

# **ACTIMMUNE**

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## **MEDICATION(S)**

ACTIMMUNE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

1. Hypersensitivity to Actimmune or E. coli derived products

## **REQUIRED MEDICAL INFORMATION**

1. Dx chronic granulomatous disease OR Dx severe malignant osteopetrosis

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

BvD

## **PART B PREREQUISITE**

N/A

# **AKEEGA**

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## **MEDICATION(S)**

AKEEGA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Dx of deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) 2. Contraindication, intolerance, or failure of Lynparza

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# ALECENSA

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## MEDICATION(S)

ALECENSA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of NSCLC that is ALK-positive
  - a. Tumors are anaplastic lymphoma kinase (ALK)-positive
2. For Alunbrig: Patient has failed/intolerance/contraindication to Alecensa

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# ALS

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## **MEDICATION(S)**

RADICAVA ORS, RADICAVA ORS STARTER KIT

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1)Dx of amyotrophic lateral sclerosis (ALS) as defined by the revised El Escorial criteria

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# ALUNBRIG

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## MEDICATION(S)

ALUNBRIG

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

- 1)Dx of metastatic non-small cell lung cancer (NSCLC)
  - a)Tumors are anaplastic lymphoma kinase (ALK)-positive
- 2)Patient has failed/intolerance/contraindication to Alecensa

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **ANDROGENS**

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### **MEDICATION(S)**

TESTOSTERONE 10 MG/ACT (2%) GEL, TESTOSTERONE 30 MG/ACT SOLUTION

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Two separate testosterone levels drawn on different dates where the serum testosterone level is below 300 ng/dL, 2. Pt experiences at least ONE of the following: a. malaise, b. fatigue, c. lethargy, d. muscle loss, e. depression, f. decreased libido,

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ANTIPSYCHOTIC**

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### **MEDICATION(S)**

CAPLYTA, FANAPT, FANAPT TITRATION PACK, LYBALVI, VERSACLOZ, VRAYLAR 1.5 MG CAP, VRAYLAR 3 MG CAP, VRAYLAR 4.5 MG CAP, VRAYLAR 6 MG CAP

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Previous trial on at least ONE of the following: aripiprazole, clozapine, fluoxetine-olanzapine, haloperidol, olanzapine, quetiapine, risperidone, ziprasidone 2. For Major Depressive Disorder (MDD) or Schizophrenia: Previous trial on Rexulti

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **APO B**

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### **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**

Pt has none of the following health conditions or health concerns: a. History of significant hepatic disease, b. Alcohol abuse,

### **REQUIRED MEDICAL INFORMATION**

1. Pt has untreated, fasting LDL cholesterol greater than 500 mg/dL AND triglycerides less than 300 mg/dL, 2. Pt meets a OR b AND c of the following: a. Pt has documented mutations in both alleles of the LDL receptor or of other genes known to affect LDL receptor function, b. Both of pt's parents have a hx of untreated total cholesterol of greater than 250 mg/dL, c. Pt has xanthomas present before age 10, 3. Pt has failed or is currently taking at least ONE of the following: a. Atorvastatin, Rosuvastatin, or Simvastatin b. Has documented intolerance (e.g. rhabdomyolysis) to statin therapy 4. Pt has previous trial of Repatha OR Praluent

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1. Initial: 6 mo, 2. Reauthorization: Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A





# ARCALYST

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## MEDICATION(S)

ARCALYST

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Combination use with a TNF-inhibitor

## REQUIRED MEDICAL INFORMATION

1. Diagnosis of cryopyrin-associated periodic syndrome 2. Diagnosis of recurrent pericarditis 3. Diagnosis of deficiency of Interleukin-1 Receptor Antagonist (DIRA)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

BvsD Determination

## PART B PREREQUISITE

N/A

## **ATOPIC DERM**

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### **MEDICATION(S)**

ADBRY 150 MG/ML SOLN PRSYR, CIBINQO

**PENDING CMS APPROVAL**

## **AUGTYRO**

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### **MEDICATION(S)**

AUGTYRO

**PENDING CMS APPROVAL**

# AUSTEDO

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## MEDICATION(S)

AUSTEDO, AUSTEDO XR, AUSTEDO XR PATIENT TITRATION

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of chorea associated with Huntington's disease 2. Dx of tardive dyskinesia

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# AYVAKIT

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## MEDICATION(S)

AYVAKIT

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1)Diagnosis of:

- a)Unresectable or metastatic GIST that is platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation positive including PDGFRA D842V mutations.
- b)Advanced Systemic Mastocytosis: AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).
- c)Indolent Systemic Mastocytosis

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **BALVERSA**

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### **MEDICATION(S)**

BALVERSA

**PENDING CMS APPROVAL**

## **BANZEL**

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### **MEDICATION(S)**

RUFINAMIDE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Pt has inadequate seizure control despite treatment with at least ONE anti-epileptic drug

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



# **BENLYSTA**

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## **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**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of lupus nephritis or systemic lupus erythematosus
2. Pt is currently autoantibody positive,
3. Pt has current active disease,
4. Pt has previous treatment with at least TWO of the following:
  - a. Corticosteroids, b. Antimalarials, c. Immunosuppressives,
5. Pt will continue to receive concomitant standard treatment with at least ONE of the following:
  - a. Corticosteroids, b. Antimalarials, c. Immunosuppressives

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

BvsD Determination

## **PART B PREREQUISITE**

N/A

## **BESREMI**

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### **MEDICATION(S)**

BESREMI

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of Polycythemia Vera 2. Inadequate response or intolerance to hydroxyurea

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 6 months Reauth: Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **BOSULIF**

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## **MEDICATION(S)**

BOSULIF

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Pt is diagnosed with Philadelphia chromosome positive (Ph+) CML a. Pt's CML is newly diagnosed in chronic phase b. Pt's CML is in chronic phase, accelerated phase, or blast phase, 2. For CML in chronic phase, accelerated phase, or blast phase: a. Pt has previous failure or intolerance to imatinib

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **BRAFTOVI**

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## **MEDICATION(S)**

BRAFTOVI 75 MG CAP, MEKTOVI

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Dx of BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma a. Will be used as combination therapy with encorafenib [Braftovi] and binimetinib [Mektovi] 2. For encorafenib [Braftovi], dx of BRAF V600E mutation-positive metastatic colorectal cancer a. Will be used as combination therapy with cetuximab [Erbix] 3. Dx of BRAF V600E mutation-positive metastatic non-small cell lung cancer (NSCLC) a. Will be used as combination therapy with encorafenib [Braftovi] and binimetinib [Mektovi]

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **BRONCHITOL**

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## **MEDICATION(S)**

BRONCHITOL, BRONCHITOL TOLERANCE TEST

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Dx of cystic fibrosis 2. Trial of both Hypersal and sodium chloride (3% or 7%)

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **BRUKINSA**

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## **MEDICATION(S)**

BRUKINSA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1)Diagnosis of

a)Mantle cell lymphoma (MCL)

b)Marginal zone lymphoma (MZL)

c)Waldenstrom macroglobulinemia

d)Chronic lymphocytic leukemia (CLL)/ Small lymphocytic lymphoma (SLL)

e)Relapsed or refractory follicular lymphoma (FL)

2)Patient has received at least one prior therapy for MCL

3)Patient has been previously treated with anti-CD20-based regimen for MZL

4)Patient has received two or more lines of therapy for FL and Brukinsa will be used in combination with obinutuzumab

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

# **CABLIVI**

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## **MEDICATION(S)**

CABLIVI

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

A. Initial authorization 1. Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) 2. Started inpatient in combination with plasma exchange B. Reauthorization 1. Signs of persistent underlying disease (e.g., suppressed ADAMTS13 concentrations) 2. Demonstrated a positive response to therapy by a clinically significant increase in platelet count, reduction in neurological symptoms, or improvement in organ-damage markers

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

3 months

## **OTHER CRITERIA**

Max Duration of therapy 58 days

## **PART B PREREQUISITE**

N/A



# CABOMETYX

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## MEDICATION(S)

CABOMETYX

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of hepatocellular carcinoma a. Previous use of sorafenib 2. Dx of advanced renal cell carcinoma 3. Dx of locally advanced or metastatic differentiated thyroid cancer (DTC) a. progression following prior VEGFR-targeted therapy b. patient is radioactive iodine-refractor or ineligible

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **CALQUENCE**

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### **MEDICATION(S)**

CALQUENCE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of mantle cell lymphoma a. Pt has been treated with at least one prior therapy 2. Dx of chronic lymphocytic leukemia 3. Dx of small lymphocytic lymphoma

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# CAPRELSA

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## MEDICATION(S)

CAPRELSA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# CARBAGLU

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## **MEDICATION(S)**

CARGLUMIC ACID, SAPROPTERIN DIHYDROCHLORIDE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. For carglumic acid: hyperammonemia due to N-acetylglutamate synthase deficiency 2. For sapropterin: hyperphenylalaninemia due to tetra hydrobiopterin- (BH4-) responsive Phenylketonuria

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# CHOLBAM

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## MEDICATION(S)

CHOLBAM

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Initial: a. Pt has abnormal results from a urinary bile acids analysis by FAB-MS and neurologic exam,
2. Reauth: a. Patient has experienced improvement in ALT/AST values, bilirubin values, and/or weight

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: Plan year Reauth: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## COMETRIQ

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### MEDICATION(S)

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

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

1. Dx of a. Progressive, metastatic medullary thyroid cancer (MMTC) 2. Max daily dose of 140 mg/day

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Plan Year

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

# COPIKTRA

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## **MEDICATION(S)**

COPIKTRA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Previous use of 2 prior therapies for indication

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# CRINONE

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## MEDICATION(S)

CRINONE 4 % GEL

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

A. Diagnosis of secondary amenorrhea

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



# CYSTAGON

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## MEDICATION(S)

CYSTAGON

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Diagnosis of nephropathic cystinosis 2. Elevated baseline WBC cysteine levels greater than 2 nmol per 1/2 cystine/mg protein 3. CTNS gene mutation 4. Clinical symptoms of an electrolyte imbalance and polyuria

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **CYSTARAN**

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## **MEDICATION(S)**

CYSTADROPS, CYSTARAN

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Initial: a. Pt has corneal cysteine accumulation that has been confirmed by slit-lamp photography,

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **CYSTIC FIBROSIS**

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### **MEDICATION(S)**

CAYSTON, TOBRAMYCIN 300 MG/5ML NEBU SOLN

**PENDING CMS APPROVAL**

# DAURISMO

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## MEDICATION(S)

DAURISMO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Equal to or greater than 75 years or has comorbidity preventing use of intensive induction chemotherapy. 2. Be given in combination with low-dose cytarabine

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# DIACOMIT

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## MEDICATION(S)

DIACOMIT

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of Dravet syndrome 2. Previous use of clobazam and valproic acid 3. To be used in combination with clobazam

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **DOPTELET**

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### **MEDICATION(S)**

DOPTELET

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Platelet count less than 50,000 2. Pt is scheduled for a procedure where there is a bleeding risk 3. Doptelet will be used for 5 days starting 10 to 13 days prior to the procedure and discontinued 5 to 8 days prior to the procedure 4. For chronic immune thrombocytopenia, has the patient had an insufficient response to a previous treatment (e.g. corticosteroid, immune globulin)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **DRONABINOL**

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## **MEDICATION(S)**

DRONABINOL

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. For HIV-associated wasting syndrome OR cancer-associated anorexia dx: a. Pt has previous trial on megestrol, 2. For CINV dx: a. Pt has previous trial on olanzapine

