISITE
N/A

CARBAGLU

MEDICATION(S)
CARGLUMIC ACID

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (generic carglumic acid)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases

COVERAGE DURATION
NAGS-Pt meets criteria no genetic test - 3mo. Pt had genetic test - 12mo, other-approve 7 days

OTHER CRITERIA
N-Acetylglutamate synthase deficiency with hyperammonemia-Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency or if the patient has hyperammonemia. Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia, Acute Treatment-approve if the patient's plasma ammonia level is greater then or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.

PART B PREREQUISITE
N/A

CAYSTON

MEDICATION(S)
CAYSTON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

COVERAGE DURATION
1 year

OTHER CRITERIA
Approve if the patient has Pseudomonas aeruginosa in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).

PART B PREREQUISITE
N/A

CHEMET

MEDICATION(S)
CHEMET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Blood lead level

AGE RESTRICTION
Approve in patients between the age of 12 months and 18 years

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a professional experienced in the use of chelation therapy (eg, a medical toxicologist or a poison control center specialist)

COVERAGE DURATION
Approve for 2 months

OTHER CRITERIA
Approve if Chemet is being used to treat acute lead poisoning (not as prophylaxis) and prior to starting Chemet therapy the patient's blood lead level was greater than 45 mcg/dL.

PART B PREREQUISITE
N/A

CHENODAL

MEDICATION(S)
CHENODAL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
For the treatment of gallstones, approve if the patient has tried or is currently using an ursodiol product.

PART B PREREQUISITE
N/A

CHOLBAM

MEDICATION(S)
CHOLBAM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Combination Therapy with Chenodal

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with hepatologist, metabolic specialist, or GI

COVERAGE DURATION
3 mos initial, 12 mos cont

OTHER CRITERIA
Bile acid synthesis d/o due to SEDs initial - Diagnosis based on an abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis or molecular genetic testing consistent with the diagnosis. Cont - responded to initial Cholbam tx with an improvement in LFTs AND does not have complete biliary obstruction. Bile-Acid Synthesis Disorders Due to Peroxisomal Disorders (PDs), Including Zellweger Spectrum Disorders initial - PD with an abnormal urinary bile acid analysis by FAB-MS or molecular genetic testing consistent with the diagnosis AND has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g., rickets). Cont - responded to initial Cholbam therapy as per the prescribing physician (e.g., improvements in liver enzymes, improvement in steatorrhea) AND does not have complete biliary obstruction.

PART B PREREQUISITE

N/A

CIBINQO

MEDICATION(S)
CIBINQO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD). Concurrent use with an Anti-Interleukin Monoclonal Antibody. Concurrent use with other Janus Kinase Inhibitors. Concurrent use with Xolair (omalizumab subcutaneous injection). Concurrent use with other potent immunosuppressants.

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
AD-12 years of age and older (initial therapy)

PRESCRIBER RESTRICTION
Atopic Dermatitis-prescribed by or in consultation with an allergist, immunologist or dermatologist (initial therapy)

COVERAGE DURATION
Initial-Atopic Dermatitis-3 months, Continuation-1 year

OTHER CRITERIA
Atopic Dermatitis, initial-approve if the patient has had a 3-month trial of at least one traditional systemic therapy OR patient has tried at least one traditional systemic therapy but was unable to tolerate a 3-month trial. Note: Examples of traditional systemic therapies include methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis. Continuation-Approve if the patient has been receiving Cibinqo for at least 90 days AND patient experienced a beneficial

clinical response, defined as improvement from baseline (prior to initiating Cibinqo) in at least one of the following: estimated body surface area affected, erythema, induration/papulation/edema, excoriations, lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis AND compared with baseline (prior to receiving Cibinqo), patient experienced an improvement in at least one symptom, such as decreased itching. Note: A patient who has received less than 3 months of therapy or who is restarting therapy with Cibinqo should be considered under initial therapy.

PART B PREREQUISITE

N/A

CIMZIA

MEDICATION(S)
CIMZIA, CIMZIA STARTER KIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous therapies tried

AGE RESTRICTION
18 years and older for CD and PP (initial therapy).

PRESCRIBER RESTRICTION
All dx initial therapy only. RA/AS, prescribed by or in consultation with a rheumatologist. Crohn's disease, prescribed by or in consultation with a gastroenterologist.PsA prescribed by or in consultation with a rheumatologist or dermatologist. PP, prescribed by or in consultation with a dermatologist. nr-axSpA-prescribed by or in consultation with a rheumatologist

COVERAGE DURATION
1 year

OTHER CRITERIA
AS initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz], Xeljanz/XR, Taltz. Note: if the patient does not meet this requirement, a previous trial of Amjevita (NDCs starting with 72511) or another non-preferred adalimumab product will also count. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product. PsA initial tx, approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-

adaz], Taltz, Stelara, Otezla, Orencia, Rinvoq, Skyrizi or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of Amjevita (NDCs starting with 72511) or another non-preferred adalimumab product will also count. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product.RA initial tx, approve if the patient has tried two of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz], Orencia, Rinvoq or Xeljanz/XR. Note: if the patient does not meet this requirement, a previous trial of Amjevita (NDCs starting with 72511) or another non-preferred adalimumab product will also count. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz, or any other adalimumab product counts as ONE Preferred Product. CD initial tx, approve if patient has previously tried an adalimumab product [i.e., Humira, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz or Amjevita (NDCs starting with 55513-)]. Note: if the patient does not meet this requirement, a previous trial of Amjevita (NDCs starting with 72511) or any other non-preferred adalimumab product will also count. Plaque Psoriasis (PP), initial tx-approve if the patient has tried TWO of the following drugs in the past: Enbrel, an adalimumab product [i.e., Humira, Amjevita (NDCs starting with 55513-), Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz], Skyrizi, Stelara SC, Otezla, or Taltz. A trial of Humira, Amjevita, Cyltezo, Hyrimoz, adalimumab-adaz counts as ONE Preferred Product. Cont tx, AS/PsA/RA/CD/PP - approve if the pt had a response as determined by the prescriber. Non-radiographic axial spondylitis (nr-axSpA), initial tx-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroilitis reported on MRI. nr-axSpA continuation tx-approve if the patient has had a response as determined by the prescriber.

PART B PREREQUISITE

N/A

CLOBAZAM

MEDICATION(S)
CLOBAZAM, SYMPAZAN

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Dravet Syndrome and treatment-refractory seizures/epilepsy

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, other medications tried

AGE RESTRICTION
2 years and older (initial therapy)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist (initial therapy)

COVERAGE DURATION
1 year

OTHER CRITERIA
Lennox-Gastaut Syndrome, initial therapy-patient has tried one of the following: lamotrigine, topiramate, rufinamide, felbamate, or Epidiolex. Treatment refractory seizures/epilepsy, initial therapy-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Continuation-prescriber confirms patient is responding to therapy.

PART B PREREQUISITE
N/A

COMETRIQ

MEDICATION(S)
COMETRIQ (100 MG DAILY DOSE), COMETRIQ (140 MG DAILY DOSE), COMETRIQ (60 MG DAILY DOSE)

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis.

AGE RESTRICTION
NSCLC/MTC-18 years and older, DTC-12 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy and patient has tried a Vascular Endothelial Growth Factor Receptor (VEGFR)-targeted therapy.

PART B PREREQUISITE
N/A

COPIKTRA

MEDICATION(S)
COPIKTRA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
T-cell Lymphoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapies

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
T-cell lymphoma-For peripheral T-cell lymphoma, approve. For breast implant-associated anaplastic large cell lymphoma, or hepatosplenic T-cell lymphoma, approve if the patient has relapsed or refractory disease.

PART B PREREQUISITE
N/A

COTELLIC

MEDICATION(S)
COTELLIC

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Central Nervous System Cancer, Histiocytic Neoplasm

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Melanoma initial - must have BRAF V600 mutation.

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf. CNS Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i) Adjuvant treatment of pilocytic astrocytoma or pleomorphic xanthoastrocytoma or ganglioglioma, OR ii) recurrent disease for low-grade glioma or anaplastic glioma or glioblastoma, OR iii) melanoma with brain metastases AND medication will be taken in combination with Zelboraf (vemurafenib tablets). Histiocytic Neoplasm-approve if the patient meets one of the following (i, ii, or iii): i) patient has Langerhans cell histiocytosis and one of the following: multisystem disease or pulmonary disease or central nervous system lesions, OR ii) patient has Erdheim Chester disease, OR iii) patient has Rosai-Dorfman disease AND patient has BRAF V600 mutation-positive disease.

PART B PREREQUISITE

N/A

CRESEMBA (ORAL)

MEDICATION(S)
CRESEMBA 186 MG CAP, CRESEMBA 74.5 MG CAP

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Candidiasis of the esophagus - HIV infection, sepsis

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CYSTEAMINE (OPHTHALMIC)

MEDICATION(S)
CYSTARAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases

COVERAGE DURATION
1 year

OTHER CRITERIA
Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination

PART B PREREQUISITE
N/A

CYSTEAMINE (ORAL)

MEDICATION(S)
CYSTAGON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use of Cystagon and Procysbi

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic tests and lab results

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)

COVERAGE DURATION
1 year

OTHER CRITERIA
Cystinosis, nephropathic-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory.

PART B PREREQUISITE
N/A

DALFAMPRIDINE

MEDICATION(S)
DALFAMPRIDINE ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older (initial and continuation therapy)

PRESCRIBER RESTRICTION
MS. If prescribed by, or in consultation with, a neurologist or MS specialist (initial and continuation).

COVERAGE DURATION
Initial-4months, Continuation-1 year

OTHER CRITERIA
Initial-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has impaired ambulation as evaluated by an objective measure (e.g., timed 25 foot walk and multiple sclerosis walking scale-12). Continuation-approve if the patient is ambulatory, the requested medication is being used to improve or maintain mobility in a patient with MS and the patient has responded to or is benefiting from therapy.

PART B PREREQUISITE
N/A

DALIRESP

MEDICATION(S)
DALIRESP, ROFLUMILAST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic Obstructive Pulmonary Disease (COPD), medications tried.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
COPD, approve in patients who meet all of the following conditions: Patients has severe COPD or very severe COPD, AND Patient has a history of exacerbations, AND Patient has tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, indacaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone).

PART B PREREQUISITE
N/A

DAURISMO

MEDICATION(S)
DAURISMO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, medications that will be used in combination, comorbidities

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
AML - approve if Daurismo will be used in combination with cytarabine.

PART B PREREQUISITE
N/A

DEFERASIROX

MEDICATION(S)
DEFERASIROX, DEFERASIROX GRANULES

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Serum ferritin level

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.

PART B PREREQUISITE
N/A

DEFERIPRONE

MEDICATION(S)
DEFERIPRONE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Serum ferritin level

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Iron overload, chronic-transfusion related due to thalassemia syndrome or related to sickle cell disease or other anemias Initial therapy - approve. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician.

PART B PREREQUISITE
N/A

DIACOMIT

MEDICATION(S)
DIACOMIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis.

AGE RESTRICTION
6 months and older (initial therapy)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an neurologist (initial therapy)

COVERAGE DURATION
1 year

OTHER CRITERIA
Dravet Syndrome-Initial therapy-approve if the patient is concomitantly receiving clobazam or is unable to take clobazam due to adverse events. Dravet Syndrome-Continuation-approve if the patient is responding to therapy.

PART B PREREQUISITE
N/A

DIMETHYL FUMARATE

MEDICATION(S)
DIMETHYL FUMARATE 120 MG CAP DR, DIMETHYL FUMARATE 240 MG CAP DR, DIMETHYL FUMARATE STARTER PACK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other disease-modifying agents used for multiple sclerosis (MS).

REQUIRED MEDICAL INFORMATION
Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or MS specialist.

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

DOPTELET

MEDICATION(S)
DOPTELET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, platelet count, date of procedure

AGE RESTRICTION
18 years and older (for chronic ITP-initial therapy only)

PRESCRIBER RESTRICTION
Chronic ITP-prescribed by or after consultation with a hematologist (initial therapy)

COVERAGE DURATION
Thrombo w/chronic liver disease-5 days, chronic ITP-initial-3 months, cont-1 year

OTHER CRITERIA
Thrombocytopenia with chronic liver disease-Approve if the patient has a current platelet count less than 50 x 109/L AND the patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. Chronic ITP initial-approve if the patient has a platelet count less than 30,000 microliters or less than 50,000 microliters and is at an increased risk of bleeding and has tried one other therapy or if the patient has undergone splenectomy. Continuation-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.

PART B PREREQUISITE
N/A

DUPIXENT

MEDICATION(S)
DUPIXENT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody.

REQUIRED MEDICAL INFORMATION
Diagnosis, prescriber specialty, other medications tried and length of trials

AGE RESTRICTION
AD-6 months and older, asthma-6 years of age and older, Esophagitis-12 and older, Chronic Rhinosinusitis/Prurigo nodularis-18 and older

PRESCRIBER RESTRICTION
Atopic Dermatitis/prurigo nodularis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Esophagitis-presc/consult-allergist or gastro

COVERAGE DURATION
AD-Init-4mo, Cont-1 yr, asthma/Rhinosinusitis/esophagitis/prurigo nod-init-6 mo, cont 1 yr

OTHER CRITERIA
AD,Init-pt 2yrs and older-pt meets a and b:a.used at least 1 med,med-high,high, and/or super-high-potency rx top CS OR AD affecting ONLY face,eyes/lids,skin folds,and/or genitalia and tried tacrolimus oint AND b.Inadeq efficacy was demonstrated w/prev tx.AD,Init-pt between 6 mo and less than 2 yr-pt meets a and b:a.used at least 1 med,med-high,high, and/or super-high-potency rx top CS and b.inadeq efficacy was demonstrated w/prev tx OR AD affecting ONLY face,eyes/lids,skin folds,and/or genitalia.Cont-pt responded to Dupixent.Asthma,init-pt meets (i, ii, and iii):i.Pt meets (a or b):a)blood eosinophil greater than or equal to 150 cells per microliter w/in prev 6 wks or within 6 wks prior to tx

with any IL tx or Xolair OR b)has oral CS-dependent asthma, AND ii.received combo tx w/following (a and b): a)ICS AND b)1 add asthma control/maint med(NOTE:exception to the requirement for a trial of 1 add asthma controller/maint med can be made if pt already received anti-IL-5 tx or Xolair used concomitantly w/an ICS AND iii.asthma uncontrolled or was uncontrolled prior to starting anti-IL tx or Xolair defined by 1 (a, b, c, d or e): a)exper 2 or more asthma exacer req tx with systemic CS in prev yr OR b)exper 1 or more asthma exacer requiring hosp or ED visit in prev yr OR c)FEV1 less than 80percent predicted OR d)FEV1/FVC less than 0.80 OR e)asthma worsens w/tapering of oral CS tx.Cont-pt meets (i and ii): i.cont to receive tx with 1 ICS or 1 ICS-containing combo inhaler AND ii.has responded to Dupixent.Chronic rhinosinusitis w/nasal polyposis,init-pt receiving tx with an intranasal CS and experi rhinosinusitis symptoms like nasal obstruction, rhinorrhea, or reduction/loss of smell AND meets 1 (a or b): a)received tx w/syst CS w/in prev 2 yrs or has contraindication to systemic CS tx OR b)prior surgery for nasal polyps. Cont-pt cont to receive tx with an intranasal CS and responded to Dupixent. Eosino esoph, init- weighs greater than or equal to 40 kg, has dx of eosino esophagitis confirmed by endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field, and does not have a secondary cause of eosino esophagitis, and has received at least 8 wks of tx with a Rx strength PPI. Cont-pt received at least 6mo of tx with Dupixent and has experi reduced intraepithelial eosinophil count or decreased dysphagia/pain upon swallowing or reduced frequency/severity of food impaction.Prurigo Nod, init-pt has greater than or equal to 20 nodular lesions and pt has experienced pruritus at least 6 wks, AND pt tried at least 1 high- or super-high-potency Rx topical CS. Cont-pt received at least 6 mo of tx with Dupixent and has experi reduced nodular lesion count, decreased pruritis or reduced nodular lesion size.

PART B PREREQUISITE

N/A

EMGALITY

MEDICATION(S)
EMGALITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Combination therapy with Aimovig, Vyepti or Ajovy

REQUIRED MEDICAL INFORMATION
Diagnosis, number of migraine or cluster headaches per month, prior therapies tried

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Cluster headache tx-6 months, migraine prevention-1 year

OTHER CRITERIA
Migraine headache prevention-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least one standard prophylactic pharmacologic therapy (e.g., anticonvulsant, beta-blocker), and has had inadequate response or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try a standard prophylactic pharmacologic therapy. Episodic cluster headache treatment-approve if the patient has between one headache every other day and eight headaches per day.

PART B PREREQUISITE

N/A

ENBREL

MEDICATION(S)
ENBREL 25 MG/0.5ML SOLN PRSYR, ENBREL 25 MG/0.5ML SOLUTION, ENBREL 50 MG/ML SOLN PRSYR, ENBREL MINI, ENBREL SURECLICK

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Graft versus host disease (GVHD), Behcet's disease

EXCLUSION CRITERIA
Concurrent use with biologic therapy or targeted synthetic DMARD

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous therapies tried.