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **DUPIXENT**

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## **MEDICATION(S)**

DUPIXENT 300 MG/2ML SOLN A-INJ, DUPIXENT 300 MG/2ML SOLN PRSYR

## **PA INDICATION INDICATOR**

2 - Some FDA-Approved Indications Only

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

1. Use in combination with any other biologic (e.g., Dupixent, Xolair, Humira, Entyvio, and Otezla, etc.)

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of corticosteroid-dependent asthma (Please note, Dupixent is only covered for corticosteroid-dependent asthma) A. Diagnosis of corticosteroid-dependent asthma evidenced by member's requirement of at least 3 months of chronic oral corticosteroids 2. 3 month failure of at least TWO of the following: A. ICS + SABA B. ICS/LABA C. Spiriva or Trelegy D. LTRA 3. Two provider/ER/Hospital admissions for asthma exacerbations within the last 12 months

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Pulmonologist or Allergist

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



# **EMGALITY**

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## **MEDICATION(S)**

EMGALITY, EMGALITY (300 MG DOSE)

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of episodic cluster headache 2. Diagnosis of Episodic Migraine (4-14 migraine days per month) or Chronic Migraine (greater than 14 migraine days per month) A. Member has tried Ajovy  
Reauthorization Criteria: 1. Patient has had a reduction in the number of migraine days per month

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **ENDARI**

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### **MEDICATION(S)**

L-GLUTAMINE 5 GM PACKET

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

1. Renal insufficiency, 2. Uncontrolled liver disease

### **REQUIRED MEDICAL INFORMATION**

1. Dx of Sickle Cell Disease (SCD), 2. Tx to prevent acute complications of sickle cell disease, 3. Previous use, concurrent use, or inability to use generic hydroxyurea, 4. Reauthorization: reduction in the number of acute complications (i.e blood transfusions, sickle cell crisis, hospitalizations) of sickle cell disease since initiating therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ENDOTHELIN ANTAGONISTS**

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### **MEDICATION(S)**

ADEMPAS, AMBRISENTAN, BOSENTAN, OPSUMIT

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. PAH:

- a) Exclusion of all secondary causes of pulmonary hypertension
- b) Must be dx with PAH with WHO class II, III, or IV
- c) For Opsumit or Adempas: Previous trial of ambrisentan or bosentan

2. CTPH (for Adempas):

- a) Pt has failed endarterectomy OR
- b) Pt considered inoperable for pulmonary endarterectomy AND
- c) Pt has previous trial on full anticoagulation for at least 90 days

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



# ENSPRYNG

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## MEDICATION(S)

ENSPRYNG

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Use of another biologic tx for NMOSD

## REQUIRED MEDICAL INFORMATION

1. Dx of neuromyelitis optica spectrum disorder (NMOSD) with one of the following: A. Idiopathic single or recurrent events of longitudinally extensive myelitis (3 or more vertebral segment spinal cord MRI lesion) B. Optic neuritis, single, recurrent or simultaneous bilateral 2. Positive for anti-aquaporin-4 (AQP4) antibody, 3. Reauthorization: A. Patient is continuing to receive benefit from treatment

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: Plan year Reauth: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# EPCLUSA

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## **MEDICATION(S)**

SOFOSBUVIR-VELPATASVIR

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Chart notes documenting genotype,

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 Weeks

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **EPIDIOLEX**

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## **MEDICATION(S)**

EPIDIOLEX

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Previous use of two alternative antiepileptic medications and used in combination with another antiepileptic

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# ERIVEDGE

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## **MEDICATION(S)**

ERIVEDGE, ODOMZO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Pt has recurring lesions after radiation therapy OR radiation therapy is contraindicated or inappropriate, 2. Pt has recurring lesions after surgical excision OR surgery is contraindicated or inappropriate

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



## **ERLEADA**

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### **MEDICATION(S)**

ERLEADA

**PENDING CMS APPROVAL**

# ESBRIET

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## MEDICATION(S)

PIRFENIDONE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx: a. Idiopathic pulmonary fibrosis (IPF) 2. Dx has been confirmed via high-resolution computed tomography scan and/or lung biopsy, 3. Forced Vital Capacity (FVC) greater than 50 percent predicted value 4. Carbon monoxide diffusing capacity (DLCO) greater than 30 percent predicted value 5. Liver function tests (ALT, AST, and bilirubin) completed prior to initiating therapy 6. Reauth: a. A repeat liver function test has been performed after 3 months of therapy has been completed

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 3 mo, Reauth: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **ETHACRYNIC ACID**

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### **MEDICATION(S)**

ETHACRYNIC ACID

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Pt needs diuresis for any of the following: a. Edema associated with congestive heart failure, b. Edema associated with cirrhosis of the liver, c. Edema associates with renal disease. d. Short-term management of ascites due to malignancy, idiopathic edema, or lymphedema. 2. Pt has previous trial and failure on a loop diuretic or thiazide diuretic

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# FARESTON

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## MEDICATION(S)

TOREMIFENE CITRATE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Pt has congenital or acquired QT prolongation, 2. Pt has uncorrected hypokalemia, 3. Pt has uncorrected hypomagnesemia

## REQUIRED MEDICAL INFORMATION

1. Pt has previous trial and failure or contraindication to tamoxifen therapy, 2. Pt has previous trial and failure or contraindication to aromatase inhibitor therapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **FASENRA**

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### **MEDICATION(S)**

FASENRA, FASENRA PEN

**PENDING CMS APPROVAL**

# FENTANYL

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## 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

Non-cancer pain use

## REQUIRED MEDICAL INFORMATION

1. Must have documented maintenance therapy with a long-acting opioid, 2. Documented failure with a short-acting opioid for breakthrough pain

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

6 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# FENTANYL PATCH

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## 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

- 1.Fentanyl used for acute intermittent pain, post-operative pain, or mild pain
- 2.Fentanyl used in combination with a benzodiazepine or other central nervous system (CNS) depressant

## REQUIRED MEDICAL INFORMATION

- 1.Patient has severe pain requiring long-term, around the clock pain management for which alternative treatment options have been inadequate
- 2.Provider is knowledgeable in the use of potent opioids for chronic pain management
- 3.Patient is opioid tolerant, having been established on the equivalent of 60 milligrams of morphine or more per day for at least a week prior to being prescribed fentanyl patches
- 4.Patient will be monitored for sedation and respiratory depression
- 5.Patient will be monitored for opioid addiction, abuse, and misuse
- 6.Appropriate use and availability of naloxone has been discussed with the patient
- 7.If requesting every 48-hour dosing, every 72-hour dosing has been tried
8. Patient has tried a dose reduction within the last 6 months

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

6 months

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A



# FILSUVEZ

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## MEDICATION(S)

FILSUVEZ

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Combination use with Vyjuvek

## REQUIRED MEDICAL INFORMATION

1. Dx of dystrophic or junctional epidermolysis bullosa
2. Prescribing physician is a dermatologist with experience in treating epidermolysis bullosa and collaborated with a wound healing specialist
3. Reauthorization:
  - a. Documentation of a response as evidenced by wound healing

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Dermatologist

## COVERAGE DURATION

Initial: 6 months

Reauth: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **FINTEPLA**

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## **MEDICATION(S)**

FINTEPLA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Dx of Dravet Syndrome or Lennox Gaustaut Syndrome
2. Previous use of two of topiramate, valproic acid, or clobazam

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **FIRAZYR**

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### **MEDICATION(S)**

ICATIBANT ACETATE

**PENDING CMS APPROVAL**

# **FIRDAPSE**

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## **MEDICATION(S)**

FIRDAPSE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

### **I. Initial authorization**

A. P/Q-type voltage-gated calcium channel antibodies OR Repetitive nerve stimulation consistent with LEMS

B. Screening for cancer related to LEMS

C. Experiences moderate to severe weakness interfering with function

D. Documentation of quantitative myasthenia gravis core and subjective global impression score

E. Patient has tried and failed pyridostigmine

### **II. Reauthorization**

A. Improvements in myasthenia gravis core and subjective global impression score

B. Screened 3-6 months after initial screening for malignancies

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 3 months Reauthorization: 6 months

## **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

## **FOTIVDA**

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### **MEDICATION(S)**

FOTIVDA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC) 2. Previous failure of two systemic therapies

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **FRUZAQLA**

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### **MEDICATION(S)**

FRUZAQLA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of metastatic colorectal cancer (mCRC) 2. Member has previously been treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy 3. Member has failed, contraindication, or intolerance to Lonsurf with or without bevacizumab

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **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**

1. Dx of non-small cell lung cancer (NSCLC) A. Metastatic NSCLC identified as rearranged during transfection (RET) fusion-positive 2. Dx of thyroid cancer A. Advanced or metastatic RET fusion-positive thyroid cancer refractory radioactive iodine (if appropriate) requiring systemic therapy

## **AGE RESTRICTION**

12 and older

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



# GILOTRIF

---

## MEDICATION(S)

GILOTRIF

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of metastatic non-small cell lung cancer (NSCLC) a. The tumor has an epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation 2. Dx of metastatic squamous non-small cell lung cancer (NSCLC) a. Progression after platinum-based chemotherapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# GLEOSTINE

---

## MEDICATION(S)

GLEOSTINE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of primary and metastatic brain tumors following appropriate surgical and/or radiotherapeutic procedures  
2. Dx of Hodgkin's lymphoma A. Disease has progressed following initial chemotherapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## GLP 1

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### MEDICATION(S)

MOUNJARO, TRULICITY

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

Type 1 diabetes mellitus

### REQUIRED MEDICAL INFORMATION

1) Diagnosis of Type 2 diabetes mellitus (T2DM) AND

2) Patient has tried and failed a 90-day trial of a sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., Farxiga, Glyxambi, Invokamet, Segluromet, Synjardy, Xigduo, etc.) or a dipeptidyl peptidase IV (DPP4) inhibitor (e.g., alogliptin, Januvia, Janumet, Onglyza, Tradjenta, etc.) as evidenced by an A1c greater than or equal to 7% in last 3 months

a) OR has ONE of the following

- i) Reduced renal function (eGFR 45mL/min/m<sup>2</sup> or less)
- ii) Urinary frequency due to BPH, LUTS, bladder spasm, etc.
- iii) Recurrent genital fungal infection
- iv) Recurrent urinary tract infection
- v) Intolerance to an SGLT2/DDP4 inhibitor

b) AND the patient has an A1c greater than or equal to 7% in the last 3 months

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Plan Year

### OTHER CRITERIA

N/A

**PART B PREREQUISITE**

N/A

## **GROWTH HORMONE**

---

### **MEDICATION(S)**

GENOTROPIN, GENOTROPIN MINIQUICK, OMNITROPE

**PENDING CMS APPROVAL**

## **HAEGARDA**

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### **MEDICATION(S)**

HAEGARDA, ORLADEYO

**PENDING CMS APPROVAL**

# HARVONI

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## **MEDICATION(S)**

LEDIPASVIR-SOFOSBUVIR

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Chart notes showing genotype

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Maximum 24 weeks

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **HEMADY**

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### **MEDICATION(S)**

HEMADY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of Multiple Myeloma (MM) 2. Previous use of generic dexamethasone tablets

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## HEPATITIS C

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### MEDICATION(S)

PEGASYS

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

1. For Hep B dx: a. Pre-treatment HBV DNA levels are greater than 20,000 IU/ml, b. Must be used as monotherapy 2. Hep C dx

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

48 weeks

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

# HETLIOZ

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## **MEDICATION(S)**

HETLIOZ LQ, TASIMELTEON

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. For Non-24 Hour Sleep-Wake Disorder: a. Pt is totally blind without light perception 2. For Nighttime Sleep Disturbances in Smith-Magenis Syndrome (SMS) a. Diagnosis been confirmed with genetic testing

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Sleep specialist or Neurologist

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# HUMIRA

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## MEDICATION(S)

AMJEVITA 20 MG/0.2ML SOLN PRSYR, AMJEVITA 40 MG/0.4ML SOLN A-INJ, AMJEVITA 40 MG/0.4ML SOLN PRSYR, AMJEVITA 80 MG/0.8ML SOLN A-INJ, HADLIMA, HADLIMA PUSHTOUCH

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Combination therapy with another biologic medication, JAK Inhibitor, or Otezla

## REQUIRED MEDICAL INFORMATION

1. Dx of AS, UC, or CD 2. Dx of RA, JIA, PsA dx: Pt has failed at least three months therapy on at least ONE of the following: a. methotrexate, b. leflunomide, c. hydroxychloroquine, d. sulfasalazine, OR contraindication to use (Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, Pregnancy, breastfeeding, or currently planning pregnancy, Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia), Elevated liver transaminases, Hypersensitivity, or history of intolerance or adverse event, Interstitial pneumonitis or clinically significant pulmonary fibrosis, Myelodysplasia, Renal impairment 3. Dx of hidradenitis suppurativa: a. Pt has failed therapy or had an inadequate response to a treatment of oral antibiotics b. Pt has lesions present in at least TWO distinct anatomical areas, one of which is Hurley Stage II or III 4. Dx of noninfectious uveitis: a. Pt has previous failure on corticosteroids 5. Dx of plaque psoriasis: Pt has failed therapy with at least ONE of the following: a. methotrexate, b. cyclosporine, c. acitretin

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## OTHER CRITERIA

N/A

**PART B PREREQUISITE**

N/A

# **HYFTOR**

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## **MEDICATION(S)**

HYFTOR

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Dx of facial angiofibroma associated with tuberous sclerosis 2. Member's facial angiofibroma cause functional impairment or symptoms such as bleeding or pain

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 weeks No reauthorization

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **IBRANCE**

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## **MEDICATION(S)**

IBRANCE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1)Dx of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer

a)Ibrance used as initial therapy:

i)Used in combination with an aromatase inhibitor,

b)Ibrance used after endocrine-based therapy:

i)Used in combination with fulvestrant

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **ICLUSIG**

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### **MEDICATION(S)**

ICLUSIG

**PENDING CMS APPROVAL**

## **IDHIFA**

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### **MEDICATION(S)**

IDHIFA

**PENDING CMS APPROVAL**



# IMBRUVICA

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## 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

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of CLL/SLL 2. Dx of CLL/SLL w/ 17p deletion 3. Dx of Waldenstrom's Macroglobinemia 4. Dx of cGVHD: a. Member has failed at least one prior systemic therapy b. Prescribing physician is a specialist in transplant

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **IMPAVIDO**

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## **MEDICATION(S)**

IMPAVIDO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of leishmaniasis (visceral, cutaneous, or mucosal) confirmed by parasite in a clinical specimen 2. Previous use of ketoconazole, fluconazole, paromomycin, or amphotericin 3. Weight 30 kg or greater

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

28 days

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **INCRELEX**

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## **MEDICATION(S)**

INCRELEX

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Height standard deviation score of less than -3 based on age and gender, 2. Basal IGF-1 standard deviation score of less than -3 based on age and gender, 3. Normal or elevated growth hormone levels, 4. Pt must have open epiphyses, 5. Gh stimulation test of greater than 10 mcg/L.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# INLYTA

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## MEDICATION(S)

INLYTA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of renal cell carcinoma 2. For first line treatment in combination with pembrolizumab (Keytruda) or avelumab (Bavencio) 3. Monotherapy as a second line treatment after previous use of one prior systemic therapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **INQOVI**

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## **MEDICATION(S)**

INQOVI

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Dx of myelodysplastic syndrome

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# INREBIC

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## MEDICATION(S)

INREBIC

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Intolerance, failure, or previous use of ruxolitinib

## REQUIRED MEDICAL INFORMATION

A. Diagnosis of intermediate or high-risk primary or secondary myelofibrosis B. Platelet count greater than or equal to  $50 \times 10^9/L$

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# IRESSA

---

## MEDICATION(S)

GEFITINIB

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Pt has ONE of the following: a. EGFR exon 19 deletion, b. EGFR exon 21 deletion, 2. Gefitinib is used as first-line therapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# ISTURISA

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## MEDICATION(S)

ISTURISA 1 MG TAB, ISTURISA 5 MG TAB

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of Cushings Disease a. Baseline mean urinary free cortisol (UFC) level at least 1.5x the upper limit of normal measured over three 24 hour measurements (ULN = 50 micrograms/24 hours or 145 nmol/24 hours) b. Symptoms of Cushings Disease (e.g diabetes, central obesity, moon face, buffalo hump, osteoporosis, muscle wasting, hypertension, depression, anxiety) c. Failure of pituitary surgery or contraindication to pituitary surgery d. Intolerance to pasireotide (Signifor) g. Exclusion of other causes of Cushings Syndrome (aside from Cushings Disease which is specifically caused by a pituitary adenoma) 2. For reauthorization: a. Recent UFC level showing improvement (less than 48 weeks of treatment) or is within normal limits (after 48 weeks of treatment) b. Symptom improvement of Cushings Disease

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE



N/A

## **IVIG**

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### **MEDICATION(S)**

BIVIGAM, GAMMAGARD, GAMMAGARD S/D LESS IGA, GAMMAKED 1 GM/10ML SOLUTION, GAMMAPLEX, GAMUNEX-C 1 GM/10ML SOLUTION, OCTAGAM 1 GM/20ML SOLUTION, OCTAGAM 10 GM/100ML SOLUTION, OCTAGAM 10 GM/200ML SOLUTION, OCTAGAM 2 GM/20ML SOLUTION, OCTAGAM 2.5 GM/50ML SOLUTION, OCTAGAM 25 GM/500ML SOLUTION, OCTAGAM 30 GM/300ML SOLUTION, OCTAGAM 5 GM/100ML SOLUTION, PRIVIGEN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

- 1) For all non-preferred IVIG products (ie Bivigam, Gammaked, Octagam, etc)
- a) Must try TWO of the following: Gammagard, Gamunex, Hizentra, and Privigen OR
  - b) Documented medical reason why preferred agents cannot be used

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

BvD Determination

### **PART B PREREQUISITE**

YES

## **IWILFIN**

---

### **MEDICATION(S)**

IWILFIN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of high risk neuroblastoma (HRNB) in patients who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy 2. Maximum duration of 2 years of therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **IXCHIQ**

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### **MEDICATION(S)**

IXCHIQ

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Confirmation that the patient is at increased risk of exposure to chikungunya virus

### **AGE RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 month

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **JADENU**

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### **MEDICATION(S)**

DEFERASIROX 180 MG PACKET, DEFERASIROX 250 MG TAB SOL, DEFERASIROX 360 MG PACKET, DEFERASIROX 500 MG TAB SOL, DEFERASIROX 90 MG PACKET, DEFERASIROX GRANULES

**PENDING CMS APPROVAL**

# JAKAFI

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## MEDICATION(S)

JAKAFI

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Diagnosis of: a. Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis b. Polycythemia vera c. Acute Graft-versus-host disease d. Chronic Graft-versus-host disease 2. For myelofibrosis or polycythemia vera, must have at least ONE of the following: a. Pt has enlarged spleen shown by MRI or CT, b. Pt has palpable splenomegaly 3. For myelofibrosis or polycythemia vera, platelet count greater than or equal to  $50 \times 10^9/L$  4. For the treatment of acute graft-versus-host disease patient has previously failed trial of corticosteroids 5. For the treatment of chronic graft-versus-host disease patient has previously failed one or two lines of systemic therapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



## **JAYPIRCA**

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### **MEDICATION(S)**

JAYPIRCA

**PENDING CMS APPROVAL**



## **JYNARQUE**

---

### **MEDICATION(S)**

JYNARQUE

**PENDING CMS APPROVAL**

# KALYDECO

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## MEDICATION(S)

KALYDECO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Initial: A. Pt genotyped by an FDA-cleared CF mutation test B. Pt have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data C. Pt has FEV1 between 40-90% 2. Reauth: A. Pt has been reassessed since starting therapy, B. Pt's FEV1 has increased since starting therapy

## AGE RESTRICTION

Tablet: 6 years old or older, Granules: 1 months old to 5 years old

## PRESCRIBER RESTRICTION

Specialist in Cystic Fibrosis or Pulmonologist

## COVERAGE DURATION

Initial: 3 months Reauth: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# KERENDIA

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## MEDICATION(S)

KERENDIA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Diagnosis of Type 2 Diabetes a. Prior treatment with one SGLT-2 inhibitor (Farxiga or Jardiance) b. Contraindication to SGLT2 inhibitor i. eGFR 45ml/min/m<sup>2</sup> or less ii. Urinary Frequency due to BPH, LUTS, bladder spasm iii. Recurrent genital fungal infection or recurrent urinary tract infection

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# KEVEYIS

---

## MEDICATION(S)

KEVEYIS

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Hypersensitivity to dichlorphenamide or other sulfonamides 2. Use in combination with high-dose aspirin 3. Severe pulmonary disease 4. Hepatic insufficiency (e.g Child-Pugh B or C)

## REQUIRED MEDICAL INFORMATION

1. Dx of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants. 2. Dx confirmed by genetic testing, provocative testing, ectromyography, or muscle biopsy 3. Previous use or contraindication to acetazolamide 4. Reauthorization: a. improvement in baseline symptoms (e.g. number of attacks per week or month, severity of attacks, duration of attacks, short-form 36 assessment, etc.)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months Reauthorization: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **KISQALI**

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### **MEDICATION(S)**

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

### **PENDING CMS APPROVAL**

# KORLYM

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## MEDICATION(S)

MIFEPRISTONE 300 MG TAB

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Pt using long-term corticosteroid

## REQUIRED MEDICAL INFORMATION

1. Pt has previously failed surgery or chemotherapy to correct Cushing's disease OR is ineligible for surgery,
2. Pt with type II diabetes diagnosis,
3. If pt is female:
  - a. Pt has negative pregnancy test within past 14 days,
  - b. Pt is currently using non-hormonal form of birth control

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Endocrinologist

## COVERAGE DURATION

Initial: 6 months, Reauth: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **KOSELUGO**

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## **MEDICATION(S)**

KOSELUGO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Patient has symptomatic, inoperable plexiform neurofibromas (PN)

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **KYNMOBI**

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### **MEDICATION(S)**

APOMORPHINE HCL

**PENDING CMS APPROVAL**



## **LAMPIT**

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### **MEDICATION(S)**

LAMPIT

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of Chagas disease (*T. cruzi*)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# LENVIMA

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## 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

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Renal cell carcinoma dx: a. Will be used in combination with everolimus OR pembrolizumab 2. Thyroid cancer dx: a. Tumor is refractory to treatment with radioactive iodine, b. Used as monotherapy 3. Unresectable hepatocellular carcinoma dx: 4. Endometrial carcinoma dx: a. Will be used in combination with pembrolizumab (Keytruda) b. Does not have microsatellite instability-high or mismatch repair deficiency c. Pt has previously been treated with systemic therapy d. Pt is not a candidate for surgery or radiation

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



# LEUKINE

---

## MEDICATION(S)

LEUKINE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of:

a. To shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections and infections resulting in death following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML).

i. Pt has trial on BOTH of the following: a. Fulphila, b. Udenyca

b, For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation.

c. For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation.

d. For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation.

e. For treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation.

f. To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

**OTHER CRITERIA**

BvD Determination

**PART B PREREQUISITE**

N/A

## **LIVTENCITY**

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### **MEDICATION(S)**

LIVTENCITY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

1. Pt is on any other CMV antivirals

### **REQUIRED MEDICAL INFORMATION**

1. Pt weighs at least 35 kg or more
2. History of HSCT or SOT
3. Diagnosis of post-transplant CMV infection/disease with CMV DNA of more than 2730 IU/mL in whole blood or more than 910 IU/mL in plasma
4. CMV disease refractory to or intolerant of first line antiviral treatment (e.g., ganciclovir, valganciclovir, foscarnet, or cidofovir)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