AGE RESTRICTION
PP-4 years and older (initial therapy)

PRESCRIBER RESTRICTION
Initial only-RA/AS/JIA/JRA,prescribed by or in consult w/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist.Plaque psoriasis (PP), prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center.Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other systemic therapy for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID), biologic or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding,

alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide.Plaque psoriasis (PP) initial approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. GVHD-approve. Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. Behcet's, GVHD-Cont-if the patient has had a response to tx according to the prescriber. Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit, approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR 4) Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months.

PART B PREREQUISITE

N/A

EPCLUSA

MEDICATION(S)
EPCLUSA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Indications consistent with current AASLD/IDSA guidance

EXCLUSION CRITERIA
Combination use with other direct acting antivirals, excluding ribavirin.

REQUIRED MEDICAL INFORMATION
Genotype (including unknown), prescriber specialty, other medications tried or used in combination with requested medication

AGE RESTRICTION
3 years or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician

COVERAGE DURATION
Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug

OTHER CRITERIA
Criteria will be applied consistent with current AASLD/IDSA guidance.

PART B PREREQUISITE
N/A

EPIDIOLEX

MEDICATION(S)
EPIDIOLEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapies

AGE RESTRICTION
Patients 1 year and older (initial therapy)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist (initial therapy)

COVERAGE DURATION
1 year

OTHER CRITERIA
Dravet Syndrome-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or if the patient has tried or is concomitantly receiving one of Diacomit or clobazam or Fintepla. Lennox Gastaut Syndrome-approve if the patient has tried or is concomitantly receiving at least two other antiepileptics drugs. Tuberous Sclerosis Complex-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Continuation of therapy-approve if the patient is responding to therapy.

PART B PREREQUISITE
N/A

EPOETIN ALFA

MEDICATION(S)
PROCRIT, RETACRIT

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Anemia due to myelodysplastic syndrome (MDS), Myelofibrosis

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
CRF anemia in patients not on dialysis.Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start.Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa, Mircera or Aranesp. Anemia w/myelosuppressive chemotx.pt must be currently receiving myelosuppressive chemo and Hb 10.0 g/dL or less to start.Hb less than or equal to 12.0 g/dL if previously on epoetin alfa or Aranesp.MDS, approve if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start.Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV with zidovudine, Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 mU/mL or less at tx start.Previously on EA approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Hgb is less than or equal to 13, surgery is elective, nonvascular and non-cardiac and pt is unwilling or unable to donate autologous blood prior to surgery

AGE RESTRICTION
MDS anemia = 18 years of age and older

PRESCRIBER RESTRICTION
MDS anemia, myelofibrosis- prescribed by or in consultation with, a hematologist or oncologist.

COVERAGE DURATION
Chemo-6m,Transfus-1m, CKD-1yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr

OTHER CRITERIA
Myelofibrosis-Initial-patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 Mu/mL. Cont-approve if according to the prescriber the patient has had a response. Anemia in patients

with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit).

PART B PREREQUISITE

N/A

ERIVEDGE

MEDICATION(S)
ERIVEDGE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Central nervous System Cancer

EXCLUSION CRITERIA
BCC (La or Met) - must not have had disease progression while on Odomzo.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Locally advanced basal cell carcinoma (LABCC), approve if 1. the patient's BCC has recurred following surgery or radiation, OR 2. the patient is not a candidate for surgery and radiation therapy. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway. Basal cell carcinoma, metastatic-approve.

PART B PREREQUISITE
N/A

ERLEADA

MEDICATION(S)
ERLEADA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) agonist or the medication is concurrently used with Firmagon or if the patient has had a bilateral orchiectomy.

PART B PREREQUISITE
N/A

ERLOTINIB

MEDICATION(S)
ERLOTINIB HCL

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Advanced or Metastatic NSCLC, approve if the patient has sensitizing EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of sensitizing EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. Advanced RCC, approve if the patient has recurrent or advanced non-clear cell histology RCC or if the patient had hereditary leiomyomatosis and renal cell carcinoma and erlotinib will be used in combination with bevacizumab. Bone cancer-approve if the patient has chordoma and has tried one previous therapy. Pancreatic cancer-approve if the medication is used in combination with gemcitabine and if the patient has locally advanced, metastatic or recurrent disease. Vulvar cancer-approve if the patient has advanced, recurrent or metastatic disease.

PART B PREREQUISITE

N/A

ESBRIET

MEDICATION(S)
ESBRIET 267 MG CAP, PIRFENIDONE 267 MG CAP, PIRFENIDONE 267 MG TAB, PIRFENIDONE 801 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist

COVERAGE DURATION
1 year

OTHER CRITERIA
IPF - must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP.

PART B PREREQUISITE
N/A

EVEROLIMUS

MEDICATION(S)
EVEROLIMUS 10 MG TAB, EVEROLIMUS 2 MG TAB SOL, EVEROLIMUS 2.5 MG TAB, EVEROLIMUS 3 MG TAB SOL, EVEROLIMUS 5 MG TAB, EVEROLIMUS 5 MG TAB SOL, EVEROLIMUS 7.5 MG TAB

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
neuroendocrine tumors of the thymus (Carcinoid tumors). Soft tissue sarcoma, classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Thymomas and Thymic carcinomas, Differentiated Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST), Meningioma, men with breast cancer, Histiocytic Neoplasm

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Breast Cancer-HER2 status, hormone receptor (HR) status.

AGE RESTRICTION
All dx except TSC associated SEGA or partial onset seizures-18 years and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Breast Cancer-approve if pt meets ALL the following (A, B, C, D, E, and F):A)pt has recurrent or metastatic,HR+ disease AND B)pt has HER2-negative breast cancer AND C)pt has tried at least 1 prior endocrine therapy AND D)pt meets 1 of the following conditions (i or ii):i.pt is a postmenopausal woman or man OR ii.pt is pre/perimenopausal woman AND is receiving ovarian suppression/ablation with a GnRH agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND E)pt meets 1 of the following conditions (i or ii): i.Afinitor will be used in combo with exemestane and pt meets 1 of

the following:pt is male and is receiving a GnRH analog or pt is a woman or ii. Afinitor will be used in combo with fulvestrant or tamoxifen AND F)pt has not had disease progression while on Afinitor. RCC, relapsed or Stage IV disease-approve if using for non-clear cell disease or if using for clear cell disease, pt has tried 1 prior systemic therapy (e.g., Inlyta, Votrient, Sutent, Cabometyx, Nexavar).TSC Associated SEGA-approve if pt requires therapeutic intervention but cannot be curatively resected. Thymomas and Thymic Carcinomas-approve if pt has tried chemotherapy or cannot tolerate chemotherapy. TSC associated renal angiomyolipoma -approve. WM/LPL - approve if pt has progressive or relapsed disease or if pt has not responded to primary therapy. Thyroid Carcinoma, differentiated-approve if pt is refractory to radioactive iodine therapy. Endometrial Carcinoma-approve if Afinitor will be used in combo with letrozole. GIST-approve if pt has tried 2 of the following drugs: Sutent, Sprycel, Stivarga, Ayvakit, Qinlock or imatinib AND there is confirmation that Afinitor will be used in combo with 1 of these drugs (Sutent, Stivarga, or imatinib) in the treatment of GIST. TSC-associated partial-onset seizures-approve. NET tumors of the pancreas, GI Tract, Lung and Thymus (carcinoid tumors)-approve. Meningioma-approve if pt has recurrent or progressive disease. Soft tissue sarcoma-approve if pt has perivascular epithloid cell tumors (PE Coma) or recurrent angiomyolipoma/lymphangioleiomyomatosis. Classic hodgkin lymphoma-approve if pt has relapsed or refractory disease. Histiocytic neoplasm-approve if pt has Erdheim-Chester disease or, Rosai-Dorfman disease or Langerhans cell histiocytosis with bone disease, central nervous system lesions, multisystem disease or pulmonary disease. Patient must also have PIK3CA mutation.

PART B PREREQUISITE

N/A

EXKIVITY

MEDICATION(S)
EXKIVITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Non-Small Cell Lung Cancer (NSCLC)-approve if the patient meets (A, B and C): A) Patient has locally advanced or metastatic NSCLC AND B) Patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutation, as determined by an approved test AND C) Patient has previously tried at least one platinum-based chemotherapy.

PART B PREREQUISITE
N/A

FASENRA

MEDICATION(S)
FASENRA, FASENRA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody

REQUIRED MEDICAL INFORMATION
Diagnosis, severity of disease, peripheral blood eosinophil count, previous therapies tried and current therapies, FEV1/FVC

AGE RESTRICTION
12 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

COVERAGE DURATION
Authorization will be for 6 months initial, 12 months continuation.

OTHER CRITERIA
Initial - must have peripheral blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks (prior to treatment with any anti-interleukin (IL)-5 therapy) AND meet both of the following criteria: 1) Patient has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following: inhaled LABA, inhaled long-acting muscarinic antagonist, Leukotriene receptor antagonist, or Theophylline, AND 2) Patient's asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy as defined by ONE of the following: a) patient experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, OR b) patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, OR c) patient has a FEV1 less than 80 percent predicted, OR d) Patient has an FEV1/FVC less than 0.80, OR e) Patient's asthma worsens

upon tapering of oral corticosteroid therapy. NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an ICS for at least 3 consecutive months. Continuation - The patient has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy) AND patient continues to receive therapy with an inhaled corticosteroid.

PART B PREREQUISITE

N/A

FINTEPLA

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
2 years and older (initial therapy)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an neurologist (initial therapy)

COVERAGE DURATION
1 year

OTHER CRITERIA
Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex, Clobazam or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome, initial-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome, continuation-approve if the patient is responding to therapy.

PART B PREREQUISITE
N/A

FIRDAPSE

MEDICATION(S)
FIRDAPSE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
History of seizures (initial therapy)

REQUIRED MEDICAL INFORMATION
Diagnosis, seizure history, lab and test results

AGE RESTRICTION
6 years and older (initial therapy)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or a neuromuscular specialist (initial therapy)

COVERAGE DURATION
Initial-3 months, Cont-1 year

OTHER CRITERIA
Initial therapy-Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive nerve stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. Continuation-patient continues to derive benefit (e.g., improved muscle strength, improvements in mobility) from Firdapse, according to the prescribing physician.

PART B PREREQUISITE
N/A

FOTIVDA

MEDICATION(S)
FOTIVDA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, other therapies

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years

OTHER CRITERIA
Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. Note: Examples of systemic regimens for renal cell carcinoma include axitinib tablets, axitinib + pembrolizumab injection, cabozantinib tablets, cabozantinib + nivolumab injection, sunitinib malate capsules, pazopanib tablets, sorafenib tablets, and lenvatinib capsules + everolimus.

PART B PREREQUISITE
N/A

GATTEX

MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
1 year and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist (initial and continuation)

COVERAGE DURATION
1 year

OTHER CRITERIA
Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced at least a 20 percent decrease from baseline in the weekly volume of parenteral nutrition.

PART B PREREQUISITE
N/A

GAVRETO

MEDICATION(S)
GAVRETO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
NSCLC-18 years and older, MTC/thyroid cancer-12 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
NSCLC-approve if the patient has metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Medullary thyroid cancer (MTC)-approve if the patient has advanced or metastatic rearranged during transfection (RET)-mutant disease and the disease requires treatment with systemic therapy. Thyroid cancer (other than MTC)-approve if the patient has advanced or metastatic rearranged during transfection (RET) fusion-positive disease, the disease is radioactive iodine-refractory AND the disease requires treatment with systemic therapy.

PART B PREREQUISITE
N/A

GILENYA

MEDICATION(S)
FINGOLIMOD HCL, GILENYA 0.5 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use of fingolimod with other disease-modifying agents used for multiple sclerosis (MS).

REQUIRED MEDICAL INFORMATION
Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist or an MS specialist.

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
For patients requesting brand name Gilenya, Initial treatment-approve if the patient has tried generic dimethyl fumarate or fingolimod, unless the patient meets one of the following: a)patient is greater than or equal to 10 years of age but less than 18 years old or, b) if the patient has highly active or aggressive multiple sclerosis defined as, rapidly advancing deterioration in physical functioning (Note: examples include loss of mobility or lower levels of ambulation, severe changes in strength or coordination), or c) disabling relapse with suboptimal response to systemic corticosteroids, or d) Magnetic resonance imaging (MRI) findings suggest highly active or aggressive multiple sclerosis (Note: Examples include new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions) or, e) manifestation of multiple sclerosis-related cognitive impairment. Note: Prior use of brand Tecfidera, Bafiertam, Vumerity or a glatiramer product (brand or generic) with inadequate efficacy or

significant intolerance (according to the prescriber) also counts. Cont tx - approve if the patient has been established on Gilenya.

PART B PREREQUISITE

N/A

GILOTRIF

MEDICATION(S)
GILOTRIF

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Head and neck cancer

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For NSCLC - EGFR exon deletions or mutations, or if NSCLC is squamous cell type

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
NSCLC EGFR pos - For the treatment of advanced or metastatic non small cell lung cancer (NSCLC) - approve if the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: examples of sensitizing EGFR mutation-positive NSCLC include the following mutations : exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. NSCLC metastatic squamous cell must have disease progression after treatment with platinum based chemotherapy. Head and neck cancer-approve if the patient has non-nasopharyngeal head and neck cancer and the patient has disease progression on or after platinum based chemotherapy.

PART B PREREQUISITE
N/A

GLATIRAMER

MEDICATION(S)
GLATIRAMER ACETATE, GLATOPA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other disease-modifying agent used for multiple sclerosis

REQUIRED MEDICAL INFORMATION
Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or after consultation with a neurologist or an MS specialist.

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

GLUCAGON-LIKE PEPTIDE-1 AGONISTS

MEDICATION(S)
BYDUREON BCISE, BYETTA 10 MCG PEN, BYETTA 5 MCG PEN, MOUNJARO, OZEMPIC (0.25 OR 0.5 MG/DOSE) 2 MG/3ML SOLN PEN, OZEMPIC (1 MG/DOSE) 4 MG/3ML SOLN PEN, OZEMPIC (2 MG/DOSE), RYBELSUS, TRULICITY, VICTOZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

MEDICATION(S)
LEUPROLIDE ACETATE 1 MG/0.2ML KIT, LUPRON DEPOT (1-MONTH), LUPRON DEPOT (3-MONTH), LUPRON DEPOT (4-MONTH), LUPRON DEPOT (6-MONTH), LUPRON DEPOT-PED (1-MONTH) 7.5 MG KIT, LUPRON DEPOT-PED (3-MONTH) 11.25 MG (PED) KIT, LUPRON DEPOT-PED (6-MONTH)

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Ovarian cancer, breast cancer, prophylaxis or treatment of uterine bleeding or menstrual suppression in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prostate cancer-prescr/consult with oncologist or urologist. For the treatment of other cancer diagnosis must be prescribed by or in consultation with an oncologist.

COVERAGE DURATION
uterine leiomyomata approve 3months/all other dx 12 mo

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

GRALISE/HORIZANT/LYRICA CR

MEDICATION(S)
GRALISE 300 MG TAB, GRALISE 450 MG TAB, GRALISE 600 MG TAB, GRALISE 750 MG TAB, GRALISE 900 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

GROWTH HORMONES

MEDICATION(S)
OMNITROPE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
CKD, SHOX, SBS

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
GHD in Children/Adolescents. Pt meets one of the following-1-had 2 GH stim tests with the following-levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are inadequate as defined by a peak GH response which is below the normal reference range of the testing laboratory OR had at least 1 GH test and results show inadequate response and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). 2.brain radiation or tumor resection and pt has 1 GH stim test and results is inadequate response or has def in at least 1 other pituitary hormone (that is, ACTH, TSH, gonadotropin deficiency [LH and/or FSH] are counted as 1 def], or prolactin).3. congenital hypopituitarism and has one GH stim test with inadequate response OR def in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk 4.pt has panhypopituitarism and has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on MRI or CT or pt has 3 or more pituitary hormone deficiencies or pt has had one GH test and results were inadequate 5.pt had a hypophysectomy. Cont-pt responding to therapy

AGE RESTRICTION
ISS 5 y/o or older, SGA 2 y/o or older, SBS 18 y/o or older

PRESCRIBER RESTRICTION
GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.

COVERAGE DURATION

ISS - 6 mos initial, 12 months cont tx, SBS 1 month, others 12 mos

OTHER CRITERIA

GHD initial in adults and adolescents 1. endocrine must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. has known mutations, embryonic lesions, congenital or genetic defects or structural hypothalamic pituitary defects, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 AND if a transitional adolescent must be off tx for at least one month before retesting. Cont tx - endocrine must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts greater than or equal to 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - prescriber confirms response to therapy. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy.Cont Tx for CKD, Noonan, PW in child/adolescents, SHOX, and TS - prescriber confirms response to therapy. SBS initial pt receiving specialized nutritional support. Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support.

PART B PREREQUISITE

N/A

HARVONI

MEDICATION(S)
HARVONI 33.75-150 MG PACKET, HARVONI 45-200 MG PACKET, HARVONI 90-400 MG TAB

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Indications consistent with current AASLD/IDSA guidance

EXCLUSION CRITERIA
Combination use with other direct acting antivirals, excluding ribavirin

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
3 years or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD

COVERAGE DURATION
Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug

OTHER CRITERIA
Criteria will be applied consistent with current AASLD/IDSA guidance.