8 weeks

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# LOKELMA

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## MEDICATION(S)

LOKELMA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Serum potassium level of 5.0 - 6.5 mmol/L on two separate screenings 2. Reauthorization: a. serum potassium of less than 5.5 mmol/L while on treatment

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial 6 months, Reauthorization Plan Year

## OTHER CRITERIA

N/A

## 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

A. Metastatic colorectal cancer 1. Pt has previous therapy on the following: a. A fluoropyrimidine, b. Oxaliplatin, c. Irinotecan, d. Bevacizumab, 2. If cancer is KRAS wild type, pt has received previous therapy with anti-EGFR therapy B. Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



# LORBRENA

---

## MEDICATION(S)

LORBRENA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

- 1) Dx of metastatic non-small cell lung cancer (NSCLC)
  - a) Tumors are anaplastic lymphoma kinase (ALK)-positive
- 2) Patient has failed/intolerance/contraindication to Alecensa

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **LUCEMYRA**

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### **MEDICATION(S)**

LUCEMYRA

**PENDING CMS APPROVAL**

## **LUMAKRAS**

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### **MEDICATION(S)**

KRAZATI, LUMAKRAS

**PENDING CMS APPROVAL**

# LUPKYNIS

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## MEDICATION(S)

LUPKYNIS

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of lupus nephritis 2. eGFR greater than 45 mL/min/1.73m<sup>2</sup>

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# LYNPARZA

---

## MEDICATION(S)

LYNPARZA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Combination therapy

## REQUIRED MEDICAL INFORMATION

1. Ovarian cancer, advanced (BRCA-mutated): a. First-line maintenance therapy for gBRCAm or sBRCAm advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in adult patients with complete or partial response to first-line platinum-based chemotherapy, OR b. First-line maintenance treatment (in combination with bevacizumab) of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults who are in complete or partial response to first-line, platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status, 2. Recurrent ovarian cancer dx: a. Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults who are in complete or partial response to platinum-based chemotherapy. 3. Breast Cancer (BRCA-mutated, HER2-negative) dx: a. For Metastatic Breast Cancer: Pt has previous trial of chemotherapy in neoadjuvant, adjuvant, or metastatic setting i. If HR positive: pt has t/f endocrine therapy or endocrine therapy is inappropriate for pt b. For High Risk Early Breast Cancer: Pt has previous trial of chemotherapy in neoadjuvant, adjuvant, or metastatic setting 4. Pancreatic cancer (BRCA-mutated): a. disease has not progressed on at least 16 weeks of a first-line, platinum-based chemotherapy regimen 5. Prostate cancer (mCRPC): a. Homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer in adults who have progressed following prior enzalutamide or abiraterone treatment b. BRCA-mutated (BRCAm) metastatic castration resistant prostate cancer (mCRPC) in combination with abiraterone and prednisone or prednisolone

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

**COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

## **LYTGOBI**

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### **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**

1. Diagnosis of metastatic cholangiocarcinoma 2. Previous treatment for metastatic cholangiocarcinoma with at least 1 line of systemic therapy 3. Fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# MAVYRET

---

## MEDICATION(S)

MAVYRET

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Confirmation of genotype

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

16 Weeks

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



# **MEKINIST**

---

## **MEDICATION(S)**

MEKINIST

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Pt is BRAF(V600E or V600K) mutation positive, 2. Monotherapy or in combination with Tafinlar 3. For Mekinist oral solution: Member has inability to swallow tablets

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **MIGRANAL**

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## **MEDICATION(S)**

DIHYDROERGOTAMINE MESYLATE 4 MG/ML SOLUTION

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Pt experiences at least 2 migraines per month,
2. Pt has trial or contraindication to at least TWO of the following:
  - a. Sumatriptan, b. Rizatriptan, c. Zolmitriptan, d. Naratriptan

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# MULPLETA

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## MEDICATION(S)

MULPLETA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Platelet count less than 50,000 2. Pt is scheduled for a procedure where there is a bleeding risk 3. Mulpleta will be used for 7 days starting 8 to 14 days prior to the procedure and discontinued 2 to 8 days prior to the procedure

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## 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

1. Pt has baseline leptin levels of less than 8 ng/mL for males OR less than 12 ng/mL for females, 2. Pt has ONE of the following: a. Diagnosis of diabetes and is being treated with Metformin AND at least one other antidiabetic agent, b. Diagnosis of hypertriglyceridemia and is being treated with at least ONE antihyperlipidemic agent, 3. Reauth: a. Pt has been screened for the presence of anti-metrelptin antibodies, b. If presence of anti-metrelptin antibodies, pt must still be receiving benefit from Myalept therapy, c. Pt shows improvement in hemoglobin A1c OR fasting triglyceride level

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months, Reauth: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **NARCOLEPSY**

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## **MEDICATION(S)**

WAKIX

## **PA INDICATION INDICATOR**

2 - Some FDA-Approved Indications Only

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Patients with severe hepatic impairment

## **REQUIRED MEDICAL INFORMATION**

1. For narcolepsy with cataplexy (please note Wakix is only covered for the narcolepsy with cataplexy indication) a. Patient has been diagnosed by a board certified sleep, pulmonology, or neurology specialist b. Patient exhibits symptoms of cataplexy 2. Reauth: a. For narcolepsy with cataplexy: i. Decrease in cataplexy episodes

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Board certified in sleep, pulmonology, or neurology

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **NERLYNX**

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### **MEDICATION(S)**

NERLYNX

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Breast cancer dx: a. Tx of early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy OR b. Tx of HER2-positive breast cancer, in combination with capecitabine, in patients who have received 2 or more prior regimens for metastatic disease

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# NEULASTA

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## MEDICATION(S)

FYLNETRA, NEULASTA, NYVEPRIA, STIMUFEND, ZIEXTENZO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of Neutropenia

a. If requesting Fylnetra, Neulasta, Nyvepria, Stimufend, or Ziextenzo, pt has trial on BOTH of the following: a. Fulphila, b. Udenyca

2. For Neulasta, Stimufend, Ziextenzo: Dx of acute hematopoietic radiation injury syndrome

a. Pt has trial of Udenyca

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

BvsD Determination

## PART B PREREQUISITE

N/A

# **NEXAVAR**

---

## **MEDICATION(S)**

SORAFENIB TOSYLATE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Used as monotherapy, 2. For HCC dx: a. Treatment for unresectable tumor or recurrent disease, 3. For Thyroid carcinoma dx: a. Tumor is refractory to treatment with iodine

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **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**

1. Dx of familial hypercholesterolemia or established atherosclerotic cardiovascular disease

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **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**

1. Dx of familial hypercholesterolemia or established atherosclerotic cardiovascular disease

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **NEXPLANON**

---

## **MEDICATION(S)**

NEXPLANON

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Use for contraception

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# NICOTROL

---

## MEDICATION(S)

NICOTROL, NICOTROL NS

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Pt has tried varenicline or bupropion OR has a contraindication to the use of varenicline or bupropion (established seizure disorder, concurrent anorexia or bulimia, concurrent use of MAOIs, etc)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **NINLARO**

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### **MEDICATION(S)**

NINLARO

### **PA INDICATION INDICATOR**

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

### **OFF LABEL USES**

Autologous Stem Cell Transplant

### **EXCLUSION CRITERIA**

1. Pt is refractory to lenalidomide or proteasome inhibitor therapy

### **REQUIRED MEDICAL INFORMATION**

1. Multiple Myeloma A. Combination with lenalidomide (Revlimid) and dexamethasone B. Pt has previous trial on at least ONE other therapy 2. Maintenance therapy after Autologous Stem Cell Transplant

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **NITROFURAN**

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## **MEDICATION(S)**

NITROFURANTOIN 25 MG/5ML SUSPENSION, NITROFURANTOIN 50 MG/10ML SUSPENSION

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Unable to swallow nitrofurantoin capsules

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **NORTHERA**

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### **MEDICATION(S)**

DROXIDOPA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Pt has previous trial on BOTH of the following: a. Midorine, b. Fludrocortisone

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

2 Weeks

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **NOXAFIL**

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## **MEDICATION(S)**

NOXAFIL 300 MG PACKET, POSACONAZOLE 100 MG TAB DR, POSACONAZOLE 40 MG/ML SUSPENSION

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. For treatment of invasive aspergillus 2. For aspergillus or candida prophylaxis: a. Pt is at high risk of developing infections secondary to being severely immunocompromised, 3. For oropharyngeal candidiasis: a. Pt has previous failure on BOTH of the following: 1) Itraconazole, 2) Fluconazole

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

6 Months

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



## **NPB INSULIN**

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### **MEDICATION(S)**

INSULIN DEGLUDEC, INSULIN DEGLUDEC FLEXTOUCH

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Is the member younger than 6 years of age? (If under 6, no further questions required) 2. Patient has failed BOTH Lantus & Toujeo or has documented intolerance to Lantus and/or Toujeo?

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **NUBEQA**

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## **MEDICATION(S)**

NUBEQA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1)Diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC)

a)Patient has PSA doubling time of less than 10 months

b)Patient has tried and failed Xtandi

2)Diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC)

a)Patient has tried and failed abiraterone 250mg AND Xtandi

b)Given in combination with docetaxel

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **NUPLAZID**

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### **MEDICATION(S)**

NUPLAZID

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Initial: a. Onset of psychosis took place after the diagnosis of Parkinson's disease, b. Pt has previous trial on treatment with clozapine or quetiapine, 2. Reauth: a. Pt experienced a decrease in psychosis related symptoms while on treatment

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 3 months, Reauth: Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# NURTEC

---

## MEDICATION(S)

NURTEC

## PA INDICATION INDICATOR

2 - Some FDA-Approved Indications Only

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. For Acute Treatment of Migraines (Please note: Nurtec is only covered for acute treatment of migraines, prophylaxis dosing is not covered): a. Patient has tried 2 generic triptan medications OR has a contraindication to the use of triptans (e.g. established cardiovascular disease or cerebrovascular disease)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **OCTREOTIDE**

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### **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**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. For acromegaly: a. Has patient failed at least TWO of the following: i. Surgical resection, ii. Pituitary irradiation, iii. Bromocriptine, b. Pt has elevated levels of growth hormone and IGF-1, 2. For carcinoid: a. Pt is suffering from severe diarrhea and flushing episodes associated with disease, 3. For VIPoma: a. Pt has profuse water diarrhea associated with disease

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan year

### **OTHER CRITERIA**

BvsD determination

### **PART B PREREQUISITE**

N/A

## **OFEV**

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### **MEDICATION(S)**

OFEV

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx: a. Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype, idiopathic pulmonary fibrosis (IPF), or scleroderma (systemic sclerosis)-associated interstitial lung disease (SSc-ILD) 2. Dx has been confirmed via high-resolution computed tomography scan and/or lung biopsy, 3. Forced Vital Capacity (FVC) greater than 40 percent predicted value 4. Carbon monoxide diffusing capacity (DLCO) greater than 30 percent predicted value 5. Liver function tests (ALT, AST, and bilirubin) completed prior to initiating therapy 6. Reauth: a. A repeat liver function test has been performed after 3 months of therapy has been completed

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 3 mo, Reauth: Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **OGSIVEO**

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## **MEDICATION(S)**

OGSIVEO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Dx of desmoid tumor/aggressive fibromatosis with documentation of tumor progression 2. Contraindication, intolerance, or failure of sorafenib

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **OJEMDA**

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### **MEDICATION(S)**

OJEMDA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

1. Patient with tumors harboring additional activating molecular alteration(s) (e.g. IDH1/2 mutations, FGFR mutations, etc) or patients with known or suspected diagnosis of neurofibromatosis type 1 (NF1)