PART B PREREQUISITE
N/A

HETLIOZ

MEDICATION(S)
HETLIOZ, TASIMELTEON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Non-24-patient is totally blind with no perception of light

AGE RESTRICTION
Non-24-18 years or older (initial and continuation), SMS-16 years and older

PRESCRIBER RESTRICTION
prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders (initial and continuation)

COVERAGE DURATION
6 mos initial, 12 mos cont

OTHER CRITERIA
Initial - patient is totally blind with no perception of light, dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy plus evaluation of sleep logs. Cont - Approve if patient is totally blind with no perception of light and pt has achieved adequate results with Hetlioz therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep). Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)-approve.

PART B PREREQUISITE

N/A

HIGH RISK MEDICATIONS - BENZODIAZEPINES

MEDICATION(S)
CLORAZEPATE DIPOTASSIUM, DIAZEPAM 10 MG TAB, DIAZEPAM 2 MG TAB, DIAZEPAM 5 MG TAB, DIAZEPAM 5 MG/5ML SOLUTION, DIAZEPAM 5 MG/ML CONC, DIAZEPAM INTENSOL, LORAZEPAM 0.5 MG TAB, LORAZEPAM 1 MG TAB, LORAZEPAM 1 MG/0.5ML CONC, LORAZEPAM 2 MG TAB, LORAZEPAM 2 MG/ML CONC, LORAZEPAM INTENSOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Procedure-related sedation = 1mo. All other conditions = 12 months.

OTHER CRITERIA
All medically accepted indications other than insomnia, approve if the physician has assessed risk versus benefit in using the High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy. Insomnia, may approve lorazepam if the patient has had a trial with two of the following: ramelteon, doxepin 3mg or 6 mg, eszopiclone, zolpidem, or zaleplon and the physician has assessed risk versus benefit in using the HRM in this patient and has confirmed that he/she would still like initiate/continue therapy.

PART B PREREQUISITE

N/A

HIGH RISK MEDICATIONS - BENZTROPINE

MEDICATION(S)
BENZTROPINE MESYLATE 0.5 MG TAB, BENZTROPINE MESYLATE 1 MG TAB, BENZTROPINE MESYLATE 2 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
For all medically-accepted indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing benztropine for the patient and he/she would still like to initiate/continue therapy

PART B PREREQUISITE
N/A

HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

MEDICATION(S)
CYCLOBENZAPRINE HCL 10 MG TAB, CYCLOBENZAPRINE HCL 5 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Patients aged less than 65 years, approve.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
The physician has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.

PART B PREREQUISITE
N/A

HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

MEDICATION(S)
HYDROXYZINE HCL 10 MG TAB, HYDROXYZINE HCL 25 MG TAB, HYDROXYZINE HCL 50 MG TAB, PROMETHAZINE HCL 12.5 MG TAB, PROMETHAZINE HCL 25 MG TAB, PROMETHAZINE HCL 50 MG TAB, PROMETHAZINE HCL 6.25 MG/5ML SOLUTION, PROMETHAZINE HCL 6.25 MG/5ML SYRUP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. Approve hydroxyzine hydrochloride if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval of promethazine and hydroxyzine, approve if the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.

PART B PREREQUISITE
N/A

HIGH RISK MEDICATIONS - PHENOBARBITAL

MEDICATION(S)

PHENOBARBITAL 100 MG TAB, PHENOBARBITAL 15 MG TAB, PHENOBARBITAL 16.2 MG TAB, PHENOBARBITAL 20 MG/5ML ELIXIR, PHENOBARBITAL 20 MG/5ML SOLUTION, PHENOBARBITAL 30 MG TAB, PHENOBARBITAL 32.4 MG TAB, PHENOBARBITAL 60 MG TAB, PHENOBARBITAL 64.8 MG TAB, PHENOBARBITAL 97.2 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

Coverage is not provided for use in sedation/insomnia.

REQUIRED MEDICAL INFORMATION

N/A

AGE RESTRICTION

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months

OTHER CRITERIA

For the treatment of seizures, approve only if the patient is currently taking phenobarbital.

PART B PREREQUISITE

N/A

HIGH RISK MEDICATIONS- ESTROGENS

MEDICATION(S)
AMABELZ, DOTTI, ESTRADIOL 0.025 MG/24HR PATCH TW, ESTRADIOL 0.025 MG/24HR PATCH WK, ESTRADIOL 0.0375 MG/24HR PATCH TW, ESTRADIOL 0.0375 MG/24HR PATCH WK, ESTRADIOL 0.05 MG/24HR PATCH TW, ESTRADIOL 0.05 MG/24HR PATCH WK, ESTRADIOL 0.06 MG/24HR PATCH WK, ESTRADIOL 0.075 MG/24HR PATCH TW, ESTRADIOL 0.075 MG/24HR PATCH WK, ESTRADIOL 0.1 MG/24HR PATCH TW, ESTRADIOL 0.1 MG/24HR PATCH WK, ESTRADIOL 0.5 MG TAB, ESTRADIOL 1 MG TAB, ESTRADIOL 2 MG TAB, ESTRADIOL-NORETHINDRONE ACET, FYAVOLV, JINTELI, LYLLANA, MENEST, MIMVEY, NORETHINDRONE-ETH ESTRADIOL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Previous medication use

AGE RESTRICTION
Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months

OTHER CRITERIA
For the treatment of Vulvar Vaginal Atrophy, approve if the patient has had a trial of one of the following for vulvar vaginal atrophy (brand or generic): Estradiol Vaginal Cream, Estring,or estradiol valerate. For prophylaxis of Postmenopausal Osteoporosis, approve if the patient has had a trial of one of the following (brand or generic): alendronate, ibandronate, risidronate or Raloxifene. The physician

has assessed risk versus benefit in using this High Risk medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.

PART B PREREQUISITE

N/A

HUMIRA

MEDICATION(S)
HUMIRA 10 MG/0.1ML PREF SY KT, HUMIRA 20 MG/0.2ML PREF SY KT, HUMIRA 40 MG/0.4ML PREF SY KT, HUMIRA 40 MG/0.8ML PREF SY KT, HUMIRA PEDIATRIC CROHNS START 80 MG/0.8ML & 40MG/0.4ML PREF SY KT, HUMIRA PEDIATRIC CROHNS START 80 MG/0.8ML PREF SY KT, HUMIRA PEN, HUMIRA PEN-CD/UC/HS STARTER, HUMIRA PEN-PEDIATRIC UC START, HUMIRA PEN-PS/UV/ADOL HS START, HUMIRA PEN-PSOR/UVEIT STARTER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with another biologic DMARD or targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous therapies tried

AGE RESTRICTION
Crohn's disease (CD), 6 or older (initial therapy only). Ulcerative colitis (UC) 5 or older (initial therapy only), PP-18 or older (initial therapy only)

PRESCRIBER RESTRICTION
Initial therapy only for all dx-RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist.UV-ophthalmologist

COVERAGE DURATION
1 year

OTHER CRITERIA
RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). JIA/JRA initial. Tried one other systemic therapy for this condition (e.g

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

PART B PREREQUISITE

N/A

IBRANCE

MEDICATION(S)
IBRANCE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Liposarcoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Breast cancer - approve recurrent or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Ibrance will be used in combination with anastrozole, exemestane, or letrozole 2, pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND meets one of the following conditions: Ibrance will be used in combination with anastrozole, exemestane, or letrozole or Ibrance will be used in combination with fulvestrant 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Ibrance with be used in combination with anastrozole, exemestane or letrozole or Ibrance will be used in combination with fulvestrant 4. Pt is postmenopausal AND Ibrance will be used in

combination with fulvestrant. Liposarcoma-approve if the patient has well-differentiated/dedifferentiated liposarcoma (WD-DDLS).

PART B PREREQUISITE

N/A

ICATIBANT

MEDICATION(S)
ICATIBANT ACETATE, SAJAZIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant - the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment.

PART B PREREQUISITE

N/A

ICLUSIG

MEDICATION(S)
ICLUSIG

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Approve if the patient meets one of the following: 1. Patient has CML or ALL that is Ph+, T315I positive or, 2. patient has CML, chronic phase with resistance or intolerance to at least two prior TKIs or, 3. patient has accelerated phase or blast phase CML or Philadelphia chromosome positive ALL for whom no other TKIs are indicated. GIST - approve if the patient tried all of the FDA-approved therapies first to align with NCCN recommendations which include: Imatinib or Ayvakit (avapritinib tablets), AND Sunitinib or Sprycel (dasatinib tablets), AND Stivarga (regorafenib tablets), AND Qinlock (ripretinib tablets). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has ABL1 rearrangement or FGFR1 rearrangement.

PART B PREREQUISITE
N/A

IDHIFA

MEDICATION(S)
IDHIFA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
IDH2-mutation status

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
AML - approve if the patient is IDH2-mutation status positive as detected by an approved test

PART B PREREQUISITE
N/A

IMATINIB

MEDICATION(S)
IMATINIB MESYLATE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Chordoma, advanced, aggressive or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.

AGE RESTRICTION
ASM, DFSP, HES, MDS/MPD/Myeloid/Lymphoid Neoplasms-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
For ALL/CML, must have Ph-positive for approval of imatinib.Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or according to the prescriber, the patient cannot take Turalio. Myelodysplastic/myeloproliferative disease-approve if the condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.Graft versus host disease, chronic-approve if the patient has tried at least one conventional systemic treatment (e.g., imbruvica). Metastatic melanoma-approve if the patient has c-Kit-positive advanced/recurrent or metastatic melanoma. Myeloid/lymphoid neoplasms with

eosinophilia-approve if the tumor has an ABL1 rearrangement or an FIP1L1-PDGFRA or PDGFRB rearrangement.

PART B PREREQUISITE

N/A

IMBRUVICA

MEDICATION(S)
IMBRUVICA 140 MG CAP, IMBRUVICA 140 MG TAB, IMBRUVICA 280 MG TAB, IMBRUVICA 420 MG TAB, IMBRUVICA 70 MG CAP, IMBRUVICA 70 MG/ML SUSPENSION

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma (e.g., gastric MALT lymphoma, nongastric MALT lymphoma, AIDS related, post-transplant lymphoproliferative disorder).

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
GVHD-1 year, all others-3 years

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

INGREZZA

MEDICATION(S)
INGREZZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
TD - Prescribed by or in consultation with a neurologist or psychiatrist. Chorea HD - prescribed by or in consultation with a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Chorea associated with Huntington's Disease- approve if diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36).

PART B PREREQUISITE
N/A

INJECTABLE TESTOSTERONE PRODUCTS

MEDICATION(S)
TESTOSTERONE CYPIONATE 100 MG/ML SOLUTION, TESTOSTERONE CYPIONATE 200 MG/ML SOLUTION, TESTOSTERONE ENANTHATE 200 MG/ML SOLUTION

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization).

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, lab results

AGE RESTRICTION
Delayed puberty or induction of puberty in males-14 years and older

PRESCRIBER RESTRICTION
Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.

COVERAGE DURATION
Delayed puberty or induction of puberty in males-6 months, all others-12 months

OTHER CRITERIA
Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has

persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. Delayed puberty or induction of puberty in males - Approve testosterone enanthate. Breast cancer in females-approve testosterone enanthate. Male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. Female is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression. Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.

PART B PREREQUISITE

N/A

INLYTA

MEDICATION(S)
INLYTA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma, Soft tissue sarcoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Advanced Renal cell carcinoma-approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy. Soft tissue sarcoma-approve if the patient has alveolar soft part sarcoma and the medication will be used in combination with Keytruda (pembrolizumab).

PART B PREREQUISITE
N/A

INPEFA

MEDICATION(S)
INPEFA 200 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Heart Failure, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit-approve. Type 2 Diabetes, to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit-approve if the patient has chronic kidney disease AND has one or more cardiovascular risk factor(s).Note: Patients with heart failure should be reviewed under criteria for Heart Failure.

PART B PREREQUISITE
N/A

INQOVI

MEDICATION(S)
INQOVI

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Myelodysplastic Syndrome/Myeloproliferative Neoplasm Overlap Neoplasms

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

INREBIC

MEDICATION(S)
INREBIC

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Myeloid/Lymphoid Neoplasms with Eosinophilia

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has intermediate-2 or high-risk disease. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement.

PART B PREREQUISITE
N/A

IRESSA

MEDICATION(S)
GEFITINIB, IRESSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
NSCLC-approve if the patient has advanced or metastatic disease and the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I.

PART B PREREQUISITE
N/A

IVERMECTIN (ORAL)

MEDICATION(S)
IVERMECTIN 3 MG TAB

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, Mansonella ozzardi infection, Mansonella streptocerca infection, Pediculosis, Scabies. Trichuriasis, Wucheria bancrofti infection

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
30 days

OTHER CRITERIA
Pediculosis-approve if the patient has infection caused by pediculus humanus capitis (head lice), pediculus humanus corporis (body lice), or has pediculosis pubis caused by phthirus pubis (pubic lice). Scabies-approve if the patient has classic scabies, treatment resistant scabies, is unable to tolerate topical treatment, has crusted scabies or is using ivermectin tablets for prevention and/or control of scabies.

PART B PREREQUISITE
N/A

IVIG

MEDICATION(S)
PRIVIGEN 20 GM/200ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
Part B versus D determination per CMS guidance to establish if drug used for PID in pt's home.

PART B PREREQUISITE
N/A

JAKAFI

MEDICATION(S)
JAKAFI

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
ALL-less than 21 years of age, GVHD-12 and older, MF/PV/CMML-2/essential thrombo/myeloid/lymphoid neoplasm-18 and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
GVHD-1 year, all others-3 years.

OTHER CRITERIA
For polycythemia vera patients must have tried hydroxyurea. ALL-approve if the mutation/pathway is Janus associated kinase (JAK)-related. GVHD, chronic-approve if the patient has tried one conventional systemic treatment for graft versus host disease. GVHD, acute-approve if the patient has tried one systemic corticosteroid. GVHD, acute-approve if the patient has tried one systemic corticosteroid. Polycythemia vera-approve if the patient has tried hydroxyurea. Atypical chronic myeloid leukemia-approve if the patient has a CSF3R mutation or a janus associated kinase mutation 2 (JAK2). Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent. Essential thrombocythemia-approve if the patient has tried hydroxyurea, peginterferon alfa-2a or anagrelide. Myeloid/lymphoid neoplasms-approve if the patient has

eosinophilia and the tumor has a janus associated kinase 2 (JAK2) rearrangement.

PART B PREREQUISITE

N/A

JAYPIRCA

MEDICATION(S)
JAYPIRCA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Chronic Lymphocytic Leukemia and Small Lymphocytic Leukemia

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Mantle cell lymphoma-approve if the patient has tried at least one systemic regimen or patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail), AND the patient has tried one Bruton tyrosine kinase inhibitor (BTK) for mantle cell lymphoma.Note: Examples of a systemic regimen contain one or more of the following products: rituximab, dexamethasone, cytarabine, carboplatin, cisplastin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, Velcade (bortezomib intravenous or subcutaneous injection), lenalidomide, gemcitabine, and Venclexta (venetoclax tablets). Note: Examples of BTK inhibitors indicated for mantle cell lymphoma include Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib capsules), and Imbruvica (ibrutinib capsules, tablets, and oral suspension). CLL/SLL-patient meets (A or B): A) patient has resistance or intolerance to Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules) or B) patient has relapsed or refractory

disease and has tried a Bruton tyrosine kinase (BTK) inhibitor and Venclexta (venetoclax tablet)-based regimen. Examples of BTK inhibitor include: Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules).

PART B PREREQUISITE

N/A

JUXTAPID

MEDICATION(S)
JUXTAPID 10 MG CAP, JUXTAPID 20 MG CAP, JUXTAPID 30 MG CAP, JUXTAPID 5 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history.

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist, an endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders.

COVERAGE DURATION
12 months

OTHER CRITERIA
Patient must meet ALL of the following criteria: 1) Patient has had genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B APOB, PCSK9, or LDLRAP1 gene locus OR the patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) and had clinical manifestation of HoFH before the age of 10 years OR both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with HeFH OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL and had clinical manifestation of HoFH before the age of 10 years OR both parents of the patient had untreated LDL-C levels or total cholesterol levels consistent with HeFH, AND 2) Patient has tried at least one PCSK9 inhibitor for greater than or equal to 8 continuous weeks and the LDL-C level after this PCSK9 inhibitor therapy remains greater

than or equal to 70 mg/dL OR the patient is known to have two LDL-receptor negative alleles, AND 3) Patient has tried one high-intensity statin therapy (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than 20 mg daily [as a single-entity or as a combination product]) for greater than or equal to 8 continuous weeks and the LDL-C level after these treatment regimens remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or patient experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.

PART B PREREQUISITE

N/A

KALYDECO

MEDICATION(S)
KALYDECO 13.4 MG PACKET, KALYDECO 150 MG TAB, KALYDECO 25 MG PACKET, KALYDECO 50 MG PACKET, KALYDECO 75 MG PACKET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Combination use with Orkambi, Trikafta or Symdeko

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
1 month of age and older

PRESCRIBER RESTRICTION
prescribed by or in consultation with a pulmonologist or a physician who specializes in CF

COVERAGE DURATION
1 year

OTHER CRITERIA
CF - must have one mutation in the CFTR gene that is responsive to the requested medication.