### **REQUIRED MEDICAL INFORMATION**

1. Dx of relapsed or refractory pediatric low-grade glioma (LGG) harboring an activating BRAF alteration based on local laboratory testing
2. At least one measurable lesion as defined by RANO 2010 criteria
3. Pt has received at least one line of prior systemic therapy and had documented evidence of radiographic progression
4. Pt has contraindication, intolerance, or failure of Tafenlar and Mekinist if BRAF V600 positive

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **OJJAARA**

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### **MEDICATION(S)**

OJJAARA

**PENDING CMS APPROVAL**

## **ONFI**

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### **MEDICATION(S)**

SYMPAZAN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Pt has previous trail on at least TWO AED medications

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ONUREG**

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### **MEDICATION(S)**

ONUREG

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of one of: A. acute myeloid leukemia (AML) who achieved first complete remission (CR) B. AML in complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and the member is not able to complete intensive curative therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# ORFADIN

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## MEDICATION(S)

NITISINONE, NITYR, ORFADIN 4 MG/ML SUSPENSION

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Initial:

- a. Diagnosis of hereditary tyrosinemia type 1 confirmed by biochemical or DNA testing
- b. Pt had a baseline succinylacetone (SA) level drawn
- c. Pt had a baseline liver function testing performed
- d. For Nityr tablets: Patient has tried and failed nitisinone capsules

2. Reauthorization:

- a. There is laboratory documentation of SA suppression on treatment when compared to baseline level

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



# ORGOVYX

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## MEDICATION(S)

ORGOVYX

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Previous treatment with another GnRH/LHR agonist/antagonist

## REQUIRED MEDICAL INFORMATION

1. Dx of castrate-sensitive metastatic prostate cancer 2. Dx of metastatic disease has been confirmed by bone scan, ultrasound, CT, MRI, or biopsy 3. Serum PSA is elevated 4. Contraindication or inability to take other GNRH/LHR agonist/antagonist medication due to one of: A. Short term (6 month) use in men at risk of toxicities from standard androgen deprivation therapy (ADT) B. Intermittent ADT in frail patients at risk of ADT toxicities C. Significant underlying cardiac risk factors

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **ORIAHNN**

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### **MEDICATION(S)**

MYFEMBREE, ORIAHNN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Maximum lifetime duration 24 months

### **REQUIRED MEDICAL INFORMATION**

- 1)For Oriahnn and Myfembree: Heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
- 2)For Myfembree: Moderate to Severe Pain Associated with Endometriosis
- 3)Premenopausal
- 4)Previous use of a combination oral contraceptive
- 5)Previous use of a progestin-only contraceptive

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# ORILISSA

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## MEDICATION(S)

ORILISSA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1) previous use of combination oral contraceptive 2) previous use of progestin-only contraceptive

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year Orilissa 150 mg, maximum lifetime duration 24 months 6 months Orilissa 200 mg

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



## **ORKAMBI**

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### **MEDICATION(S)**

ORKAMBI

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Initial A. Pt genotyped by an FDA-cleared CF mutation test B. Pt has cystic fibrosis with the homozygous F508del mutation in the CTFR gene that has been confirmed by an FDA approved test, C. Pt has FEV1 between 40-90% 2. Reauth A. Pt has been reassessed since starting therapy, B. Pt's FEV1 has increased since starting therapy

### **AGE RESTRICTION**

Tablet: 6 years old or older, Granules: 1 year old to 5 years old

### **PRESCRIBER RESTRICTION**

Specialist in Cystic Fibrosis or Pulmonologist

### **COVERAGE DURATION**

Initial: 3 months Reauth: Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ORSERDU**

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### **MEDICATION(S)**

ORSERDU

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Postmenopausal female or male with a diagnosis of advanced or metastatic ER+, HER2- breast cancer 2. Confirmation of ESR1-mutated breast cancer 3. The member has experienced disease progression following at least one line of endocrine therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **OSTEOPOROSIS**

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## **MEDICATION(S)**

EVENITY, TERIPARATIDE (RECOMBINANT) 620 MCG/2.48ML SOLN PEN, TYMLOS

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

1. Duration not to exceed 24 months of cumulative treatment between all anabolic agents (Forteo, Tymlos, Evenity) unless the patient has returned to high risk or remains at high risk for fracture 2. Duration not to exceed 12 months with Evenity 3. For Evenity: Myocardial infarction or stroke in the last 12 months and Male pts

## **REQUIRED MEDICAL INFORMATION**

1. For teriparatide: Member must fail Tymlos 2. Evenity only: for females only per FDA label 3. Diagnosis of osteoporosis or osteopenia 4. At least one of the following: a. T-score worse than -3.5 b. T-score from -2.5 to -3.5 and at least one of the following: i. History of multiple or recent fragility fracture ii. T/f of oral or IV bisphosphonate or Prolia c. T-score from -1.0 to -2.5 and BOTH of the following: i. History of fragility fracture OR FRAX score of greater than 20% for major fracture or greater than 3% for hip fracture ii. T/f of oral or IV bisphosphonate or Prolia

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

BvD Determination

## **PART B PREREQUISITE**

N/A

## **PAH**

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### **MEDICATION(S)**

SILDENAFIL CITRATE 10 MG/ML RECON SUSP, SILDENAFIL CITRATE 20 MG TAB, TADALAFIL (PAH), TADLIQ

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Initial: a. Pt is diagnosed with pulmonary arterial hypertension, confirmed by right heart catheterization b. Pt with positive vasoreactivity test: i. Pt has contraindications to or failed maximum tolerated doses of calcium channel blockers, c. For Tadliq and sildenafil oral suspension requests: Inability to swallow tablets 2. Reauth: a. Pt has been reassessed within the past 6 months

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **PALYNZIQ**

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### **MEDICATION(S)**

PALYNZIQ

**PENDING CMS APPROVAL**

# PANRETIN

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## MEDICATION(S)

PANRETIN

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Systemic anti-KS therapy is required (e.g., more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement)

## REQUIRED MEDICAL INFORMATION

1. Dx of cutaneous lesions in patients with AIDS-related Kaposi's Sarcoma. 2. Reauthorization: Patient is stable on therapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months Reauth: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **PART D VS PART B**

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### **MEDICATION(S)**

ABILIFY ASIMTUFII, ABILIFY MAINTENA, ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, 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, ANZEMET 50 MG TAB, APREPITANT, ARANESP (ALBUMIN FREE) 10 MCG/0.4ML SOLN PRSYR, ARANESP (ALBUMIN FREE) 100 MCG/0.5ML SOLN PRSYR, ARANESP (ALBUMIN FREE) 100 MCG/ML SOLUTION, ARANESP (ALBUMIN FREE) 150 MCG/0.3ML SOLN PRSYR, ARANESP (ALBUMIN FREE) 200 MCG/0.4ML SOLN PRSYR, ARANESP (ALBUMIN FREE) 200 MCG/ML SOLUTION, ARANESP (ALBUMIN FREE) 25 MCG/0.42ML SOLN PRSYR, ARANESP (ALBUMIN FREE) 25 MCG/ML SOLUTION, ARANESP (ALBUMIN FREE) 300 MCG/0.6ML SOLN PRSYR, ARANESP (ALBUMIN FREE) 40 MCG/0.4ML SOLN PRSYR, ARANESP (ALBUMIN FREE) 40 MCG/ML SOLUTION, ARANESP (ALBUMIN FREE) 500 MCG/ML SOLN PRSYR, ARANESP (ALBUMIN FREE) 60 MCG/0.3ML SOLN PRSYR, ARANESP (ALBUMIN FREE) 60 MCG/ML SOLUTION, ARFORMOTEROL TARTRATE, ARISTADA, ARISTADA INITIO, ASTAGRAF XL, AZATHIOPRINE, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, 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, DEPO-TESTOSTERONE, ELIGARD 22.5 MG KIT, ELIGARD 30 MG KIT, ELIGARD 7.5 MG KIT, ENGERIX-B, ENVARSUS XR, EPOGEN, EVEROLIMUS 0.25 MG TAB, EVEROLIMUS 0.5 MG TAB, EVEROLIMUS 0.75 MG TAB, EVEROLIMUS 1 MG TAB, FIRMAGON, FIRMAGON (240 MG DOSE), FLUPHENAZINE DECANOATE, FLUPHENAZINE HCL 2.5 MG/ML SOLUTION, FORMOTEROL FUMARATE, FULPHILA, GENGRAF, GRANISETRON HCL 1 MG TAB, GRANIX, HALOPERIDOL DECANOATE, HALOPERIDOL LACTATE 5 MG/ML SOLUTION, HEPLISAV-B 20 MCG/0.5ML SOLN PRSYR, INVEGA HAFYERA, INVEGA SUSTENNA, INVEGA TRINZA, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, LEUPROLIDE ACETATE 22.5 MG INJECTABLE, LEVALBUTEROL HCL, LILETTA (52 MG), 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, METHOTREXATE SODIUM 1000 MG/40ML SOLUTION, METHOTREXATE SODIUM 50 MG/2ML SOLUTION, METHOTREXATE SODIUM (PF) 1 GM/40ML SOLUTION, METHOTREXATE SODIUM (PF) 50 MG/2ML SOLUTION, MICAFUNGIN SODIUM, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG TAB,



MYCOPHENOLATE SODIUM, MYCOPHENOLIC ACID, NIVESTYM 300 MCG/0.5ML SOLN PRSYR, NIVESTYM 480 MCG/0.8ML SOLN PRSYR, OLANZAPINE 10 MG RECON SOLN, ONDANSETRON 4 MG TAB DISP, ONDANSETRON 8 MG TAB DISP, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 4 MG/5ML SOLUTION, ONDANSETRON HCL 8 MG TAB, PENTAMIDINE ISETHIONATE, PERSERIS, PREHEVBRIO, PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PROLIA, PULMOZYME, RECOMBIVAX HB, RETACRIT, RISPERIDONE MICROSPHERES ER, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TAB, SODIUM CHLORIDE 0.9 % SOLUTION, STREPTOMYCIN SULFATE, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TRELSTAR MIXJECT, TWINRIX, UDENYCA, UZEDY, VARUBI (180 MG DOSE), ZIPRASIDONE MESYLATE, ZYPREXA RELPREVV 210 MG RECON SUSP

### **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.

## **PCSK**

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### **MEDICATION(S)**

REPATHA, REPATHA PUSHTRONEX SYSTEM, REPATHA SURECLICK

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Did the patient fail to achieve LDL-C goal after two separate trials of maximally tolerated statins OR one high-intensity statin (atorvastatin 40-80 mg or rosuvastatin) OR has documented intolerance (e.g. rhabdomyolysis) to statin therapy? 2. ONE of the following: A. Dx of HoFH , untreated LDL-C greater than 500mg/dL or treated LDL-C greater than 300mg/dL i. AND cutaneous or tendon xanthoma before age 10 years, OR ii. Elevated LDL-C levels consistent with heterozygous FH in both parents B. Dx of HeFH or primary hyperlipidemia with fasting LDL-C of 190 mg/dL or greater on at least two separate dates at least 3 months apart i. AND LDL-C remains greater than 100 mg/dL despite treatment on medication therapy C. Dx of ASCVD consisting of MI, stroke, TIA, persistent intermittent claudication, coronary intervention revascularization or angina with proven ischemia i. AND LDL-C remains greater than 70 mg/dL despite treatment on medication therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

# PEMAZYRE

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## MEDICATION(S)

PEMAZYRE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Previously treated, unresectable locally advanced or metastatic cholangiocarcinoma A. Fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test
2. Relapsed or refractory myeloid/lymphoid neoplasms i. Fibroblast growth factor receptor 1 (FGFR1) rearrangement as detected by an FDA-approved test

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **PHENOXYBENZAMINE**

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### **MEDICATION(S)**

METYROSINE, PHENOXYBENZAMINE HCL

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Phenoxybenzamine will be used for short-term treatment of hypertension prior to surgical removal of a pheochromocytoma 2. For metyrosine, pt has failed phenoxybenzamine