PART B PREREQUISITE
N/A

KERENDIA

MEDICATION(S)
KERENDIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with spironolactone or eplerenone

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older (initial and continuation therapy)

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Diabetic kidney disease, initial-approve if the patient meets the following criteria (i, ii and iii): i. Patient has a diagnosis of type 2 diabetes, AND ii. Patient meets one of the following (a or b): a)Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR b)According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy, AND iii.At baseline (prior to the initiation of Kerendia), patient meets all of the following (a, b, and c): a)Estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73 m2 AND b)Urine albumin-to-creatinine ratio greater than or equal to 30 mg/g AND c)Serum potassium level less than or equal to 5.0 mEq/L. Diabetic kidney disease, continuation-approve if the patient meets the following criteria (i and ii): i.Patient has a diagnosis of type 2 diabetes, AND ii. Patient meets one of the following (a or b): a.Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker

(ARB) OR b.According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy.

PART B PREREQUISITE

N/A

KISQALI

MEDICATION(S)
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 INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Breast cancer - approve recurrent or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer when the pt meets ONE of the following 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH

agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and Kisqali (not Co-Pack) will be used in combination with fulvestrant. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane or letrozole.

PART B PREREQUISITE

N/A

KORLYM

MEDICATION(S)
KORLYM

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Patients with Endogenous Cushing's Syndrome, awaiting surgery. Patients with Endogenous Cushing's syndrome, awaiting a response after radiotherapy

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior surgeries

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome

COVERAGE DURATION
Endogenous Cushing's Synd-1 yr. Patients awaiting surgery or response after radiotherapy-4 months

OTHER CRITERIA
Endogenous Cushing's Syndrome-Approve if, according to the prescribing physician, the patient is not a candidate for surgery or surgery has not been curative AND if Korlym is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance.

PART B PREREQUISITE
N/A

KRAZATI

MEDICATION(S)
KRAZATI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine.

PART B PREREQUISITE
N/A

LAPATINIB

MEDICATION(S)
LAPATINIB DITOSYLATE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Bone cancer-chordoma, colon or rectal cancer

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis for which lapatinib is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
HER2-positive recurrent or metastatic breast cancer, approve if lapatinib will be used in combination with capecitabine OR trastuzumab and the patient has tried at least two prior anti-HER2 based regimens OR the medication will be used in combination with an aromatase inhibitor and and the patient has HR+ dusease and the patient is a postmenopausal woman or the patient is premenopausal or perimenopausal woman and is receiving ovarian suppression/ablation with a GnRH agonist, surgical bilateral oophorectomy or ovarian irradiation OR the patient is a man and is receiving a GnRH analog. Colon or rectal cancer-approve if the patient has unresectable advanced or metastatic disease that is human epidermal receptor 2 (HER2) amplified and with wild-type RAS and BRAF disease and the patient has tried at least one chemotherapy regimen or is not a candidate for intensive therapy and the medication is used in combination with trastuzumab and the patient has not been previously treated

with a HER2-inhibitor. Bone Cancer-approve if the patient has recurrent chordoma and if the patient has epidermal growth-factor receptor (EGFR)-positive disease.

PART B PREREQUISITE

N/A

LENVIMA

MEDICATION(S)
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 INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Renal cell carcinoma with non-clear cell histology and Melanoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
DTC - must be refractory to radioactive iodine treatment for approval. RCC - approve if the pt meets ALL of the following criteria: 1) pt has advanced disease AND if the patient meets i or ii-i. Lenvima is is being used in combination with Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b-a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND B) The medication is used in

combination with Keytruda (pembrolizumab for intravenous injection) AND C)the disease has progressed on at least one prior systemic therapy AND D) The patient is not a candidate for curative surgery or radiation. Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. Melanoma - approve if the patient has unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy.

PART B PREREQUISITE

N/A

LEUKINE

MEDICATION(S)
LEUKINE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Neuroblastoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Neuroblastoma-less than 18 years of age

PRESCRIBER RESTRICTION
AML if prescribed by or in consultation with an oncologist or hematologist, PBPC/BMT - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation, Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome.Neuroblastoma-prescribed by or in consultation with an oncologist.

COVERAGE DURATION
Radiation Syndrome/BMT - 1 mo, AML/Neuroblastoma-6 months, PBPC-14 days

OTHER CRITERIA
Neuroblastoma-approve if the patient is receiving Leukine in a regimen with dinutuximab.

PART B PREREQUISITE
N/A

LIDOCAINE PATCH

MEDICATION(S)
LIDOCAINE 5 % PATCH

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Diabetic neuropathic pain, chronic back pain

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LONG ACTING OPIOIDS

MEDICATION(S)
BELBUCA, BUPRENORPHINE 10 MCG/HR PATCH WK, BUPRENORPHINE 15 MCG/HR PATCH WK, BUPRENORPHINE 20 MCG/HR PATCH WK, BUPRENORPHINE 5 MCG/HR PATCH WK, BUPRENORPHINE 7.5 MCG/HR PATCH WK, HYDROMORPHONE HCL ER, METHADONE HCL 10 MG TAB, METHADONE HCL 10 MG/5ML SOLUTION, METHADONE HCL 5 MG TAB, METHADONE HCL 5 MG/5ML SOLUTION, MORPHINE SULFATE ER 100 MG TAB ER, MORPHINE SULFATE ER 15 MG TAB ER, MORPHINE SULFATE ER 200 MG TAB ER, MORPHINE SULFATE ER 30 MG TAB ER, MORPHINE SULFATE ER 60 MG TAB ER, OXYCONTIN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Acute (ie, non-chronic) pain

REQUIRED MEDICAL INFORMATION
Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance

prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, sickle cell disease, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.

PART B PREREQUISITE

N/A

LONSURF

MEDICATION(S)
LONSURF

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Gastric or Gastroesophageal Junction Adenocarcinoma-approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma. Colon and rectal cancer-approve per labeling if the patient has been previously treated with a fluropyrimidine, oxaliplatin and irinotecan. If the patient's tumor or metastases are wild-type RAS (KRAS wild type and NRAS wild type) they must also try Erbitux or Vectibix.

PART B PREREQUISITE
N/A

LORBRENA

MEDICATION(S)
LORBRENA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive, Erdheim Chester Disease, Inflammatory Myofibroblastic Tumor (IMT)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, ALK status, ROS1 status, previous therapies

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Erdheim Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has IMT with ALK translocation. NSCLC - Approve if the patient has ALK-positive metastatic NSCLC, as detected by an approved test. NSCLC-ROS1 Rearrangement-Positive, metastatic NSCLC-approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib.

PART B PREREQUISITE
N/A

LOTRONEX

MEDICATION(S)
ALOSETRON HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LUMAKRAS

MEDICATION(S)
LUMAKRAS

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Pancreatic Adenocarcinoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years

OTHER CRITERIA
Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease, as determined by an approved test AND either (i or ii): (i) patient has locally advanced or metastatic disease and has been previously treated with at least one systemic regimen OR (ii) patient has recurrent disease after resection.

PART B PREREQUISITE
N/A

LYNPARZA

MEDICATION(S)
LYNPARZA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Uterine Leiomyosarcoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Ovarian Cancer - Treatment-initial-Approve if the patient meets the following criteria (i and ii): i. The patient has a germline BRCA-mutation as confirmed by an approved test AND has progressed on two or more prior lines of chemotherapy. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient meets one of the following criteria (A or B): A) The patient meets both of the following criteria for first-line maintenance therapy (i and ii): i. The patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND ii. The patient is in complete or partial response to first-line platinum-based chemotherapy regimen (e.g., carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin) OR B) The patient is in complete or partial response after at least two platinum-based chemotherapy regimens (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used

in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has recurrent or metastatic disease, and has germline BRCA mutation-positive breast cancer. Pancreatic Cancer-maintenance therapy-approve if the patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate cancer-castration resistant-approve if the patient has metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or the pateint has had a bilateral orchiectomy, and the patient meets either (i or ii): i) the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test and the patient has been previously treated with at least one androgen receptor directed therapy or ii) the patient has a BRCA mutation and the medication is used in combination with abiraterone plus one of prednisone or prednisolone. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen.

PART B PREREQUISITE

N/A

LYTGOBI

MEDICATION(S)
LYTGOBI (12 MG DAILY DOSE), LYTGOBI (16 MG DAILY DOSE), LYTGOBI (20 MG DAILY DOSE)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements as detected by an approved test and if the patient has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, and gemcitabine + cisplatin + Abraxane.

PART B PREREQUISITE
N/A

MEGACE

MEDICATION(S)
MEGESTROL ACETATE 20 MG TAB, MEGESTROL ACETATE 40 MG TAB, MEGESTROL ACETATE 40 MG/ML SUSPENSION, MEGESTROL ACETATE 400 MG/10ML SUSPENSION, MEGESTROL ACETATE 625 MG/5ML SUSPENSION, MEGESTROL ACETATE 800 MG/20ML SUSPENSION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Coverage is not provided for weight gain for cosmetic reasons.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MEKINIST

MEDICATION(S)
MEKINIST

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Biliary Tract Cancer, Central Nervous System Cancer, Histiocytic Neoplasm

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations

AGE RESTRICTION
6 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Melanoma must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery.For NSCLC requires BRAF V600E Mutation and use in combination with Tafinlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafinlar, unless intolerant AND the patient has BRAF V600-positive disease. Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for low-grade serous carcinoma. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease

and the medication will be taken in combination with Tafinlar. Central Nervous System Cancer-approve if the medication is being used for one of the following situations (i, ii, or iii): i) adjuvant treatment of one of the following conditions: pilocytic astrocytoma or pleomorphic xanthoastrocytoma or ganglioglioma, OR ii) recurrent disease for one of the following conditions: low-grade glioma OR anaplastic glioma OR glioblastoma, OR iii) melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Tafinlar (dabrafenib). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following: multisystem disease or pulmonary disease or central nervous system lesions or patient has Erdheim Chester disease or Rosai-Dorfman disease AND patient has BRAF V600-mutation positive disease. Metastatic or Solid Tumors-Approve if the patient meets the following (A, B, and C): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafinlar (dabrafenib capsules), AND C) Patient has no satisfactory alternative treatment options.

PART B PREREQUISITE

N/A

MEKTOVI

MEDICATION(S)
MEKTOVI

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Histiocytic Neoplasms

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, BRAF V600 status, concomitant medications

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. Histiocytic neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. multisystem disease OR, ii. pulmonary disease or, iii. central nervous system lesions. NSCLC-approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Braftovi (encorafenib capsules).

PART B PREREQUISITE
N/A

MEMANTINE

MEDICATION(S)
MEMANTINE HCL 10 MG TAB, MEMANTINE HCL 10 MG/5ML SOLUTION, MEMANTINE HCL 2 MG/ML SOLUTION, MEMANTINE HCL 5 MG TAB, MEMANTINE HCL ER, NAMZARIC

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Patients with mild to moderate vascular dementia.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Indication for which memantine is being prescribed.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

MODAFINIL/ARMODAFINIL

MEDICATION(S)
ARMODAFINIL, MODAFINIL

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Excessive daytime sleepiness (EDS) associated with myotonic dystrophy. Adjunctive/augmentation for treatment of depression in adults.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Excessive daytime sleepiness associated with narcolepsy-prescribed by or in consultation with a sleep specialist physician or neurologist

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD) - approve if patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome-approve. Excessive daytime sleepiness associated with Narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).

PART B PREREQUISITE
N/A

MYALEPT

MEDICATION(S)
MYALEPT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an endocrinologist or a geneticist physician specialist

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

NATPARA

MEDICATION(S)
NATPARA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
Chronic hypoparathyroidism, initial therapy - approve if before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician. Chronic hypoparathyroidism, continuing therapy - approve if during Natpara therapy, the patient's 25-hydroxyvitamin D stores are sufficient per the prescribing physician, AND the patient is responding to Natpara therapy, as determined by the prescriber.

PART B PREREQUISITE
N/A

NAYZILAM

MEDICATION(S)
NAYZILAM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, other medications used at the same time

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)- approve if the patient is currently receiving maintenance antiepileptic medication(s).

PART B PREREQUISITE
N/A

NERLYNX

MEDICATION(S)
NERLYNX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Stage of cancer, HER2 status, previous or current medications tried

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Adjuvant tx-Approve for 1 year (total), advanced or metastatic disease-3yrs

OTHER CRITERIA
Breast cancer, adjuvant therapy - approve if the patient meets all of the following criteria: patient will not be using this medication in combination with HER2 antagonists, patient has HER2-positive breast cancer AND Patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has HER-2 positive breast cancer, Nerlynx will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens.

PART B PREREQUISITE
N/A

NEXAVAR

MEDICATION(S)
SORAFENIB TOSYLATE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Osteosarcoma, angiosarcoma, desmoids tumors (aggressive fibromatosis), gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, Chordoma with recurrent disease, solitary fibrous tumor and hemangiopericytoma, ovarian, fallopian tube, primary peritoneal cancer

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Osteosarcoma, approve if the patient has tried standard chemotherapy and have relapsed/refractory or metastatic disease. GIST, approve if the patient has tried TWO of the following: Gleevec (imatinib mesylate), Ayvakit (avapritinib), Sutent (sunitinib), Sprycel (dasatinib), Qinlock (ripretinib) or Stivarga (regorafenib). Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried Caprelsa (vandetanib) or Cometriq (cabozantinib). AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test. Renal cell carcinoma (RCC)-approve if the patient has relapsed or Stage IV clear cell histology and the patient has tried at least one prior systemic

therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and Nexavar (sorafenib) is used in combination with topotecan.

PART B PREREQUISITE

N/A

NEXLETOL

MEDICATION(S)
NEXLETOL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
Heterozygous Familial Hypercholesterolemia (HeFH) -approve if pt meets one of the following: patient has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL (prior to treatment with antihyperlipidemic agents) OR patient has genetic confirmation of HeFH by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 or low-density lipoprotein receptor adaptor protein 1 gene OR patient has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds (a or b): a) The prescriber used the Dutch Lipid Network criteria and the patient has a score greater than 5 OR b) The prescriber used the Simon Broome criteria and the patient met the threshold for definite or possible familial hypercholesterolemia AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly for

greater than or equal to 8 continuous weeks and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt meets all of the following: Pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly for greater than or equal to 8 continuous weeks and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.

PART B PREREQUISITE

N/A

NEXLIZET

MEDICATION(S)
NEXLIZET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
Heterozygous Familial Hypercholesterolemia (HeFH) -approve if pt meets one of the following: has an untreated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 190 mg/dL (prior to treatment with antihyperlipidemic agents) OR has genetic confirmation of HeFH by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 or low-density lipoprotein receptor adaptor protein 1 gene OR has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds (a or b): a) The prescriber used the Dutch Lipid Network criteria and the patient has a score greater than 5 OR b) The prescriber used the Simon Broome criteria and the patient met the threshold for definite or possible familial hypercholesterolemia AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) for greater than or equal to 8 continuous weeks and LDL-C

remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt meets all of the following: Pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) for greater than or equal to 8 continuous weeks and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.

PART B PREREQUISITE

N/A

NILUTAMIDE

MEDICATION(S)
NILUTAMIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Prostate cancer-approve if nilutamide is used concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist.

PART B PREREQUISITE
N/A

NINLARO

MEDICATION(S)
NINLARO

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
MM - be used in combination with Revlimid and dexamethasone OR pt had received at least ONE previous therapy for multiple myeloma OR the agent will be used following autologous stem cell transplantation (ASCT). Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma-approve if used in combination with a rituximab product and dexamethasone.

PART B PREREQUISITE
N/A

NITISINONE

MEDICATION(S)
NITISINONE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant therapy with nitisinone products

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic tests and lab results (as specified in the Other Criteria field)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)

COVERAGE DURATION
1 year

OTHER CRITERIA
HereditaryTyrosinemia, Type 1-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming a mutation of the FAH gene OR elevated levels of succinylacetone.

PART B PREREQUISITE
N/A

NIVESTYM

MEDICATION(S)
NIVESTYM

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome).

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.

COVERAGE DURATION
chemo/SCN/AML-6mo.HIV/AIDS-4mo.MDS-3mo.PBPC,Drug induce A/N,AA,ALL,BMT-3mo. Radi-1mo. Other=12mo.

OTHER CRITERIA
Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile

neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).

PART B PREREQUISITE

N/A

NON-INJECTABLE TESTOSTERONE PRODUCTS

MEDICATION(S)
TESTOSTERONE 1.62 % GEL, TESTOSTERONE 10 MG/ACT (2%) GEL, TESTOSTERONE 12.5 MG/ACT (1%) GEL, TESTOSTERONE 20.25 MG/1.25GM (1.62%) GEL, TESTOSTERONE 20.25 MG/ACT (1.62%) GEL, TESTOSTERONE 25 MG/2.5GM (1%) GEL, TESTOSTERONE 30 MG/ACT SOLUTION, TESTOSTERONE 40.5 MG/2.5GM (1.62%) GEL, TESTOSTERONE 50 MG/5GM (1%) GEL

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria

are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication.

PART B PREREQUISITE

N/A

NORTHERA

MEDICATION(S)
DROXIDOPA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Medication history

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist or a neurologist

COVERAGE DURATION
12 months

OTHER CRITERIA
NOH, approve if the patient meets ALL of the following criteria: a) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND b) Patient has tried midodrine

PART B PREREQUISITE
N/A

NUBEQA

MEDICATION(S)
NUBEQA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy or if the medication is used concurrently with Firmagon. Prostate cancer-metastatic, castration sensitive-approve if (A and B): A) the medication is used in combination with docetaxel or patient has completed docetaxel therapy, and B) the medication will be used in combination with a GnRH agonist or in combination with Firmagon or if the patient had a bilateral orchiectomy.

PART B PREREQUISITE
N/A

NUCALA

MEDICATION(S)
NUCALA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Xolair or another Anti-Interleukin (IL) Monoclonal Antibody.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Asthma-6 years of age and older. EGPA/Polyps-18 years of age and older. HES-12 years and older.

PRESCRIBER RESTRICTION
Asthma-Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. EGPA-prescribed by or in consultation with an allergist, immunologist, pulmonologist or rheumatologist. HES-prescribed by or in consultation with an allergist, immunologist, hematologist, pulmonologist or rheumatologist. Polyps-prescribed by or in consult with allergist, immunologist or Otolaryngologist.

COVERAGE DURATION
Initial-Asthma/EGPA/polyps-6 months, HES-8 months. 12 months continuation.

OTHER CRITERIA
Asthma initial - must have blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks (prior to tx with any anti-IL-5) AND has received at least 3 consecutive months of combo tx w/inhaled corticosteroid AND at least 1 additional asthma controller/maintenance med AND pt's asthma cont to be uncontrolled, or was uncontrolled prior to starting any anti-IL tx as defined by 1 of following-pt experi 2 or more asthma exacer req tx w/systemic corticosteroids in prev yr, pt experienced 1 or more asthma exacer requiring hospitalization or ED visit in the prev yr, pt has a FEV1 less than 80 percent predicted, Pt has FEV1/FVC less than 0.80, or Pt's asthma worsens upon taper of oral corticosteroid therapy.NOTE:An exception to requirement for trial of 1 additional asthma

controller/maintenance med can be made if pt has already received anti-IL-5 tx used concomitantly with an ICS for at least 3 consecutive months.Cont-pt responded to Nucala tx as determined by the prescribing physician AND Pt cont to receive tx with an inhaled corticosteroid. EGPA initial-approve if pt has active, non-severe disease, has/had a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 wks or within 6 wks prior to tx w/any anti-IL-5 tx. Cont-pt responded to Nucala tx as determined by the prescribing physician.HES initial-pt has had hypereosinophilic synd for greater than or equal to 6 months AND has FIP1L1-PDGFRalpha-negative dis AND pt does NOT have identifiable non-hematologic secondary cause of hypereosinophilic synd AND prior to initiating tx with any anti-IL-5 tx, pt has/had a blood eosinophil level of greater than or equal to 1,000 cells per microliter. Cont-approve if the patient has received at least 8 months of tx with Nucala (pts who have received less than 8 months of tx or who are restarting tx should be reviewed under initial tx) and pt has responded to Nucala tx. Nasal polyps, initial-approve if pt meets ALL of the following criteria(A, B, C and D):A) pt has chronic rhinosinusitis w/nasal polyposis as evidenced by direct examination, endoscopy, or sinus CT scan AND B)pt experienced 2 or more of the following sympt for at least 6 months:nasal congest/obstruct/discharge, and/or reduction/loss of smell AND C)pt meets BOTH of the following (a and b): a)Pt has received at least 8 weeks of tx with intranasal corticosteroid AND b)Pt will continue to receive tx with intranasal corticosteroid concomitantly with Nucala AND D)pt meets 1 of the following (a, b or c): a)Pt has received at least 1 course of tx with a systemic corticosteroid for 5 days or more within the previous 2 years, OR b)Pt has a contraindication to systemic corticosteroid tx, OR c)Pt had prior surgery for nasal polyps.Cont-approve if the pt has received at least 6 months of therapy, continues to receive tx with an intranasal corticosteroid and has responded to tx.

PART B PREREQUISITE

N/A

NUEDEXTA

MEDICATION(S)
NUEDEXTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

NUPLAZID

MEDICATION(S)
NUPLAZID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

NURTEC

MEDICATION(S)
NURTEC

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Migraine, Acute treatment-approve. Preventive treatment of episodic migraine-approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication) and has tried at least two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician. A patient who has already tried an oral or injectable calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of migraine or Botox (onabotulinumtoxinA injection) for the prevention of migraine is not required to try two standard prophylactic pharmacologic therapies.

PART B PREREQUISITE

N/A

NYVEPRIA

MEDICATION(S)
NYVEPRIA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Patients undergoing PBPC collection and therapy

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation

COVERAGE DURATION
Cancer pts receiving chemo-6 mo. PBPC-1 mo

OTHER CRITERIA
Cancer patients receiving chemotherapy, approve if - the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, OR the patient has had a neutropenic complication from prior chemotherapy and did not receive

prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.

PART B PREREQUISITE

N/A

OCALIVA

MEDICATION(S)
OCALIVA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prescriber specialty, lab values, prior medications used for diagnosis and length of trials

AGE RESTRICTION
18 years and older (initial)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial)

COVERAGE DURATION
6 months initial, 1 year cont.

OTHER CRITERIA
Initial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following:a)Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b)Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative c)Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)).

PART B PREREQUISITE

N/A

OCTREOTIDE INJECTABLE

MEDICATION(S)
OCTREOTIDE ACETATE 100 MCG/ML SOLUTION, OCTREOTIDE ACETATE 1000 MCG/ML SOLUTION, OCTREOTIDE ACETATE 200 MCG/ML SOLUTION, OCTREOTIDE ACETATE 50 MCG/ML SOLUTION, OCTREOTIDE ACETATE 500 MCG/ML SOLUTION

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-presc/consult with oncologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. Patient has had an inadequate response to surgery and/or radiotherapy OR ii. Patient is NOT an appropriate candidate for surgery and/or radiotherapy OR iii. Patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND Patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory.

PART B PREREQUISITE

N/A

ODOMZO

MEDICATION(S)
ODOMZO

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Metastatic BCC

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
BCC - Must not have had disease progression while on Erivedge (vismodegib).

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metastatic BCC - approve.

PART B PREREQUISITE
N/A

OFEV

MEDICATION(S)
OFEV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
IPF - must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. Interstitial lung disease associated with systemic sclerosis-approve if the FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography. Chronic fibrosing interstitial lung disease-approve if the forced vital capacity is greater than or equal to 45 percent of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10 percent of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression.

PART B PREREQUISITE

N/A

OJJAARA

MEDICATION(S)
OJJAARA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Myelofibrosis-approve if the patient has intermediate-risk or high-risk disease and the patient has anemia, defined as hemoglobin less than 10g/dL.

PART B PREREQUISITE
N/A

ONUREG

MEDICATION(S)
ONUREG

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
AML - Approve if the patient meets the following criteria (both A and B): A)Following intensive induction chemotherapy, the patient achieves one of the following according to the prescriber (i or ii): i. First complete remission OR ii. First complete remission with incomplete blood count recovery AND B) Patient is not able to complete intensive curative therapy.

PART B PREREQUISITE
N/A

OPSUMIT

MEDICATION(S)
OPSUMIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
PAH WHO group, right heart catheterization results, WHO functional status, previous drugs tried

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist.

COVERAGE DURATION
Authorization will be for 3 years

OTHER CRITERIA
Pulmonary arterial hypertension (PAH) WHO Group 1 patients are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment.

PART B PREREQUISITE
N/A

ORENCIA

MEDICATION(S)
ORENCIA 125 MG/ML SOLN PRSYR, ORENCIA 50 MG/0.4ML SOLN PRSYR, ORENCIA 87.5 MG/0.7ML SOLN PRSYR, ORENCIA CLICKJECT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous drugs tried.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Initial therapy only-RA and JIA/JRA prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
RA initial, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD). PsA, initial -approve. Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], initial - approve if the patient has tried one other agent for this condition or the patient will be starting on Orencia concurrently with methotrexate, sulfasalazine or leflunomide or the patient has an absolute contraindication to methotrexate, sulfasalazine or leflunomide or the patient has aggressive disease as determined by the prescribing physician. Cont tx - responded to therapy as per the prescriber.

PART B PREREQUISITE

N/A

ORGOVYX

MEDICATION(S)
ORGOVYX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Prostate Cancer-approve.

PART B PREREQUISITE
N/A

ORKAMBI

MEDICATION(S)
ORKAMBI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Combination use with Kalydeco, Trikafta or Symdeko.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
1 year of age and older

PRESCRIBER RESTRICTION
prescribed by or in consultation with a pulmonologist or a physician who specializes in CF

COVERAGE DURATION
3 years

OTHER CRITERIA
CF - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation)

PART B PREREQUISITE
N/A

ORLADEYO

MEDICATION(S)
ORLADEYO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant Use with Other HAE Prophylactic Therapies (e.g., Cinryze, Haegarda, Takhzyro).

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
12 years and older (initial and continuation)

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders. (initial and continuation)

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Prophylaxis, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Continuation-According to the prescriber the patient has had a favorable clinical response since initiating Orladeyo prophylactic therapy compared with baseline.

PART B PREREQUISITE
N/A

ORSERDU

MEDICATION(S)
ORSERDU

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Breast cancer in postmenopausal women or Men-approve if the patient meets the following criteria (A, B, C, D, and E): A) Patient has recurrent or metastatic disease, AND B) Patient has estrogen receptor positive (ER+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has estrogen receptor 1 gene (ESR1)-mutated disease, AND E) Patient has tried at least one endocrine therapy. Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen.

PART B PREREQUISITE
N/A

OTEZLA

MEDICATION(S)
OTEZLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous drugs tried

AGE RESTRICTION
18 years and older (initial)

PRESCRIBER RESTRICTION
All dx-initial only-PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist. Behcet's-prescribed by or in consultation with a dermatologist or rheumatologist

COVERAGE DURATION
1 year

OTHER CRITERIA
PP initial-approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to step back and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. PsA initial-approve. Behcet's-patient has oral ulcers or other mucocutaneous involvement AND patient has tried at least ONE other systemic therapy. PsA/PP/Behcet's cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician.

PART B PREREQUISITE

N/A

OXERVATE

MEDICATION(S)
OXERVATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Treatment duration greater than 16 weeks per affected eye(s)

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by an ophthalmologist or an optometrist.

COVERAGE DURATION
Initial-8 weeks, continuation-approve for an additional 8 weeks

OTHER CRITERIA
Patients who have already received Oxervate-approve if the patient has previously received less than or equal to 8 weeks of treatment per affected eye(s) and the patient has a recurrence of neurotrophic keratitis.

PART B PREREQUISITE
N/A

PANRETIN

MEDICATION(S)
PANRETIN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist

COVERAGE DURATION
1 year

OTHER CRITERIA
Kaposi Sarcoma-approve if the patient is not receiving systemic therapy for Kaposi Sarcoma.

PART B PREREQUISITE
N/A

PART D VS PART B

MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, ACTIMMUNE, ACYCLOVIR SODIUM, ALBUTEROL SULFATE (2.5 MG/3ML) 0.083% NEBU SOLN, ALBUTEROL SULFATE (5 MG/ML) 0.5% NEBU SOLN, ALBUTEROL SULFATE 0.63 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 1.25 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 2.5 MG/0.5ML NEBU SOLN, AMPHOTERICIN B 50 MG RECON SOLN, APREPITANT, ARFORMOTEROL TARTRATE, AZATHIOPRINE 50 MG TAB, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, CLINIMIX/DEXTROSE (4.25/10), CLINIMIX/DEXTROSE (4.25/5), CLINIMIX/DEXTROSE (5/15), CLINIMIX/DEXTROSE (5/20), CROMOLYN SODIUM 20 MG/2ML NEBU SOLN, CYCLOPHOSPHAMIDE 25 MG CAP, CYCLOPHOSPHAMIDE 25 MG TAB, CYCLOPHOSPHAMIDE 50 MG CAP, CYCLOPHOSPHAMIDE 50 MG TAB, CYCLOSPORINE 100 MG CAP, CYCLOSPORINE 25 MG CAP, CYCLOSPORINE MODIFIED, DRONABINOL, EMEND 125 MG/5ML RECON SUSP, ENGERIX-B, ENVARSUS XR, EVEROLIMUS 0.25 MG TAB, EVEROLIMUS 0.5 MG TAB, EVEROLIMUS 0.75 MG TAB, EVEROLIMUS 1 MG TAB, FIRMAGON, FIRMAGON (240 MG DOSE), FORMOTEROL FUMARATE 20 MCG/2ML NEBU SOLN, GENGRAF, GRANISETRON HCL 1 MG TAB, HEPLISAV-B 20 MCG/0.5ML SOLN PRSYR, INTRALIPID 20 % EMULSION, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, JYNNEOS, LEVALBUTEROL HCL 0.31 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 0.63 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/0.5ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/3ML NEBU SOLN, METHOTREXATE SODIUM 2.5 MG TAB, METHOTREXATE SODIUM 50 MG/2ML SOLUTION, METHOTREXATE SODIUM (PF) 50 MG/2ML SOLUTION, METHYLPREDNISOLONE 16 MG TAB, METHYLPREDNISOLONE 32 MG TAB, METHYLPREDNISOLONE 4 MG TAB, METHYLPREDNISOLONE 8 MG TAB, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE SODIUM, ONDANSETRON, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 4 MG/5ML SOLUTION, ONDANSETRON HCL 8 MG TAB, PENTAMIDINE ISETHIONATE, PLENAMINE, PREHEVBRIO, PREMASOL, PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PULMOZYME, RECOMBIVAX HB, SANDIMMUNE 100 MG/ML SOLUTION, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TAB, SYNRIBO, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TRAVASOL, TRELSTAR MIXJECT, TROPHAMINE 10 % SOLUTION, VARUBI (180 MG DOSE), XATMEP, XGEVA

DETAILS

This drug may be covered under Medicare Part B or D depending on the circumstances. Information

may need to be submitted describing the use and setting of the drug to make the determination.

PEMAZYRE

MEDICATION(S)
PEMAZYRE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Myeloid/Lymphoid Neoplasms

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior therapies

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years

OTHER CRITERIA
Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease and the tumor has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the cancer has fibroblast growth factor receptor 1 (FGFR1) rearrangement, as detected by an approved test and the cancer is in chronic phase or blast phase.

PART B PREREQUISITE
N/A

PENICILLAMINE

MEDICATION(S)
PENICILLAMINE 250 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Wilson's Disease-Prescribed by or in consultation with a gastroenterologist, hepatologist or liver transplant physician

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PHENYLBUTYRATE

MEDICATION(S)
RAVICTI, SODIUM PHENYLBUTYRATE 3 GM/TSP POWDER, SODIUM PHENYLBUTYRATE 500 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use of Ravicti and Buphenyl

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic tests and lab results

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)

COVERAGE DURATION
Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval

OTHER CRITERIA
Urea cycle disorders-approve if genetic testing confirmed a mutation resulting in a urea cycle disorder or if the patient has hyperammonemia.

PART B PREREQUISITE
N/A

PHEOCHROMOCYTOMA

MEDICATION(S)
METYROSINE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior medication trials

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial and continuation therapy for metyrosine)

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin). If the requested drug is metyrosine for continuation therapy, approve if the patient is currently receiving metyrosine or has received metyrosine in the past.

PART B PREREQUISITE
N/A

PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

MEDICATION(S)
ALYQ, SILDENAFIL CITRATE 20 MG TAB, TADALAFIL (PAH)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, right heart cath results

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist.

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets and suspension require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception.

PART B PREREQUISITE
N/A

PIQRAY

MEDICATION(S)
PIQRAY (200 MG DAILY DOSE), PIQRAY (250 MG DAILY DOSE), PIQRAY (300 MG DAILY DOSE)

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Treatment of breast cancer in premenopausal women

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior therapies

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, E and F): A) The patient is a postmenopausal female or a male or premenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) analog or has had surgical bilateral oophorectomy or ovarian irradiation AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene) AND F) Piqray will be used in combination with fulvestrant injection.

PART B PREREQUISITE

N/A

PLEGRIDY

MEDICATION(S)
PLEGRIDY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS).

REQUIRED MEDICAL INFORMATION
Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a neurologist or an MS specialist.

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
Cont tx-approve if the patient has been established on Plegridy.

PART B PREREQUISITE
N/A

POMALYST

MEDICATION(S)
POMALYST

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Systemic Light Chain Amyloidosis, Central Nervous System (CNS) Lymphoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Kaposi Sarcoma/MM-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years

OTHER CRITERIA
CNS Lymphoma-approve if the patient has relapsed or refractory disease. Kaposi Sarcoma-Approve if the patient meets one of the following (i or ii): i. patient is Human Immunodeficiency Virus (HIV)-negative OR ii. patient meets both of the following (a and b): a) The patient is Human Immunodeficiency Virus (HIV)-positive AND b) The patient continues to receive highly active antiretroviral therapy (HAART). MM-approve if the patient has received at least one other Revlimid (lenalidomide tablets)-containing regimen.