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 mo

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **PIQRAY**

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### **MEDICATION(S)**

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

**PENDING CMS APPROVAL**

# POMALYST

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## MEDICATION(S)

POMALYST

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Multiple myeloma dx: a. Pt has tried BOTH of the following: i. Revlimid, ii. Velcade, b. Pt has demonstrated disease progression within 60 days of completion of prior therapy 2. Kaposi sarcoma dx: a. Experienced failure of highly active antiretroviral therapy (HAART) in patient with AIDS b. HIV-negative

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **PRETOMANID**

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## **MEDICATION(S)**

PRETOMANID

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of tuberculosis 2. Used as part of an appropriate treatment regimen (e.g. bedaquiline and linezolid)

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

6 months

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



# PREVYMIS

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## MEDICATION(S)

PREVYMIS 240 MG TAB, PREVYMIS 480 MG TAB

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Pt has Child-Pugh class C hepatic impairment

## REQUIRED MEDICAL INFORMATION

1. For: CMV prophylaxis in HSCT recipients a. Pt is post allogenic hematopoietic stem cell transplant within the last 28 days b. Pt is a CMV-seropositive recipient [R+] 2. For: CMV prophylaxis in kidney transplant recipients a. Pt is post kidney transplant within last 7 days b. Pt is high risk (Donor CMV seropositive/Recipient CMV seronegative) 3. Medication will be discontinued on or before 200 days post-transplantation

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

200 days

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# PROMACTA

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## MEDICATION(S)

PROMACTA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. For ITP dx: a. Previous failure to corticosteroids, immunoglobulins, OR splenectomy, b. Initial: Evidence of bleeding OR platelet count less than 50,000/microL, c. For Reauth: Platelet count less than 400,000/microL, 2. For Hep C with Thrombocytopenia dx: a. Platelet count less than 75,000/microL, 3. For aplastic anemia dx: a. Pt has an insufficient response to immunosuppressive therapy b. In combination with immunosuppressive therapy for severe aplastic anemia

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

6 Months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# PURIXAN

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## MEDICATION(S)

PURIXAN

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Used in conjunction with a combination chemotherapy treatment regimen for ALL, 2. Pt has previous failure on mercaptopurine tablets

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **PYRUKYND**

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## **MEDICATION(S)**

PYRUKYND, PYRUKYND TAPER PACK

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Homozygous R479H mutation or 2 non-missense mutations, without the presence of another missense mutation, in the PKLR gene

## **REQUIRED MEDICAL INFORMATION**

1. Documented pyruvate kinase deficiency (PKD), presence of at least 2 mutant alleles in PKLR gene, of which at least 1 is a missense mutation 2. 6 or more transfusions in the last 12 months A. If 5 or fewer transfusions, Hb concentration less than or equal to 10.0 g/dL

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **QINLOCK**

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## **MEDICATION(S)**

QINLOCK

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of advanced GIST 2. Prior treatment with 3 or more kinase inhibitors, including imatinib

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# QULIPTA

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## MEDICATION(S)

QULIPTA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of Episodic Migraine (4-14 migraine days per month) or Chronic Migraine (greater than 14 migraine days per month) 2. Member has trial on prophylactic therapy on at least TWO of the following: A. Anti-Epileptic (ie topiramate, valproic acid) B. Beta-blocker (ie atenolol, bisoprolol, metoprolol, nadolol, nebivolol, pindolol, propranolol, timolol) C. Anti-depressant (ie amitriptyline, nortriptyline, venlafaxine) Reauthorization Criteria: 1. Patient has had a reduction in the number of migraine days per month

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: Plan Year Reauthorization: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# RCC

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## **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, TORPENZ

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

For renal angiomyolipoma, requires immediate surgery

## **REQUIRED MEDICAL INFORMATION**

1. For RCC dx: a. Previous failure on either sunitinib or Nexavar, 2. For SEGA or TS dx: a. Patient must require therapeutic intervention and not be a candidate for surgical resection 3. Diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) or with well-differentiated, nonfunctional neuroendocrine tumors (NET) of gastrointestinal (GI), or lung origin which are unresectable, locally advanced or metastatic 4. Diagnosed with renal angiomyolipoma with tuberous sclerosis complex with at least one angiomyolipoma greater than or equal to 3cm where there is not an immediate need for surgery 5. Hormone receptor positive HER2-negative breast cancer a. Previous use of one of letrozole or anastrozole b. Use in combination with one of exemastane, tamoxifen, or fulvestrant

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A



# RETEVMO

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## MEDICATION(S)

RETEVMO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Diagnosis of: a. Metastatic RET fusion-positive non-small cell lung cancer (NSCLC) b. Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in patients who require systemic therapy c. Advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and refractory to radioactive iodine, if appropriate 2. Identification of a RET gene alteration using next generation sequencing (NGS), polymerase chain reaction (PCR), or fluorescence in situ hybridization (FISH)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months Reauth: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## REVCIVI

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### MEDICATION(S)

REVCIVI

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

1. Diagnosis of adenosine deaminase deficiency (ADA) with Severe Combined Immunodeficiency (SCID) phenotype confirmed by one of the following: A. Deficiency of adenosine deaminase (ADA) in plasma, lysed erythrocytes, fibroblasts (cultured from amniotic fluid), or chorionic villus (less than 1% of normal) B. Increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates compared to laboratory standard C. Decrease in ATP concentration in erythrocytes D. Molecular genetic confirmation of mutations in both alleles of the ADA1 gene E. Positive screening by T cell receptor excision circles (TRECs) 2. Not a candidate for or has failed bone marrow transplantation (BMT) 3. Platelets greater than 50,000cell/microL 4. Reauthorization A. The patient has experienced improvement in their plasma ADA activity, red blood cell dATP levels, immune function, and/or red blood cell dAXP levels

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Plan year

### OTHER CRITERIA

N/A

**PART B PREREQUISITE**

N/A

## **REVLIMID**

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### **MEDICATION(S)**

LLENALIDOMIDE, REVLIMID

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. For Multiple Myeloma dx: a. Used in combination with dexamethasone, OR b. As maintenance following autologous hematopoietic stem cell transplantation (auto HSCT) 2. For MCL: a. Pt has previous trial on bortezomib AND pt has trial on at least ONE other previous therapy 3. For transfusion-dependent anemia due to myelodysplastic syndrome a. Low or imediate-1-risk myelodysplastic syndrome (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities 4. For follicular lymphoma and Marginal zone lymphoma (MZL) a. Used in combination with a rituximab product

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# REXULTI

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## MEDICATION(S)

REXULTI

## 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

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# REYVOW

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## MEDICATION(S)

REYVOW

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Patient has tried 2 generic triptan medications OR has a contraindication to the use of triptans (e.g. established cardiovascular disease or cerebrovascular disease)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **REZDIFFRA**

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### **MEDICATION(S)**

REZDIFFRA

**PENDING CMS APPROVAL**

## **REZLIDHIA**

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### **MEDICATION(S)**

REZLIDHIA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of relapsed or refractory AML 2. Confirmed IDH-1 mutation

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



# REZUROCK

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## MEDICATION(S)

REZUROCK

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial Authorization 1. Dx of chronic graft-versus-host disease (chronic GVHD) a. Failure of two previous lines of systemic therapy 2. For BID dosing in the setting of a PPI: a. Member must try a 30-day trial of one of the following alternative GERD treatment modalities: i. antacids ii. H2RA (ranitidine, famotidine, etc) b. Member must have not responded to daily dosing of Rezerock following at least 30 days of therapy Reauthorization 3. Documentation of stable or improved disease

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# ROZLYTREK

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## MEDICATION(S)

ROZLYTREK

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Diagnosis of non-small cell lung cancer A. Has reactive oxygen species 1 positive 2. Diagnosis of Neurotrophic receptor tyrosine kinase-positive solid tumors A. Tumor is metastatic or surgical resection likely to result in severe morbidity B. Progression following previous treatment or there is not an adequate alternative treatment 3. For the oral pellets: patient has inability to swallow capsules and solution made from capsules.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **RUBRACA**

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### **MEDICATION(S)**

RUBRACA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of recurrent ovarian cancer a. Complete or partial response to platinum-based chemotherapy 2. Rubraca will be used as monotherapy 3. Dx of mCRPC that has deleterious BRCA mutation a. Previous treatment with androgen receptor-directed therapy and a taxane-based chemotherapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **RYDAPT**

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## **MEDICATION(S)**

RYDAPT

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

1. Used for post-consolidation therapy (maintenance) for dx of AML

## **REQUIRED MEDICAL INFORMATION**

1. For AML dx: a. Cancer is FLT3 mutation positive 2. Dx of systemic mastocytosis a. Systemic mastocytosis is identified as aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# SABRIL

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## MEDICATION(S)

VIGABATRIN, VIGADRONE 500 MG PACKET, VIGAFYDE, VIGPODER

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. For solution:

a. For infantile spasms:

i. Must be used as monotherapy

b. For refractory complex partial seizures

i. Pt has inability to swallow tablets

ii. Must be used as adjunctive therapy,

iii. Must have tried at least TWO of the following:

a. Rufinamide, b. Carbamazepine, c. Celontin, d. Dilantin, e. Divalproex, f. Epitol, g. Equetro, h. Ethosuximide, i. Felbamate, j. Tiagabine, k. Lamictal, l. Lamotrigine, m. Levetiracetam, n. Pregabalin, o. Primidone, p. Oxcarbazepine, q. Phenytoin, r. Topiramate, s. Valproic Acid, t. Lacosamide, u. Zonisamide

2. For tablets:

a. Must be used as adjunctive therapy,

b. Must have tried at least TWO of the following:

i. Rufinamide, ii. Carbamazepine, iii. Celontin, iv. Dilantin, v. Divalproex, vi. Epitol, vii. Equetro, viii. Ethosuximide, ix. Felbamate, x. Tiagabine, xi. Lamictal, xii. Lamotrigine, xiii. Levetiracetam, xiv. Pregabalin, xv. Primidone, xvi. Oxcarbazepine, xvii. Phenytoin, xviii. Topiramate, xix. Valproic Acid, xx. Lacosamide, xxi. Zonisamide

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

**COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

1. Periodic vision testing

**PART B PREREQUISITE**

N/A

# **SCEMBLIX**

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## **MEDICATION(S)**

SCEMBLIX

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) 2. Trial and failure of at least 2 TKIs 3. For T315I mutation: Documentation of testing for mutation a. Must try and fail ponatinib

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **SIGNIFOR**

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### **MEDICATION(S)**

SIGNIFOR

**PENDING CMS APPROVAL**



# **SIRTURO**

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## **MEDICATION(S)**

SIRTURO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Pt has previous failure on at least TWO of the following: a. Ethambutol, b. Streptomycin, c. Pyrazinamide, d. Amikacin/kanamycin, e. Cycloserine/terizidone, f. Ethionamide, g. Capreomycin, h. Levofloxacin, i. Moxifloxacin, j. Ofloxacin

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

6 Months

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# SOHONOS

---

## **MEDICATION(S)**

SOHONOS

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Dx of fibrodysplasia ossificans progressiva (FOP) confirmed by genetic testing (documentation must be submitted)

## **AGE RESTRICTION**

Females age 8 years or older and Males age 10 years or older

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **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

1. Pt has had surgical resection of the pituitary gland OR is not a candidate for surgery/radiation therapy, 2. Patient has tried at least ONE of the following: a. Bromocriptine, b. Cabergoline, c. Octreotide acetate 3. Patient has tried sandostatin LAR, somatuline depot, or lanreotide

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **SPRYCEL**

---

## **MEDICATION(S)**

SPRYCEL

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of CML or ALL

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **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