PART B PREREQUISITE
N/A

POSACONAZOLE (ORAL)

MEDICATION(S)
POSACONAZOLE 100 MG TAB DR

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
esophageal candidiasis - treatment, mucomycosis - maintenance, fusariosis, invasive - treatment fungal infections (systemic) in patients with human immunodeficiency virus (HIV) infections (e.g., histoplasmosis, coccidioidomycosis) - treatment.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Aspergillus/Candida prophy, mucormycosis-6 mo, all others-3 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PROLIA

MEDICATION(S)
PROLIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with other medications for osteoporosis

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
Treatment of postmenopausal osteoporosis/Treatment of osteoporosis in men (to increase bone mass) [a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression], approve if the patient meets one of the following: 1. has had inadequate response after 12 months of therapy with an oral bisphosphonate, had osteoporotic fracture or fragility fracture while receiving an oral bisphosphonate, or intolerability to an oral bisphosphonate, OR 2. the patient cannot take an oral bisphosphonate because they cannot swallow or have difficulty swallowing, they cannot remain in an upright position, or they have a pre-existing GI medical condition, OR 3. pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR 4. the patient has severe renal impairment (eg, creatinine clearance less than 35 mL/min) or chronic kidney disease, or if the patient has an osteoporotic fracture or fragility fracture . Treatment of bone loss in patient at high risk for fracture receiving ADT for nonmetastatic prostate cancer, approve if the patient has prostate cancer

that is not metastatic to the bone and the patient is receiving ADT (eg, leuprolide, triptorelin, goserelin) or the patient has undergone a bilateral orchiectomy. Treatment of bone loss (to increase bone mass) in patients at high risk for fracture receiving adjuvant AI therapy for breast cancer, approve if the patient has breast cancer that is not metastatic to the bone and in receiving concurrent AI therapy (eg, anastrozole, letrozole, exemestane). Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture.

PART B PREREQUISITE

N/A

PROMACTA

MEDICATION(S)
PROMACTA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Thrombocytopenia in Myelodysplastic Syndrome (MDS)

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Immune Thrombocytopenia or Aplastic Anemia, approve if prescribed by, or after consultation with, a hematologist (initial therapy). Thrombocytopenia in pt with chronic Hep C, approve if prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease (initial therapy). MDS-presc or after consult with heme/onc (initial therapy).

COVERAGE DURATION
Immune Thrombo/MDS initial-3 mo, cont 1yr, AA-initial-4 mo, cont-1 yr, Thrombo/Hep C-1 yr

OTHER CRITERIA
Thrombocytopenia in patients with immune thrombocytopenia, initial-approve if the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy or has undergone a splenectomy. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Treatment of thrombocytopenia in patients with Chronic Hepatitis C initial-approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND to allow for initiation of antiviral therapy if the patient has low platelet counts at baseline (eg, less than

75,000 microliters). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000 microliters) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate moefetil, sirolimus) OR patient will be using Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.

PART B PREREQUISITE

N/A

PYRIMETHAMINE

MEDICATION(S)
PYRIMETHAMINE 25 MG TAB

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient's immune status

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist.

COVERAGE DURATION
12 months

OTHER CRITERIA
Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed.

PART B PREREQUISITE
N/A

QINLOCK

MEDICATION(S)
QINLOCK

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Melanoma, cutaneous

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, other therapies tried

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years

OTHER CRITERIA
Gastrointestinal stromal tumor (GIST), advanced-approve if, the patient has two of the following imatinib, sunitinib, Sprycel or Stivarga OR if the patient has tried Ayvakit and Sprycel. Melanoma, cutaneous-approve if the patient has metastatic or unresectable disease, AND the patient has an activating KIT mutation, AND the patient has tried at least one systemic regimen.

PART B PREREQUISITE
N/A

REPATHA

MEDICATION(S)
REPATHA, REPATHA PUSHTRONEX SYSTEM, REPATHA SURECLICK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use of Leqvio or Praluent.

REQUIRED MEDICAL INFORMATION
LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history

AGE RESTRICTION
ASCVD/Primary Hyperlipidemia - 18 yo and older, HoFH/HeFH - 10 yo and older.

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders

COVERAGE DURATION
Approve for 1 year

OTHER CRITERIA
Hyperlipidemia with HeFH - approve if: 1) diagnosis of HeFH AND 2) tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the symptoms resolved upon discontinuation. Hyperlipidemia with ASCVD -approve if: 1) has one of the following conditions: prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) tried ONE high intensity statin (defined above) and LDL remains 70 mg/dL or higher unless pt is statin intolerant (defined above). HoFH - approve if: 1) has one of the following: a) genetic

confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha, Kynamro or Juxtapid), OR d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity statin (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the patient has tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above).

PART B PREREQUISITE

N/A

RETEVMO

MEDICATION(S)
RETEVMO

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Anaplastic thyroid carcinoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Medullary Thyroid Cancer/Thyroid Cancer-12 years and older, all others 18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years

OTHER CRITERIA
Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has metastatic disease AND the tumor is RET fusion-positive. Medullary Thyroid Cancer-approve if the patient has advanced or metastatic RET-mutant disease and the disease requires treatment with systemic therapy.Thyroid Cancer-approve if the patient has advanced or metastatic RET fusion positive disease, the disease is radioactive iodine-refractory (if radioactive iodine is appropriate) and the disease requires treatment with systemic therapy. Anaplastic thyroid cancer-approve if the patient has RET fusion-positive anaplastic thyroid carcinoma. Solid tumors-approve if the patient has recurrent, advanced or metastatic disease and the tumor is rearranged during transfection (RET) fusion-positive.

PART B PREREQUISITE
N/A

REVCOVI

MEDICATION(S)
REVCOVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, lab values, genetic tests

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with, an immunologist, hematologist/oncologist, or physician that specializes in ADA-SCID or related disorders.

COVERAGE DURATION
12 months

OTHER CRITERIA
ADA-SCID - approve if the patient had absent or very low (less than 1% of normal) ADA catalytic activity at baseline (i.e., prior to initiating enzyme replacement therapy) OR if the patient had molecular genetic testing confirming bi-allelic mutations in the ADA gene

PART B PREREQUISITE
N/A

REVLIMID

MEDICATION(S)
LENALIDOMIDE, REVLIMID

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Off label uses for Revlimid and lenalidomide include-Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system Lymphoma,Kaposi's sarcoma. Off label uses for lenalidomide include-follicular lymphoma, marginal zone lymphoma and multiple myeloma following autologous hematopoietic stem cell transplantation.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis and previous therapies or drug regimens tried.

AGE RESTRICTION
18 years and older (except Kaposi's Sarcoma, Castleman's Disease, CNS Lymphoma)

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Follicular lymphoma-approve if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least on prior therapy. MCL-approve -if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least two other therapies or therapeutic regimens. MZL-approve if the patient is using lenalidomide (brand or generic) in combination with rituximab or has tried at least one other therapy or therapeutic regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has

transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). B-cell-lymphoma (other)-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia and the pt has serum erythropoietin levels greater than or equal to 500 mU/mL or according to the prescriber the patient has anemia, has serum erythropoietin levels less than 500 mU/mL and patient has experienced no response or loss of response to erythropoietic stimulating agents. Peripheral T-Cell Lymphoma or T-Cell Leukemia/Lymphoma-approve if the pt has tried at least one other therapy or regimen. CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease. Hodgkin lymphoma, classical-approve if the patient has tried at least one other therapy or therapeutic regimen. Castleman's disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi's Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide (brand or generic) is used in combination with dexamethasone.

PART B PREREQUISITE

N/A

REZLIDHIA

MEDICATION(S)
REZLIDHIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Acute myeloid leukemia-approve if the patient has relapsed or refractory disease and the patient has isocitrate dehydrogenase-1 (IDH1) mutation positive disease as detected by an approved test.

PART B PREREQUISITE
N/A

RILUZOLE

MEDICATION(S)
RILUZOLE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.

COVERAGE DURATION
1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

RINVOQ

MEDICATION(S)
RINVOQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants. Concurrent use with an anti-interleukin monoclonal antibody, Concurrent use with other janus kinase inhibitors, or concurrent use with Xolair.

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous drugs tried.

AGE RESTRICTION
PsA/RA/UC/AS/CD-18 years and older (initial therapy), AD-12 years and older (initial therapy)

PRESCRIBER RESTRICTION
RA/AS/Non-Radiographic Spondy, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or derm. UC/CD-prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
RA/PsA/UC/AS/CD initial-approve if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AD-approve if the patient has had a 3 month trial of at least one traditional systmic therapy or has tried at least one traditional systemic therapy but was unable to tolerate a 3 month trial. Note: Examples of traditional systemic therapies include methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to step back and try a traditional systemic agent for atopic dermatitis. Non-Radiographic

Axial Spondyloarthritis-approve if the patient has objective signs of inflammation defined as at least one of the following: C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory OR sacroiliitis reported on MRI and patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3- month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber

PART B PREREQUISITE

N/A

ROZLYTREK

MEDICATION(S)
ROZLYTREK 100 MG CAP, ROZLYTREK 200 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Solid Tumors-12 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Solid Tumors-Approve if the patient's tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease.

PART B PREREQUISITE
N/A

RUBRACA

MEDICATION(S)
RUBRACA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Uterine Leiomyosarcoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3years

OTHER CRITERIA
Ovarian, Fallopian Tube or Primary Peritoneal Cancer-treatment - Approve if the patient meets the following criteria (i and ii): i.The patient has a BRCA-mutation (germline or somatic) as confirmed by an approved test, AND ii.The patient has progressed on two or more prior lines of chemotherapy. Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-Approve if the patient is in complete or partial response after at least two platinum-based chemotherapy regimens. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy

AND D) The patient meets one of the following criteria (i or ii): i. The patient has been previously treated with at least one taxane-based chemotherapy OR ii. The patient is not a candidate or is intolerant to taxane-based chemotherapy. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen.

PART B PREREQUISITE

N/A

RUFINAMIDE

MEDICATION(S)
RUFINAMIDE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Treatment-Refractory Seizures/Epilepsy

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Patients 1 years of age or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Initial therapy-approve if rufinamide is being used for adjunctive treatment. Continuation-approve if the patient is responding to therapy

PART B PREREQUISITE
N/A

RYDAPT

MEDICATION(S)
RYDAPT

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Myeloid or lymphoid Neoplasms with eosinophilia

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For AML, FLT3 status

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
AML -approve if the patient is FLT3-mutation positive as detected by an approved test. Myeloid or lymphoid Neoplasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement.

PART B PREREQUISITE
N/A

SAPROPTERIN

MEDICATION(S)
SAPROPTERIN DIHYDROCHLORIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Palynziq (continuation only), concurrent use with Palynziq is permitted during Palynziq dose titration

REQUIRED MEDICAL INFORMATION
Diagnosis, Phe concentration

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)

COVERAGE DURATION
Initial-12 weeks, Continuation-1 year

OTHER CRITERIA
Initial - approve. Continuation (Note-if the patient has received less than 12 weeks of therapy or is restarting therapy with sapropterin should be reviewed under initial therapy) - approve if the patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescribing physician OR patient had a 20 percent or greater reduction in blood Phe concentration from baseline OR treatment with sapropterin has resulted in an increase in dietary phenylalanine tolerance.

PART B PREREQUISITE
N/A

SCEMBLIX

MEDICATION(S)
SCEMBLIX

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Myeloid/Lymphoid Neoplasms with Eosinophilia

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Chronic Myeloid Leukemia (CML)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i or ii): i. The chronic myeloid leukemia is T315I-positive, OR ii. Patient has tried at least two other tyrosine kinase inhibitors indicated for use in Philadelphia chromosome-positive chronic myeloid leukemia. Note: Examples of tyrosine kinase inhibitors include imatinib tablets, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), Sprycel (dasatinib tablets), and Tasigna (nilotinib capsules). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has an ABL1 rearrangement.

PART B PREREQUISITE
N/A

SENSIPAR

MEDICATION(S)
CINACALCET HCL

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
hyperparathyroidism in post-renal transplant patients

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Hypercalcemia d/t parathyroid CA-prescr/consult w/onco or endo.Hypercalcemia w/primary hyperparathyroidism-prescr/consult w/nephro or endo. Hyperparathyroidism in post-renal transplant-prescr/consult w/transplant physician/nephro/endo.

COVERAGE DURATION
12 months

OTHER CRITERIA
Hypercalcemia due to parathyroid carcinoma-approve. Hypercalcemia in patients with primary hyperparathyroidism-approve if the patient has failed or is unable to undergo a parathyroidectomy due to a contraindication. Secondary Hyperparathyroidism in patients with chronic kidney disease on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundles payment benefit). Hyperparathyroidism in Post-Renal Transplant Patients-approve if the baseline (prior to starting cinacalcet therapy) calcium and intact parathyroid hormone (iPTH) levels are above the normal range, as defined by the laboratory reference values.

PART B PREREQUISITE

N/A

SIGNIFOR

MEDICATION(S)
SIGNIFOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older (initial therapy)

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy)

COVERAGE DURATION
Cushing's disease/syndrome-Initial therapy - 4 months, Continuation therapy - 1 year.

OTHER CRITERIA
Cushing's disease, initial therapy - approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushing's disease, continuation therapy - approve if the patient has already been started on Signifor/Signifor LAR and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.

PART B PREREQUISITE
N/A

SIRTURO

MEDICATION(S)
SIRTURO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients weighing less than 15 kg

REQUIRED MEDICAL INFORMATION
Diagnosis, concomitant therapy

AGE RESTRICTION
Patients 5 years of age or older

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with an infectious diseases specialist

COVERAGE DURATION
9 months

OTHER CRITERIA
Tuberculosis (Pulmonary)-Approve if the patient has multidrug-resistant tuberculosis and the requested medication is prescribed as part of a combination regimen with other anti-tuberculosis agents

PART B PREREQUISITE
N/A

SKYRIZI

MEDICATION(S)
SKYRIZI 150 MG/ML SOLN PRSYR, SKYRIZI 180 MG/1.2ML SOLN CART, SKYRIZI 360 MG/2.4ML SOLN CART, SKYRIZI PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)

REQUIRED MEDICAL INFORMATION
Diagnosis, Previous medication use

AGE RESTRICTION
18 years of age and older (initial therapy)

PRESCRIBER RESTRICTION
PP-Prescribed by or in consultation with a dermatologist (initial therapy), PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD-presc/consult-gastro

COVERAGE DURATION
1 year

OTHER CRITERIA
PP-Initial Therapy-The patient meets ONE of the following conditions (a or b): a) The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant. NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g., an adalimumab product [Humira], a certolizumab pegol product [Cimzia], an etanercept product [Enbrel, Erelzi], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Stelara [ustekinumab SC

injection], Taltz [ixekizumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional systemic agent for psoriasis)b) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician.Continuation Therapy - Patient must have responded, as determined by the prescriber. Psoriatic arthritis (initial)-approve. Continuation-patient must have responded as determined by the prescriber. CD, initial-approve if the patient has tried or is currently taking crticosteroids, or corticosteroids are contraindicated or if the patient has tried one other conventional systemic therapy for CD (Please note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for Crohn's disease.) or if the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas or if the patient had ileocolonic resection (to reduce the chance of CD recurrence). Patients must be receiving an induction dosing with Skyrizi IV within 3 month of initiating therapy with Skyrizi subcutaneous. Continuation-patient must have responded as determined by the prescriber.

PART B PREREQUISITE

N/A

SOLARAZE

MEDICATION(S)
DICLOFENAC SODIUM 3 % GEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 6 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SOMAVERT

MEDICATION(S)
SOMAVERT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapy, concomitant therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. patient has had an inadequate response to surgery and/or radiotherapy OR ii. The patient is NOT an appropriate candidate for surgery and/or radiotherapy OR iii. The patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender for the reporting laboratory.

PART B PREREQUISITE
N/A

SPRYCEL

MEDICATION(S)
SPRYCEL

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
GIST, chondrosarcoma, chordoma, melanoma cutaneous

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis for which Sprycel is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For melanoma, cutaneous- KIT mutation and previous therapies.

AGE RESTRICTION
GIST/chondrocarcoma or chordoma/melanoma, cutaneous-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
For CML, patient must have Ph-positive CML. For ALL, patient must have Ph-positive ALL. GIST - approve if the patient has tried imatinib or avapritinib. For melanoma, cutaneous - approve if patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.

PART B PREREQUISITE
N/A

STELARA

MEDICATION(S)
STELARA 45 MG/0.5ML SOLN PRSYR, STELARA 45 MG/0.5ML SOLUTION, STELARA 90 MG/ML SOLN PRSYR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous drugs tried.

AGE RESTRICTION
18 years and older CD/UC (initial therapy). PP-6 years and older (initial therapy).

PRESCRIBER RESTRICTION
Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy).

COVERAGE DURATION
1 year

OTHER CRITERIA
PP initial - Approve Stelara SC. CD, induction therapy - approve single dose of IV formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other conventional systemic therapy for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumab, infliximab) OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). UC, initial therapy-approve SC if the patient received a single IV loading dose within 2 months of initiating therapy with Stelara SC. CD,

initial therapy (only after receiving single IV loading dose within 2 months of initiating therapy with Stelara SC) - approve 3 months of the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD. PP/PsA/CD/UC cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy.PP initial - approve Stelara SC. CD, initial therapy - approve 3 months of the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other conventional systemic therapy for CD OR 3) patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR 4) patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). UC, initial therapy-approve SC if the patient received a single IV loading dose within 2 months of initiating therapy with Stelara SC. PP/PsA/CD/UC cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy.

PART B PREREQUISITE

N/A

STIVARGA

MEDICATION(S)
STIVARGA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Soft tissue Sarcoma, Osteosarcoma, Glioblastoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
For GIST, patient must have previously been treated with imatinib or Ayvakit and sunitinib or Sprycel. For HCC, patient must have previously been treated with at least one systemic regimen. Soft tissue sarcoma, advanced or metastatic disease-approve if the patient has non-adipocytic sarcoma, angiosarcoma, solitary fibrous tumor, or pleomorphic rhabdomyosarcoma.Osteosarcoma-approve if the patient has relapsed/refractory or metastatic disease and the patient has tried one systemic chemotherapy regimen. Colon and Rectal cancer-approve if the patient has advanced or metastatic disease, has been previously treated with a fluoropyrimidine, oxaliplatin, irinotecan and if the patient's tumor or metastases are wild-type RAS, the patient has tried Erbitux or Vectibix. Glioblastoma-approve if the patient has recurrent disease.

PART B PREREQUISITE

N/A

SUCRAID

MEDICATION(S)
SUCRAID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic and lab test results

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a geneticist, gastroenterologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of congenital diarrheal disorders

COVERAGE DURATION
1 year

OTHER CRITERIA
Approve if the patient has a laboratory test demonstrating deficient sucrase or isomaltase activity in duodenal or jejunal biopsy specimens OR patient has a sucrose hydrogen breath test OR has a molecular genetic test demonstrating sucrose-isomaltase mutation in saliva or blood.

PART B PREREQUISITE
N/A

SUTENT

MEDICATION(S)
SUNITINIB MALATE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and Hurthle) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Gastrointestinal stromal tumors (GIST), approve if the patient tried imatinib (Gleevec). Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried chemotherapy or radiation therapy. Renal Cell Carcinoma (RCC), clear cell or non-clear cell histology-approve if the patient is at high risk of recurrent clear cell RCC following nephrectomy and Sutent is used for adjuvant therapy or if the patient has relapsed or Stage IV disease. Neuroendocrine tumors of the pancreas-approve for advanced or metastatic disease.

PART B PREREQUISITE

N/A

SYMDEKO

MEDICATION(S)
SYMDEKO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with unknown CFTR gene mutations, Combination therapy with Orkambi, Kalydeco or Trikafta

REQUIRED MEDICAL INFORMATION
Diagnosis, specific CFTR gene mutations

AGE RESTRICTION
Six years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF

COVERAGE DURATION
3 years

OTHER CRITERIA
CF - must be homozygous for the F508del mutation or have at least one mutation in the CFTR gene that is responsive to the requested medication.

PART B PREREQUISITE
N/A

SYMLIN

MEDICATION(S)
SYMLINPEN 120, SYMLINPEN 60

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SYNAREL

MEDICATION(S)
SYNAREL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Endometriosis-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Central Precocious Puberty-12 months, Endometriosis-6 months

OTHER CRITERIA
Central precocious puberty-approve. Endometriosis-approve if the patient has tried one of the following, unless contraindicated, a contraceptive, an oral progesterone or a depo-medroxyprogesterone injection. Note: An exception to the requirement for a trial of the above therapies can be made if the patient has previously used a gonadotropin-releasing hormone (GnRH) agonist or antagonist for endometriosis.

PART B PREREQUISITE
N/A

TABRECTA

MEDICATION(S)
TABRECTA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Non-small cell lung cancer with high-level MET amplification.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping or high-level MET amplification, as detected by an approved test.

PART B PREREQUISITE
N/A

TAFAMIDIS

MEDICATION(S)
VYNDAMAX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with Onpattro or Tegsedi.Concurrent use of Vyndaqel and Vyndamax.

REQUIRED MEDICAL INFORMATION
Diagnosis, genetic tests and lab results

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis

COVERAGE DURATION
1 year

OTHER CRITERIA
Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis-approve if the diagnosis was confirmed by one of the following (i, ii or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy), ii. Amyloid deposits are identified on cardiac biopsy OR iii. patient had genetic testing which, according to the prescriber, identified a TTR mutation AND Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum).

PART B PREREQUISITE
N/A

TAFINLAR

MEDICATION(S)
TAFINLAR

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Patients with Differentiated Thyroid Cancer, Biliary tract cancer, central nervous system cancer, histiocytic neoplasm

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis for which Tafinlar is being used. BRAF V600 mutations

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC, must have BRAF V600E mutation. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease. Biliary Tract Cancer-approve if the patient has tried at least one systemic chemotherapy regimen, patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Mekinist. Central Nervous System Cancer-approve if the medication is being

used for one of the following situations (i, ii, or iii): i) adjuvant treatment of pilocytic astrocytoma OR pleomorphic xanthoastrocytoma OR ganglioglioma, OR ii) recurrent disease for one of the following: low-grade glioma OR anaplastic glioma OR glioblastoma, OR iii) melanoma with brain metastases AND patient has BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib tablets). Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis and one of the following: multisystem disease OR pulmonary disease OR central nervous system lesions OR patient has Erdheim Chester disease AND patient has BRAF V600-mutation positive disease.

PART B PREREQUISITE

N/A

TAGRISSO

MEDICATION(S)
TAGRISSO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
NSCLC-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)- approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note-examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC-Post resection-approve if the patient has completely resected stage IB-IIIA disease and has received previous adjuvant chemotherapy or if the patient is ineligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test.

PART B PREREQUISITE

N/A

TALTZ

MEDICATION(S)
TALTZ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)

REQUIRED MEDICAL INFORMATION
Diagnosis, Previous medication use

AGE RESTRICTION
PP-6 years and older (initial therapy), all other dx-18 years of age and older (initial therapy)

PRESCRIBER RESTRICTION
All dx initial therapy only-PP-Prescribed by or in consultation with a dermatologist. PsA prescribed by or in consultation with a rheumatologist or a dermatologist. AS/spondylo -prescribed by or in consultation with a rheum.

COVERAGE DURATION
1 year

OTHER CRITERIA
Initial Therapy - Plaque Psoriasis-approve if the patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant OR the patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic. PsA Initial-Approve. AS initial-approve. Non-Radiographic Axial Spondyloarthritis-approve if the patient has objective signs of inflammation, defined as at least one of the following: C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or sacroiliitis reported on magnetic resonance imaging. Continuation Therapy -

approve if the patient has responded, as determined by the prescriber.

PART B PREREQUISITE

N/A

TALZENNA

MEDICATION(S)
TALZENNA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Recurrent or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive disease. Prostate cancer - approve if the patient has metastatic castration resistant prostate cancer, AND is using this medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy AND the patient has homologous recombination repair (HRR) gene-mutated disease [Note: HRR gene mutations include ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C] AND the medication is used in combination with Xtandi (enzalutamide capsules and tablets).

PART B PREREQUISITE
N/A

TARGRETIN TOPICAL

MEDICATION(S)
BEXAROTENE 1 % GEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapies tried

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)

COVERAGE DURATION
3 years

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TASIGNA

MEDICATION(S)
TASIGNA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST), Pigmented villonodular synovitis/tenosynovial giant cell tumor, Myeloid/Lymphoid neoplasms with Eosinophilia, melanoma cutaneous.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and melanoma, cutaneous, prior therapies tried. For melanoma, cutaneous, KIT mutation status.

AGE RESTRICTION
ALL/GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
For CML, patient must have Ph-positive CML. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafinib or ripretinib. For ALL, Approve if the patient has philadelphia chromosome-positive acute lymphoblastic leukemia. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement. Pigmented villonodular synovitis/tenosynovial giant cell tumor-approve if the patient has tried Turalio or cannot take Turalio, according to the prescriber. For melanoma, cutaneous - approve if the patient has metastatic or

unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen.

PART B PREREQUISITE

N/A

TAZAROTENE

MEDICATION(S)
TAZAROTENE 0.05 % GEL, TAZAROTENE 0.1 % CREAM, TAZAROTENE 0.1 % GEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Cosmetic uses

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene).

PART B PREREQUISITE
N/A

TAZVERIK

MEDICATION(S)
TAZVERIK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Epitheliod Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if the patient has relapsed or refractory disease and according to the prescriber, there are no appropriate alternative therapies or the patient's tumor is positive for an EZH2 mutation and the patient has tried at least two prior systemic therapies.

PART B PREREQUISITE
N/A

TEPMETKO

MEDICATION(S)
TEPMETKO

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Non-small cell lung cancer with high-level MET amplification.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
NSCLC-approve if the patient has metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutations or patient has high-level MET amplification, as detected by an approved test.

PART B PREREQUISITE
N/A

TERIPARATIDE

MEDICATION(S)
TERIPARATIDE (RECOMBINANT)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with other medications for osteoporosis

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/lifetime.

OTHER CRITERIA
Treatment of PMO, approve if pt has tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR pt has severe renal impairment (creatinine clearance less than 35 mL/min) or CKD or pt has had an osteoporotic fracture or fragility fracture. Increase bone mass in men (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) with primary or hypogondal osteoporosis/Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position

post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture. Patients who have already taken teriparatide for 2 years - approve if the patient is at high risk for fracture.

PART B PREREQUISITE

N/A

TETRABENAZINE

MEDICATION(S)
TETRABENAZINE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist.

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing.

PART B PREREQUISITE
N/A

THALOMID

MEDICATION(S)
THALOMID

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi's Sarcoma, Castleman's Disease.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
MM, myelofibrosis-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Myelofibrosis, approve if according to the prescriber the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/mL or if the patient has serum erythropoietin level less than 500 mU/mL and experienced no response or loss of response to erythropoietic stimulating agents. Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). Kaposi's Sarcoma-approve if the

patient has tried at least one regimen or therapy and has relapsed or refractory disease. Castleman's disease-approve if the patient has multicentric Castleman's disease, and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).

PART B PREREQUISITE

N/A

TIBSOVO

MEDICATION(S)
TIBSOVO

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Chondrosarcoma, Central nervous system cancer

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, IDH1 Status

AGE RESTRICTION
All diagnoses (except chondrosarcoma)-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive, as detected by an approved test. Cholangiocarcinoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and has been previously treated with at least one chemotherapy regimen (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan). Chondrosarcoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Central nervous system cancer-approve if the patient has recurrent or progressive disease, AND patient has World Health Organization (WHO) grade 2 or 3 oligodendroglioma, OR Patient has WHO grade 2 astrocytoma.

PART B PREREQUISITE
N/A

TOBRAMYCIN (NEBULIZATION)

MEDICATION(S)
TOBRAMYCIN 300 MG/4ML NEBU SOLN, TOBRAMYCIN 300 MG/5ML NEBU SOLN

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Bronchiectasis, non-cystic fibrosis

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Bronchiectasis, Non-cystic fibrosis-18 years and older

PRESCRIBER RESTRICTION
CF-prescr/consult w/pulm/phys specializes in tx of CF.Bronchiectasis, non CF-prescr/consult w/pulm

COVERAGE DURATION
1 year

OTHER CRITERIA
Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Cystic fibrosis/Bronchiectasis, non-cystic fibrosis-approve if the patient has pseudomonas aeruginosa in the culture of the airway.

PART B PREREQUISITE
N/A

TOLVAPTAN

MEDICATION(S)
TOLVAPTAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with Jynarque.

REQUIRED MEDICAL INFORMATION
Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 30 days

OTHER CRITERIA
Hyponatremia - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on tolvaptan and has received less than 30 days of therapy.

PART B PREREQUISITE
N/A

TOPICAL AGENTS FOR ATOPIC DERMATITIS

MEDICATION(S)
PIMECROLIMUS, TACROLIMUS 0.03 % OINTMENT, TACROLIMUS 0.1 % OINTMENT

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid.

PART B PREREQUISITE
N/A

TOPICAL RETINOID PRODUCTS

MEDICATION(S)
TRETINOIN 0.01 % GEL, TRETINOIN 0.025 % CREAM, TRETINOIN 0.025 % GEL, TRETINOIN 0.05 % CREAM, TRETINOIN 0.05 % GEL, TRETINOIN 0.1 % CREAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Coverage is not provided for cosmetic use.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TOPIRAMATE/ZONISAMIDE

MEDICATION(S)
EPRONTIA, TOPIRAMATE 100 MG TAB, TOPIRAMATE 15 MG CAP SPRINK, TOPIRAMATE 200 MG TAB, TOPIRAMATE 25 MG CAP SPRINK, TOPIRAMATE 25 MG TAB, TOPIRAMATE 50 MG TAB, ZONISADE, ZONISAMIDE 100 MG CAP, ZONISAMIDE 25 MG CAP, ZONISAMIDE 50 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Coverage is not provided for weight loss or smoking cessation.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TRANSDERMAL FENTANYL

MEDICATION(S)
FENTANYL 100 MCG/HR PATCH 72HR, FENTANYL 12 MCG/HR PATCH 72HR, FENTANYL 25 MCG/HR PATCH 72HR, FENTANYL 50 MCG/HR PATCH 72HR, FENTANYL 75 MCG/HR PATCH 72HR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Acute (i.e., non-chronic) pain.

REQUIRED MEDICAL INFORMATION
Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been optimized and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer,

sickle cell disease, in hospice or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids (including transdermal fentanyl products) require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception.

PART B PREREQUISITE

N/A

TRANSMUCOSAL FENTANYL DRUGS

MEDICATION(S)
FENTANYL CITRATE 1200 MCG LOZ HANDLE, FENTANYL CITRATE 1600 MCG LOZ HANDLE, FENTANYL CITRATE 200 MCG LOZ HANDLE, FENTANYL CITRATE 400 MCG LOZ HANDLE, FENTANYL CITRATE 600 MCG LOZ HANDLE, FENTANYL CITRATE 800 MCG LOZ HANDLE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 12 months.

OTHER CRITERIA
For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer pain (ie, FDA labeled use) prior to reviewing for quantity exception.

PART B PREREQUISITE

N/A

TRIENTINE

MEDICATION(S)
TRIENTINE HCL 250 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, medication history, pregnancy status, disease manifestations

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.

COVERAGE DURATION
Authorization will be for 1 year

OTHER CRITERIA
For Wilson's Disease, approve if the patient meets A and B: A) Diagnosis of Wilson's disease is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, or d): a. Presence of Kayser-Fleischer rings, OR b. Serum ceruloplasmin levels less than 20mg/dL, OR c. Liver biopsy findings consistent with Wilson's disease, OR d. 24-hour urinary copper greater than 40 micrograms/24 hours, AND B) Patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic

manifestations of Wilson's disease, OR 5) The patient is pregnant, OR 6) the patient has been started on therapy with trientine.

PART B PREREQUISITE

N/A

TRIKAFTA

MEDICATION(S)
TRIKAFTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with unknown CFTR gene mutations. Combination therapy with Orkambi, Kalydeco or Symdeko.

REQUIRED MEDICAL INFORMATION
Diagnosis, specific CFTR gene mutations, concurrent medications

AGE RESTRICTION
2 years of age and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF

COVERAGE DURATION
3 years

OTHER CRITERIA
CF - must have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication.

PART B PREREQUISITE
N/A

TUKYSA

MEDICATION(S)
TUKYSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior therapies

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Breast Cancer-approve if the patient has advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-positive disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type).

PART B PREREQUISITE
N/A

TURALIO

MEDICATION(S)
TURALIO 125 MG CAP

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Histiocytic Neoplasms

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis)- approve if, according to the prescriber, the tumor is not amenable to improvement with surgery. Histiocytic Neoplasms-approve if the patient has a colony stimulating factor 1 receptor (CSF1R) mutation AND has one of the following conditions (i, ii, or iii): i. Langerhans cell histiocytosis OR ii. Erdheim-Chester disease OR iii. Rosai-Dorfman disease.

PART B PREREQUISITE
N/A

UBRELVY

MEDICATION(S)
UBRELVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Migraine, Acute treatment-approve

PART B PREREQUISITE
N/A

UPTRAVI

MEDICATION(S)
UPTRAVI 1000 MCG TAB, UPTRAVI 1200 MCG TAB, UPTRAVI 1400 MCG TAB, UPTRAVI 1600 MCG TAB, UPTRAVI 200 & 800 MCG TAB THPK, UPTRAVI 200 MCG TAB, UPTRAVI 400 MCG TAB, UPTRAVI 600 MCG TAB, UPTRAVI 800 MCG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of right heart catheterization, medication history.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection).

PART B PREREQUISITE
N/A

VALCHLOR

MEDICATION(S)
VALCHLOR

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Adults with T-cell leukemia/lymphoma, Langerhans Cell Histiocytosis

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
Cutaneous lymphoma-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has chronic/smoldering subtype of adult T-cell leukemia/lymphoma. Langerhans cell histiocytosis-approve if the patient has unifocal Langerhans cell histiocytosis with isolated skin disease.

PART B PREREQUISITE
N/A

VALTOCO

MEDICATION(S)
VALTOCO 10 MG DOSE, VALTOCO 15 MG DOSE, VALTOCO 20 MG DOSE, VALTOCO 5 MG DOSE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, other medications used at the same time

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)- approve if the patient is currently receiving maintenance antiepileptic medication(s).

PART B PREREQUISITE
N/A

VANCOMYCIN

MEDICATION(S)
VANCOMYCIN HCL 125 MG CAP, VANCOMYCIN HCL 250 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
2 weeks

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VANFLYTA

MEDICATION(S)
VANFLYTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Acute Myeloid Leukemia: approve if the patient has FLT3-ITD mutation-positive disease as detected by an approved test and this medication is being used for induction, consolidation, or maintenance treatment.

PART B PREREQUISITE
N/A

VENCLEXTA

MEDICATION(S)
VENCLEXTA, VENCLEXTA STARTING PACK

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Mantle Cell Lymphoma, waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, multiple myeloma, systemic light chain amyloidosis

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Systemic light chain amyloidosis-approve if the patient has t (11, 14) translocation and has tried at least one systemic regimen.