Combination therapy with another biologc medication, JAK inhibitor, or Otezla

## REQUIRED MEDICAL INFORMATION

1. Crohn's disease dx 2. Ulcerative Colitis dx 3. Plaque Psoriasis dx: Pt has previous failure with at least ONE of the following: a. methotrexate, b. cyclosporine, c. acitretin 4. Psoriatic arthritis dx: Pt has previous failure with at least ONE of the following: a. methotrexate, b. leflunomide, c. hydroxychloroquine, d. sulfasalazine, e. injectable gold, f. oral gold, g. azathioprine, h. D-penicillamine, i. cyclosporine

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# STIVARGA

---

## MEDICATION(S)

STIVARGA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx metastatic colorectal cancer, 2. Dx gastrointestinal stromal tumor, 3. Dx hepatocellular carcinoma

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## 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

1. Dx is confirmed by a Small Bowel Biopsy Disaccharidase Measurement demonstrating 2 SD or more below mean for sucrase activity with or without isomaltase activity

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# SUTENT

---

## MEDICATION(S)

SUNITINIB MALATE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Sutent used as combination therapy with other chemotherapies

## REQUIRED MEDICAL INFORMATION

1. For GIST dx: a. Disease progression or intolerance to imatinib, 2. For pNET dx: a. Tumor is unresectable locally advanced or metastatic

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan 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

Pt has previous trial on leuprolide acetate

## AGE RESTRICTION

1. For CPP: Treatment initiated at or before 8 years of age in girls and 9 years of age in boys 2. For Endometriosis: 18 years old or older

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **SYPRINE**

---

## **MEDICATION(S)**

TRIENTINE HCL

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Pt has failure on penicillamine,

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# TABRECTA

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## MEDICATION(S)

TABRECTA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of metastatic non-small cell lung cancer (NSCLC) 2. Tumor mutation leading to mesenchymal-epithelial transition (MET) exon 14 skipping

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# TADALAFIL

---

## **MEDICATION(S)**

TADALAFIL 5 MG TAB

## **PA INDICATION INDICATOR**

2 - Some FDA-Approved Indications Only

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Dx of Benign Prostatic Hypertrophy (BPH)

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# TAFINLAR

---

## MEDICATION(S)

TAFINLAR

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1)For unresectable or metastatic melanoma dx:

a)Pt is BRAF (V600E or V600K) mutation positive

2)For adjuvant treatment of melanoma dx:

a)Pt is BRAF (V600E or V600K) mutation positive

b)Pt has failed Opdivo AND Keytruda

3)For metastatic NSCLC dx:

a)Pt is BRAF V600E positive

4)For Locally Advanced or Metastatic Anaplastic Thyroid Cancer dx:

a)Pt is BRAF V600E positive with no satisfactory locoregional treatment options

5)For Unresectable or Metastatic Solid Tumors dx:

a)Pt is BRAF V600E positive and has progressed following prior treatment and have no satisfactory alternative treatment options

6)For Low-Grade Glioma dx"

a)Pt is BRAF V600E mutation positive and requires systemic therapy

b)Pt has failed Zelboraf (with or without Cotellic)

7)For Tafinlar tablets for oral suspension: Member has inability to swallow capsules

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

**COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

YES

## **TAGRISSO**

---

### **MEDICATION(S)**

TAGRISSO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Pt is positive for EGFR T790M mutation, a. Pt has previous therapy after EGFR TKI therapy 2. Epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# TALTZ

---

## **MEDICATION(S)**

TALTZ 80 MG/ML SOLN A-INJ, TALTZ 80 MG/ML SOLN PRSYR

## **PA INDICATION INDICATOR**

2 - Some FDA-Approved Indications Only

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Combination therapy with another biologic medication, JAK inhibitor, or Otezla

## **REQUIRED MEDICAL INFORMATION**

1. Dx of Ankylosing Spondylitis (Please note, Taltz is not covered for indications other than Ankylosing spondylitis)
2. Member has tried adalimumab and Renflexis

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

YES



# TALZENNA

---

## MEDICATION(S)

TALZENNA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of HRR Gene-mutated mCRPC, in combination with enzalutamide (Xtandi) 2. Deleterious or suspected deleterious germline BRCA, HER2-negative locally advanced or metastatic breast cancer

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# TARCEVA

---

## MEDICATION(S)

ERLOTINIB HCL

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. For NSCLC dx: a. Pt with EGFR mutation, b. Erlotinib is not used in combination with platinum-based chemotherapy, 2. For pancreatic cancer dx: a. Combination with gemcitabine

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# TARGRETIN

---

## MEDICATION(S)

BEXAROTENE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. If female: Pt planning to become pregnant

## REQUIRED MEDICAL INFORMATION

1. Capsules: a. Pt has previous failure on at least ONE of the following: i. Antineoplastic chemotherapy, ii. Interferon alfa and gamma, iii. Interleuking-12, iv. Interleukin-2, 2. Gel: a. Pt has previous failure on at least ONE of the following: i. PUVA, ii. UVB, iii. EVT, iv. Photophoresis, v. Systemic cytotoxic chemotherapy, vi. Topical nitrogen mustard, vii. Topical carmustine

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# TARPEYO

---

## MEDICATION(S)

FILSPARI, TARPEYO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Currently receiving dialysis or has undergone kidney transplant

## REQUIRED MEDICAL INFORMATION

1. Dx of biopsy verified primary immunoglobulin A (IgA) nephropathy
2. Proteinuria defined as a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g
3. Failure of at least a 3-month trial on SGLT2
4. For Tarpeyo: Failure of three months of Filspari

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

For Tarpeyo: 9 months, no reauthorization

For Filspari: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# TASIGNA

---

## MEDICATION(S)

TASIGNA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

For Ph+ CML Dx: Pts who have BCR-ABL1 mutations T315I, Y253H, E255K/V, F359V/C/I, or G250E

## REQUIRED MEDICAL INFORMATION

1. Adult or pediatric with newly diagnosed Philadelphia chromosome positive (Ph+) CML in chronic phase  
2. Adult with chronic phase and accelerated phase Ph+ CML a. Resistant or intolerant to imatinib  
3. Pediatric patient with chronic phase or accelerated phase Ph+ CML a. Resistant or intolerant to prior TKI therapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# TAVALISSE

---

## MEDICATION(S)

TAVALISSE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Initial: a. Pt has previous trial on previous therapy of at least ONE of the following: i. Corticosteroids ii. Immunoglobulins iii. Splenectomy iv. Thrombopoietin Receptor Agonist b. Platelet count is less than 50000/microl 2. Reauth: a. Platelet count is greater than 50000/microl

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 3 Months Reauth: Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# TAVNEOS

---

## MEDICATION(S)

TAVNEOS

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Patient currently requires dialysis

## REQUIRED MEDICAL INFORMATION

Initial: 1. Diagnosis of ANCA-associated vasculitis 2. ANCA-antibody titer test 3. BVAS score (1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria) 4. Patient is currently receiving rituximab or cyclophosphamide Reauth: 1. Patient has experienced improvement in BVAS score

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months Reauth: Plan Year

## OTHER CRITERIA

N/A

## 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

1. Dx: Metastatic or locally advanced epithelioid sarcoma a. Diagnosis confirmed by pathology b. SMARCB1/INI1 deficient tumor c. Tumor is not eligible for complete resection 2. Dx: Follicular lymphoma a. Relapsed or refractory tumor i. positive for EZH2 mutation ii. Previous use of at least 2 prior systemic therapies b. No satisfactory alternative treatment options available

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



## **TEGSEDI**

---

### **MEDICATION(S)**

TEGSEDI

**PENDING CMS APPROVAL**

# TEPMETKO

---

## MEDICATION(S)

TEPMETKO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Diagnosis of metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **TIBSOVO**

---

### **MEDICATION(S)**

TIBSOVO

**PENDING CMS APPROVAL**

# TOLCAPONE

---

## MEDICATION(S)

TOLCAPONE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. The member is currently receiving carbidopa/levodopa therapy
2. Member is experiencing `off episodes that requires adjunctive therapy and has failed at least two of the following: Entacapone, Ongentys, Dopamine agonist (pramipexole, ropinirole, etc), MAO B inhibitor (rasagiline, selegiline)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# TRUQAP

---

## MEDICATION(S)

TRUQAP 160 MG TAB, TRUQAP 200 MG TAB

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. diabetes mellitus type 1, type 2, requiring insulin treatment or HbA1c greater than or equal to 8%

## REQUIRED MEDICAL INFORMATION

1. Dx of HR-positive, HER2-negative, locally advanced or metastatic breast cancer
2. Patient has PIK3CA/AKT1/PTEN-alterations.
  - A. If PIK3CA, patient must have failed Piqray
3. Patient has failed at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy
4. Truqap will be used in combination with fulvestrant

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## 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

1. For RAS wild-type unresectable or metastatic HER2-positive breast cancer
  - a. Used in combination with trastuzumab and capecitabine
2. For unresectable or metastatic colorectal cancer
  - a. Used in combination with trastuzumab
  - b. Following treatment with fluoropyrimidine, oxaliplatin, and irinotecan based chemotherapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **TURALIO**

---

## **MEDICATION(S)**

TURALIO 125 MG CAP

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

- A. Diagnosis of Tenosynovial Giant Cell Tumor
- B. Condition is associated with severe morbidity or functional limitations
- C. Surgery will NOT improve status

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **TYENNE**

---

### **MEDICATION(S)**

TYENNE 162 MG/0.9ML SOLN A-INJ, TYENNE 162 MG/0.9ML SOLN PRSYR

**PENDING CMS APPROVAL**



## **TYKERB**

---

### **MEDICATION(S)**

LAPATINIB DITOSYLATE

**PENDING CMS APPROVAL**

# UBRELVY

---

## MEDICATION(S)

UBRELVY

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Patient has tried 2 generic triptan medications OR has a contraindication to the use of triptans (e.g. established cardiovascular disease or cerebrovascular disease)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# VALCHLOR

---

## MEDICATION(S)

VALCHLOR

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Pt has previous trial on at least ONE previous skin directed therapy of the following:
  - a. Topical corticosteroid, b. Topical carmustine, c. Topical retinoid, d. Radiation therapy, e. Phototherapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## 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

1. Newly diagnosed acute myeloid leukemia that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA approved test.
2. Will be taken in combination with standard cytarabine and anthracycline induction, cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **VAXCHORA**

---

### **MEDICATION(S)**

VAXCHORA

**PENDING CMS APPROVAL**

## **VELTASSA**

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### **MEDICATION(S)**

VELTASSA 16.8 GM PACKET, VELTASSA 25.2 GM PACKET, VELTASSA 8.4 GM PACKET

**PENDING CMS APPROVAL**

# VEMLIDY

---

## MEDICATION(S)

VEMLIDY

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Pt has decompensated hepatic impairment

## REQUIRED MEDICAL INFORMATION

Pt has previous trial on entecavir

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# VENCLEXTA

---

## **MEDICATION(S)**

VENCLEXTA, VENCLEXTA STARTING PACK

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. For CLL/SLL dx
2. For AML dx: a. Pt is ineligible for induction therapy OR b. Pt is 75 years or older

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



# VERQUVO

---

## MEDICATION(S)

VERQUVO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Pregnancy

## REQUIRED MEDICAL INFORMATION

1. Dx of chronic heart failure

A. New York Heart Association class II-IV

B. Left ventricular ejection fraction less than 45%

2. Previous hospitalization due to heart failure within the last 6 months or outpatient IV diuretic treatment within the last 3 months

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## 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

1. Dx of Early HR-positive, HER-2 negative, node positive breast cancer at high risk of recurrence
  - a. Will be used in combination with tamoxifen or aromatase inhibitor
2. Dx of Advanced or Metastatic breast cancer: Must meet a, b, OR c of the following:
  - a. Pt is receiving Verzenio in combination with an aromatase inhibitor
  - b. Pt has received prior endocrine therapy AND Verzenio will be given in combination with fulvestrant,
  - c. Pt has experienced disease progression following endocrine therapy and prior chemotherapy in the metastatic setting AND Verzenio will be used as monotherapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **VIJOICE**

---

### **MEDICATION(S)**

VIJOICE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Confirmed/documented diagnosis of PIK3CA Related Overgrowth Spectrum (PROS)
  - a. Patient has mutation in the PIK3CA gene.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# VITRAKVI

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## MEDICATION(S)

VITRAKVI

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. solid tumor with a NTRK gene fusion
2. Metastatic or unable to have surgery
3. Received previous treatment

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **VIVJOA**

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### **MEDICATION(S)**

VIVJOA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Hx of recurrent vulvovaginal candidiasis, defined as at least 3 acute episodes in the last 12 months
2. Patient must be one of the following:
  - A. Post-menopausal
  - B. Not of reproductive potential (i.e. tubal ligation, hysterectomy, etc)
3. Patient has experienced a recurrence during or following 6 months of oral fluconazole maintenance therapy

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

14 weeks

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# VIZIMPRO

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## MEDICATION(S)

VIZIMPRO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1) First line therapy 2) EGFR exon 19 deletion or EFGR exon 21 L858R substitution

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

**VONJO**

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**MEDICATION(S)**

VONJO

**PENDING CMS APPROVAL**

# VOSEVI

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## MEDICATION(S)

VOSEVI

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Confirmation of genotype

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 Weeks

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



# VOTRIENT

---

## **MEDICATION(S)**

PAZOPANIB HCL

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Soft Tissue Sarcoma dx:
  - a. Previous trial on at least ONE prior therapy
2. Advanced renal cell carcinoma dx

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **VOXZOGO**

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### **MEDICATION(S)**

VOXZOGO

**PENDING CMS APPROVAL**

# VYNDAQEL

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## MEDICATION(S)

VYNDAMAX, VYNDAQEL

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Use in combination with Onpattro or Tegsedi

## REQUIRED MEDICAL INFORMATION

I. For cardiomyopathy of hereditary transthyretin-mediated amyloidosis (ATTR-CM)

A. Applicable mutation to the transthyretin (TTR) gene (e.g., Val122Ile, Thr60Ala, or Ile68Leu)

B. Clinical manifestations of amyloid fibrosis in the myocardium (e.g., AV bundle branch block, restrictive cardiomyopathy and heart failure with preserved ejection fraction [HFpEF])

II. For cardiomyopathy of wild type transthyretin-mediated amyloidosis (ATTR-CM)

B. Negative for monoclonal protein in blood or urine (evaluated by serum free light chains and serum protein electrophoresis with urine immunofixation)

C. Absence of monoclonal proteins has the patient undergone nuclear scintigraphy diagnosis OR presence of monoclonal proteins has the patient undergone tissue biopsy to rule out light chain cardiac amyloidosis

D. Clinical manifestations of amyloid fibrosis in the myocardium (e.g., AV bundle branch block, restrictive cardiomyopathy and heart failure with preserved ejection fraction [HFpEF])

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

**PART B PREREQUISITE**

N/A

## **WEGOVY**

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### **MEDICATION(S)**

WEGOVY

**PENDING CMS APPROVAL**

## **WELIREG**

---

### **MEDICATION(S)**

WELIREG

**PENDING CMS APPROVAL**

# WINREVAIR

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## MEDICATION(S)

WINREVAIR

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Diagnosis of pulmonary arterial hypertension WHO Groups 2, 3, 4, or 5
2. Diagnosis of the following PAH Group 1 subtypes: human immunodeficiency virus (HIV)-associated PAH and PAH associated with portal hypertension. Exclusions in PAH group 1 should also include schistosomiasis associated PAH and pulmonary veno-occlusive disease

## REQUIRED MEDICAL INFORMATION

1. Dx of pulmonary arterial hypertension (PAH), classified as WHO functional class (FC) II or III
2. Documented diagnostic right heart catheterization confirming the diagnosis of World Health Organization (WHO) pulmonary arterial hypertension (PAH) Group1 in any of the following subtypes:
  - a. Idiopathic PAH
  - b. Heritable PAH
  - c. Drug/Toxin-induced PAH
  - d. PAH associated with connective tissue disorder
  - e. PAH associated with simple, congenital tissue disease
3. Patient has undergone vasoreactivity testing and failed maximum tolerated doses of calcium channel blockers (if applicable)
4. Pulmonary capillary wedge pressure (PCWP) or left ventricular end-diastolic pressure of less than or equal to 15 mmHg
5. Patients current therapy consists of 3 background PAH medications including:
  - a. PDE-5 inhibitor (tadalafil, sildenafil), plus endothelin receptor antagonist (ambrisentan, bosentan, Opsumit), and a prostacyclin agonist (treprostinil or epoprostenol, or selexipag)
6. Patient has a documented intolerance or disease progression on a three-drug regimen

## AGE RESTRICTION

18 years of age or older

**PRESCRIBER RESTRICTION**

Pulmonologist or Cardiologist

**COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A



**XALKORI**

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**MEDICATION(S)**

XALKORI

**PENDING CMS APPROVAL**

**XDEMZY**

---

**MEDICATION(S)**

XDEMZY

**PENDING CMS APPROVAL**

# **XELJANZ**

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## **MEDICATION(S)**

XELJANZ, XELJANZ XR

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

1. Combination therapy with another biologic medication, JAK inhibitor, or Otezla

## **REQUIRED MEDICAL INFORMATION**

1. Dx of RA, JIA, PsA: Pt has failed at least three months therapy on at least ONE of the following:
  - a. methotrexate, b. leflunomide, c. hydroxychloroquine, d. sulfasalazine, OR contraindication to use (Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease, Pregnancy, breastfeeding, or currently planning pregnancy, Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia), Elevated liver transaminases, Hypersensitivity, or history of intolerance or adverse event, Interstitial pneumonitis or clinically significant pulmonary fibrosis, Myelodysplasia, Renal impairment
2. Dx of RA, JIA, PsA, UC, AS: Pt has failed a TNF inhibitor

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



## **XENAZINE**

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### **MEDICATION(S)**

TETRABENAZINE

**PENDING CMS APPROVAL**

# **XERMELO**

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## **MEDICATION(S)**

XERMELO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Initial:

- a. Pt has more than 4 bowel movements a day despite treatment with sandostatin analog therapy for at least 3 months
- b. Pt has previous trial of lomotil AND loperamide
- c. Xermelo will be used in combination with sandostatin analog

2. Reauth:

- a. Pt has experienced improvement in bowel movement frequency since starting Xermelo

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

6 Months

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **XGEVA**

---

## **MEDICATION(S)**

XGEVA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Must meet at least ONE of the following:

- a. Pt has giant cell tumor of the bone that is unresectable or where surgical resection is likely to result in severe morbidity,
- b. Pt has a diagnosis of bone metastases related to a solid tumor,
- c. Pt has a diagnosis of metastatic breast or prostate cancer,
- d. Pt has previously been treated with Zometa and had disease progression OR adverse reaction to the treatment

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

BvsD determination

## **PART B PREREQUISITE**

YES

## **XHANCE**

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### **MEDICATION(S)**

XHANCE

**PENDING CMS APPROVAL**



# **XIFAXAN**

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## **MEDICATION(S)**

XIFAXAN

## **PA INDICATION INDICATOR**

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

## **OFF LABEL USES**

1. Clostridium difficile infection

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of:

- a. Clostridium difficile (C. diff.) infection
- b. Hepatic encephalopathy (HE)
- c. Irritable bowel syndrome (IBS)
- d. Traveler's diarrhea

2. Diagnosis of Hepatic encephalopathy (HE)

- a. Previous failure on or has intolerance to lactulose therapy

3. Diagnosis of Irritable bowel syndrome (IBS)

- a. Previous failure of at least TWO antispasmodic or antibiotic treatments (e.g., amoxicillin-clavulanate, cephalexin, ciprofloxacin, dicyclomine, doxycycline, gentamicin, metronidazole, neomycin, trimethoprim-sulfamethoxazole)

4. Diagnosis of Clostridium difficile (C. diff) infection

- a. Patient has experienced relapse after prior use of oral vancomycin

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

## **XOLAIR**

---

### **MEDICATION(S)**

XOLAIR

**PENDING CMS APPROVAL**

# **XOSPATA**

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## **MEDICATION(S)**

XOSPATA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Relapsed or refractory AML
2. patient has a FLT3 mutation detected by an FDA-approved test

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# XPOVIO

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## 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

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of relapsed or refractory multiple myeloma
  - a. Previous use of at least one prior therapies
2. Dx of diffuse large B-cell lymphoma
  - a. Previous use of at least two lines of systemic therapy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## 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**

- 1) Diagnosis of non-metastatic castration sensitive prostate cancer (nmCSPC)
  - a) Patient has failed androgen deprivation therapy (ADT) with one of the following: orchiectomy, LHRH agonist (leuprolide, Lupron, Zoladex), LHRH antagonist (Firmagon)
- 2) Diagnosis of metastatic castration-sensitive prostate cancer (mCSPC)
  - a) Patient has failed ADT and abiraterone 250mg
- 3) Diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC)
  - a) Patient has PSA doubling time of less than 10 months

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# ZARXIO

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## **MEDICATION(S)**

NEUPOGEN, RELEUKO 300 MCG/0.5ML SOLN PRSYR, RELEUKO 480 MCG/0.8ML SOLN PRSYR, ZARXIO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1)Dx of Neutropenia

2)If requesting Neupogen, Releuko or Zarxio, pt has trial on BOTH of the following: a. Nivestym, b. Granix

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **ZEJULA**

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## **MEDICATION(S)**

ZEJULA 100 MG TAB, ZEJULA 200 MG TAB, ZEJULA 300 MG TAB

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer
  - a. Complete or partial response to first-line platinum-based chemotherapy
2. Deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
  - a. Complete or partial response to platinum-based chemotherapy

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



# ZELAPAR

---

## MEDICATION(S)

ZELAPAR

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Pt diagnosed with Parkinson's
2. Pt is treated with carbidopa/levodopa and will continue to be treated with carbidopa/levodopa in combination with Zelapar
3. Pt has failed generic selegiline

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# ZELBORAF

---

## MEDICATION(S)

COTELLIC, ZELBORAF

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. For Metastatic Melanoma dx:
  - a. Pt is BRAF V600E positive for Zelboraf monotherapy OR
  - b. BRAF V600E or V600K positive for Zelboraf plus Cotellic
2. For Erdheim-Chester Disease:
  - a. Zelboraf monotherapy
  - b. Pt is BRAF V600 positive

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## 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

1. Pt has progressive, persistent, or recurrent disease,
2. Pt has tried at least TWO prior systemic therapies

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Plan Year

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

# ZONISADE

---

## MEDICATION(S)

ZONISADE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of partial-onset seizures
2. Inability to swallow tablets and capsules

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## 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

1. Confirmation of CDKL5 deficiency based on genetic testing
2. Trial and failure of at least two previous antiepileptic therapies

### AGE RESTRICTION

2 years of age or older

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Plan year

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

# ZURZUVAE

---

## MEDICATION(S)

ZURZUVAE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of moderate to severe PPD
2. Major Depressive episode began in third trimester of pregnancy or within 4 weeks following delivery
3. Treatment will be initiated less than or equal to 12 months after delivery
4. Maximum duration 14 days per pregnancy

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 month

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## ZYDELIG

---

### MEDICATION(S)

ZYDELIG

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

1. CLL dx:

a. Used in combination with rituximab

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Plan Year

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

# ZYKADIA

---

## MEDICATION(S)

ZYKADIA 150 MG TAB

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive
2. Patient has failed/intolerance/contraindication to Alecensa

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A