PART B PREREQUISITE
N/A

VERZENIO

MEDICATION(S)
VERZENIO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Breast cancer, early-approve for 2 years, all other-3 years

OTHER CRITERIA
Breast Cancer, Early-Approve if pt meets (A,B,C and D): A)Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets the following:Pt has node-positive disease at high risk of recurrence (Note-High risk includes patients with greater than or equal to 4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: Grade 3 disease, tumor size greater than or equal to 5 cm, or a Ki-67 score of greater than or equal to 20percent) AND D)Pt meets ONE of the following (i or ii): i.Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one of the following (a,b, or c): a)Pt is a postmenopausal woman, OR b)Pt is a pre/perimenopausual woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, OR 2-Pt has had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is a man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets one of the following (a or

b): a)Pt is a postmenopausal woman or man OR b)Pt is a pre/perimenopausual woman and meets one of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Patient has had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer,Recurrent or Metastatic in Women-Approve if pt meets (A, B, C and D): A) Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i or ii): i.Pt is a postmenopausal woman, OR ii.Pt is a pre/perimenopausal woman and meets one of the following (a or b): a)Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt has had surgical bilateral oophorectomy or ovarian irradiation, AND D)Pt meets ONE of the following criteria (i, ii, or iii): i.Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least one prior endocrine therapy, AND c)Pt has tried chemotherapy for metastatic breast cancer.Breast Cancer,Recurrent or Metastatic in Men-Approve if pt meets the following criteria (A,B and C): A)Pt has HR+ disease, AND B)Pt has HER2-negative breast cancer, AND C)Pt meets ONE of the following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)Pt is receiving a GnRH analog, AND b)Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.Pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least one prior endocrine therapy, AND c)Pt has tried chemotherapy for metastatic breast cancer.

PART B PREREQUISITE

N/A

VITRAKVI

MEDICATION(S)
VITRAKVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, NTRK gene fusion status

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Solid tumors - approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity.

PART B PREREQUISITE
N/A

VIZIMPRO

MEDICATION(S)
VIZIMPRO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, EGFR status, exon deletions or substitutions

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
NSCLC-approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681.

PART B PREREQUISITE
N/A

VONJO

MEDICATION(S)
VONJO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Myelofibrosis (MF), including primary MF, post-polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has intermediate risk or high risk disease and the patient has a platelet count of less than 50 X 10 9/L (less than 50,000/mcL)

PART B PREREQUISITE
N/A

VORICONAZOLE (ORAL)

MEDICATION(S)
VORICONAZOLE 200 MG TAB, VORICONAZOLE 40 MG/ML RECON SUSP, VORICONAZOLE 50 MG TAB

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Aspergillus Infections - prophylaxis, oropharyngeal candidiasis (fluconazole-refractory) - treatment, candidia endophthalmitis - treatment, blastomycosis - treatment, fungal infections (systemic) in patients at risk of neutropenia - prophylaxis, fungal infections (systemic) in patients with human immunodeficiency virus (HIV) - prophylaxis or treatment.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Aspergillus-Prophy, systemic w/risk neutropenia-Prophy, systemic w/HIV-Prophy/Tx-6 mo, others-3 mo

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VOSEVI

MEDICATION(S)
VOSEVI

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Indications consistent with current AASLD/IDSA guidance

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Genotype, prescriber specialty, other medications tried or used in combination with requested medication

AGE RESTRICTION
18 years or older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician

COVERAGE DURATION
Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug

OTHER CRITERIA
Criteria will be applied consistent with current AASLD/IDSA guidance.

PART B PREREQUISITE
N/A

VOTRIENT

MEDICATION(S)
VOTRIENT

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Soft tissue sarcoma other than GIST [angiosarcoma, Pleomorphic rhabdomyosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive, soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma, or solitary fibrous tumor/hemangiopericytoma or alveolar soft part sarcoma], approve. Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has recurrent, advanced or metastatic disease. Advanced Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or stage IV disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has

tried TWO of the following: Gleevec, Sutent, or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq).

PART B PREREQUISITE

N/A

VUMERITY

MEDICATION(S)
VUMERITY, VUMERITY (STARTER)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)

REQUIRED MEDICAL INFORMATION
Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of MS.

COVERAGE DURATION
Authorization will be for 1 year.

OTHER CRITERIA
Cont tx-approve if the patient has been established on Vumerity.

PART B PREREQUISITE
N/A

WELIREG

MEDICATION(S)
WELIREG

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Van Hippel-Lindau Disease-approve if the patient meets the following (A, B, and C): A) Patient has a von Hippel-Lindau (VHL) germline alteration as detected by genetic testing, B) Does not require immediate surgery and C) Patient requires therapy for ONE of the following conditions (i, ii, iii, or iv): i. Central nervous system hemangioblastomas, OR ii. Pancreatic neuroendocrine tumors, OR iii. Renal cell carcinoma, OR iv. Retinal hemangioblastoma.

PART B PREREQUISITE
N/A

XALKORI

MEDICATION(S)
XALKORI

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Dignosis

AGE RESTRICTION
Anaplastic large cell lymphoma-patients greater than or equal to 1 year of age. All other diagnoses (except soft tissue sarcoma)-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test or ROS1 rearrangement positive disease, as detected by an approved test. Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test or ROS1 rearrangement positive disease, as detected by an approved test. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND has received at least one prior systemic treatment. Histiocytic neoplasm-approve if the patient has ALK rearrangement/fusion-positive disease and meets one of the following criteria (i, ii, or iii): (i. Patient has Langerhans cell histiocytosis, OR ii. Patient has Erdheim-Chester disease OR iii. Patient has Rosai-

Dorfman disease. NSCLC with MET mutation-approve if the patient has high level MET amplification or MET exon 14 skipping mutation. Soft Tissue Sarcoma - Inflammatory Myofibroblastic Tumor with Anaplastic Lymphoma Kinase (ALK) Translocation-approve. Melanoma, cutaneous-approve if the patient has ALK fusion disease or ROS1 fusion disease.

PART B PREREQUISITE

N/A

XDEMVY

MEDICATION(S)
XDEMVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

XELJANZ

MEDICATION(S)
XELJANZ, XELJANZ XR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with a biologic or with a Targeted Synthetic DMARD for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].

REQUIRED MEDICAL INFORMATION
Diagnosis, concurrent medications, previous drugs tried.

AGE RESTRICTION
AS/PsA/RA/UC-18 years and older (initial therapy)

PRESCRIBER RESTRICTION
RA, JIA/JRA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION
1 year

OTHER CRITERIA
RA initial-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. PsA initial, approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial and the requested medication will be used in combination with methotrexate or another conventional synthetic disease modifying antirheumatic drug (DMARD), unless contraindicated. UC-Approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least ONE

tumor necrosis factor inhibitor for ulcerative colitis or was unable to tolerate a 3-month trial. Juvenile Idiopathic Arthritis (JIA) [or Juvenile Rheumatoid Arthritis] (regardless of type of onset) [Note: This includes patients with juvenile spondyloarthropathy/active sacroiliac arthritis]-initial-approve Xeljanz immediate release tablets or solution if the patient meets the following: patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. AS-approve Xeljanz/XR tablets if the patient has had a 3 month trial of at least one tumor necrosis factor inhibitor or was unable to tolerate a 3 month trial. Continuation Therapy - Patient must have responded, as determined by the prescriber.

PART B PREREQUISITE

N/A

XERMELO

MEDICATION(S)
XERMELO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, previous therapy, concomitant therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 year

OTHER CRITERIA
Initial therapy - approve if the patient meets ALL of the following criteria: 1) patient has been on long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]) AND 2) while on long-acting SSA therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day, AND 3) Xermelo will be used concomitantly with a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with a long-acting SSA therapy for carcinoid syndrome diarrhea.

PART B PREREQUISITE
N/A

XOLAIR

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with an Interleukin (IL) Antagonist Monoclonal Antibody

REQUIRED MEDICAL INFORMATION
Moderate to severe persistent asthma, baseline IgE level of at least 30 IU/mL. For asthma, patient has a baseline positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay (eg, immunoCAP, ELISA) or the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). CIU - must have urticaria for more than 6 weeks (prior to treatment with Xolair), with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine).

AGE RESTRICTION
Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Polyps-18 years and older.

PRESCRIBER RESTRICTION
Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist. Polyps-prescribed by or in consult with an allergist, immunologist, or otolaryngologist.

COVERAGE DURATION
asthma/CIU-Initial tx 4 months, Polyps-initial-6 months, continued tx 12 months

OTHER CRITERIA
Moderate to severe persistent asthma approve if pt meets criteria 1 and 2: 1) pt has received at least 3

months of combination therapy with an inhaled corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2) patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80 percent predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For CIU cont tx - must have responded to therapy as determined by the prescribing physician. Nasal Polyps Initial-Approve if the patient has a baseline IgE level greater than or equal to 30 IU/ml, patient is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell and patient is currently receiving therapy with an intranasal corticosteroid. Nasal polyps continuation-approve if the patient continues to receive therapy with an intranasal corticosteroid and has responded to therapy.

PART B PREREQUISITE

N/A

XOSPATA

MEDICATION(S)
XOSPATA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Lymphoid, Myeloid Neoplasms

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, FLT3-mutation status

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
AML - approve if the patient has relapsed or refractory disease AND the disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test.

PART B PREREQUISITE
N/A

XPOVIO

MEDICATION(S)
XPOVIO (100 MG ONCE WEEKLY) 50 MG TAB THPK, XPOVIO (40 MG ONCE WEEKLY) 40 MG TAB THPK, XPOVIO (40 MG TWICE WEEKLY) 40 MG TAB THPK, XPOVIO (60 MG ONCE WEEKLY) 60 MG TAB THPK, XPOVIO (60 MG TWICE WEEKLY), XPOVIO (80 MG ONCE WEEKLY) 40 MG TAB THPK, XPOVIO (80 MG TWICE WEEKLY)

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Treatment of multiple myeloma in combination with daratumumb or pomalidomide

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, prior therapies

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Multiple Myeloma-Approve if the patient meets the following (A and B): A) The medication will be taken in combination with dexamethasone AND B) Patient meets one of the following (i, ii, or iii): i. Patient has tried at least four prior regimens for multiple myeloma OR ii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib OR iii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with Darzalex (daratumumb infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Pomalyst (pomalidomide capsules). Note: Examples of regimens for multiple myeloma

include bortezomib/Revlimid (lenalidomide capsules)/dexamethasone, Kyprolis (carfilzomib infusion)/Revlimid/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma-approve if the patient has been treated with at least two prior systemic therapies.

PART B PREREQUISITE

N/A

XTANDI

MEDICATION(S)
XTANDI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis for which Xtandi is being used.

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Prostate cancer-castration-resistant [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) agonist or the medication is concurrently used with Firmagon or if the patient has had a bilateral orchiectomy.

PART B PREREQUISITE
N/A

XYREM

MEDICATION(S)
SODIUM OXYBATE, XYREM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with Xywav, Wakix or Sunosi

REQUIRED MEDICAL INFORMATION
Medication history

AGE RESTRICTION
7 years and older

PRESCRIBER RESTRICTION
Prescribed by a sleep specialist physician or a Neurologist

COVERAGE DURATION
12 months.

OTHER CRITERIA
For Excessive daytime sleepiness (EDS) in patients with narcolepsy, 18 years and older - approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). For EDS in patients with narcolepsy, less than 18 years old-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextramphetamine) or modafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).

PART B PREREQUISITE
N/A

YONSA

MEDICATION(S)
YONSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis, concomitant medications

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Metastatic castration-resistant prostate cancer (mCRPC) - approve if the patient will be using Yonsa in combination with methylprednisolone or dexamethasone and the patient meets ONE of the following criteria (i or ii): i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy.

PART B PREREQUISITE
N/A

ZARXIO

MEDICATION(S)
ZARXIO

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL). Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome).

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.

COVERAGE DURATION
chemo/SCN/AML-6mo.HIV/AIDS-4mo.MDS-3mo.PBPC,Drug induce A/N,AA,ALL,BMT- 3mo. Radi-1mo. Other-12mo.

OTHER CRITERIA
Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile

neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgramstim products, pegfilgrastim products) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).

PART B PREREQUISITE

N/A

ZEJULA

MEDICATION(S)
ZEJULA

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Uterine Leiomyosarcoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after platinum-based chemotherapy regimen. Uterine leiomyosarcoma- approve if the patient has BRCA2 mutation and has tried one systemic regimen.

PART B PREREQUISITE
N/A

ZELBORAF

MEDICATION(S)
ZELBORAF

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or Hurthle cell) with BRAF-positive disease, Central Nervous System Cancer, Histiocytic Neoplasm

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
BRAFV600 mutation status required.

AGE RESTRICTION
All diagnoses (except CNS cancer)-18 years and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Melanoma, patient new to therapy must have BRAFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. HCL - must have tried at least one other systemic therapy for hairy cell leukemia OR is unable to tolerate purine analogs and Zelboraf will be used in combination with Gazyva (obinutuzumab intravenous infusion) as initial therapy. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy. Erdheim-Chester disease, in patients with the BRAF V600 mutation-approve. Central Nervous System Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i) adjuvant treatment of pilocytic astrocytoma OR pleomorphic xanthoastrocytoma OR ganglioglioma, OR ii) recurrent disease for one of the following conditions: low-grade glioma OR

anaplastic glioma OR glioblastoma, OR iii) melanoma with brain metastases AND the medication with be taken in combination with Cotellic (cobimetinib tablets). Histiocytic Neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following: multisystem disease OR pulmonary disease OR central nervous system lesions AND the patient has BRAF V600-mutation positive disease.

PART B PREREQUISITE

N/A

ZEPOSIA

MEDICATION(S)
ZEPOSIA, ZEPOSIA 7-DAY STARTER PACK, ZEPOSIA STARTER KIT 0.23MG &0.46MG 0.92MG(21) CAP THPK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
MS-Concurrent use with other disease-modifying agents used for multiple sclerosis.UC- Concurrent Use with a Biologic or with a Targeted Synthetic Disease-modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
UC-18 years and older

PRESCRIBER RESTRICTION
MS-Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis. UC-Prescribed by or in consultation with a gastroenterologist

COVERAGE DURATION
1 year

OTHER CRITERIA
MS-approve. Ulcerative Colitis, initial-approve if the patient has tried Humira, Cyltezo, Hyrimoz (NDCs starting with 61314-), adalimumab-adaz or Amjevita (NDCs starting with 55513-). Note-a trial of Simponi SC, Amjevita (NDCs starting with 72511), any other non-preferred adalimumab or infliximab would also count). Cont tx-approve if the patient has been established on Zeposia.

PART B PREREQUISITE
N/A

ZIEXTENZO

MEDICATION(S)
ZIEXTENZO

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Patients undergoing PBPC collection and therapy

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation.

COVERAGE DURATION
Cancer pts receiving chemo-6 mo. PBPC-1 mo

OTHER CRITERIA
Cancer patients receiving chemotherapy, approve if-the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20 percent based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20 percent based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, OR the patient has had a neutropenic complication from prior chemotherapy and did not receive

prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment.

PART B PREREQUISITE

N/A

ZOLINZA

MEDICATION(S)
ZOLINZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 years

OTHER CRITERIA
Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve.

PART B PREREQUISITE
N/A

ZTALMY

MEDICATION(S)
ZTALMY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
2 years and older

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist

COVERAGE DURATION
1 year

OTHER CRITERIA
Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder-approve if the patient has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene.

PART B PREREQUISITE
N/A

ZYDELIG

MEDICATION(S)
ZYDELIG

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
small lymphocytic lymphoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ZYKADIA

MEDICATION(S)
ZYKADIA 150 MG TAB

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Soft Tissue Sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Patients with NSCLC with ROS1 Rearrangement. Erdheim-Chester disease.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Must have metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test or ROS1 Rearrangement. IMT - ALK Translocation status.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Erdheim-Chester Disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease.

PART B PREREQUISITE
N/A

ZYTIGA

MEDICATION(S)
ABIRATERONE ACETATE

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Prostate Cancer-Regional Risk Group, Prostate cancer-very-high-risk group, Prostate cancer-radical prostatectomy

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Authorization will be for 3 years.

OTHER CRITERIA
Prostate Cancer-Metastatic, Castration-Resistant (mCRPC)-Approve if abiraterone is being used in combination with prednisone or dexamethasone and the medication is concurrently used with a gonadotropin-releasing hormone (GnRH) agonist, or the medication is concurrently used with Firmagon or the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration-sensitive (mCSPC)- approve if the medication is used in combination with prednisone and the medication is concurrently used with a GnRH agonist or concurrently used with Firmagon or the patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the patient meets all of the following criteria (A, B, and C): A)abiraterone is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i, ii or iii): i.abiraterone with prednisone is used in combination with GnRH agonist OR

ii. Patient has had a bilateral orchiectomy OR iii. the medication is used in combination with Firmagon. Prostate cancer-very-high-risk-group-approve if according to the prescriber the patient is in the very-high-risk group, the medication will be used in combination with external beam radiation therapy and the patient meets one of the following criteria (i, ii or iii): i. abiraterone is used in combination with GnRH agonist OR ii. Patient has had a bilateral orchiectomy OR iii. the medication is used in combination with Firmagon. Prostate cancer-radical prostatectomy-approve if the medication is used in combination with prednisone, the patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy, patient has pelvic recurrence, the medication will be used concurrently with GnRH agonist, Firmagon or the patient has had a bilateral orchiectomy.

PART B PREREQUISITE

N/A