

## **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

### **PREREQUISITE THERAPY REQUIRED**

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

## PREREQUISITE THERAPY REQUIRED

YES

# 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

## AGE RESTRICTION

N/A

## PREScriBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

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

## **PREREQUISITE THERAPY REQUIRED**

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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **ANTIPSYCHOTIC**

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## **MEDICATION(S)**

CAPLYTA, COBENFY, COBENFY STARTER PACK, FANAPT, FANAPT TITRATION PACK A, LYBALVI, OPIPZA, 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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **APO B**

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### **MEDICATION(S)**

JUXTAPID

### **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

**PREREQUISITE THERAPY REQUIRED**

YES

# AQNEURSA

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## MEDICATION(S)

AQNEURSA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Use in combination with Miplyffa

## REQUIRED MEDICAL INFORMATION

1. Pt has tried and failed at least 3 months of therapy with miglustat as evidenced by a lack of improvement in disease progression (e.g. horizontal saccadic eye movements, SARA scale, R4DNPCCSS score) 2. Pt weighs greater than or equal to 15kg 3. Dx is genetically confirmed (deoxyribonucleic acid [DNA] sequence analysis) by mutations in both alleles of NPC1 or NPC2 OR if there is a mutation in only one allele of NPC1 or NPC2, pt has positive filipin staining or elevated cholestanetriol/oxysterols (greater than 2x upper limit of normal) 4. Pt is presenting with at least one neurological symptom of the disease (for example, but not limited to, hearing loss, vertical supranuclear gaze palsy, ataxia, dementia, dystonia, seizures, dysarthria, or dysphagia) 5. Pt is able to walk either independently or with assistance 6. Pt has a SARA score of greater than or equal to 7 and less than or equal to 34 points (out of 40) AND one of the following: A. Within in 2-7 range (0-8 range) of the Gait subtest of the SARA scale B. Be able to perform the 9-Hole Peg Test with Dominant Hand ((HPT-D) (SCAFI subtest) in greater than or equal to 20 to less than or equal to 150 seconds 7. Reauthorization A. fSARA score has remained stable/improved

## AGE RESTRICTION

N/A

## PREScriBER RESTRICTION

Neurologist

## COVERAGE DURATION

6 months

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# 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

## PREREQUISITE THERAPY REQUIRED

N/A

## **ATOPIC DERM**

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### **MEDICATION(S)**

ADBRY, CIBINQO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Used in combination with another biologic (e.g., Dupixent, Xolair, Humira, Entyvio, and Otezla, etc.)

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of moderate to severe atopic dermatitis (AD)
  - A. Greater than or equal to 10 percent body surface area coverage
  - B. Failure of two of the following:
    - i. Topical corticosteroid (e.g., fluocinonide, clobetasol, etc.)
    - ii. Topical calcineurin inhibitor (eg. tacrolimus ointment 0.1%)
    - iii. Phototherapy
    - iv. Oral immunomodulator (azathioprine, cyclosporine, or mycophenolate)
    - v. Topical PDE-4 (Eucrisa)
2. For reauthorization of Adbry
  - A. a) For patients less than 100kg who achieved clear or almost clear skin, every 4 week dosing has been tried

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# AUGTYRO

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## MEDICATION(S)

AUGTYRO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) or NTRK gene fusion-positive solid tumors
2. Contraindication, intolerance, or failure of Rozlytrek

## AGE RESTRICTION

N/A

## PREScriBER RESTRICTION

N/A

## COVERAGE DURATION

Plan year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# 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

## PREREQUISITE THERAPY REQUIRED

N/A

# AVMAPKI FAKZYNJA

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## MEDICATION(S)

AVMAPKI FAKZYNJA CO-PACK

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Diagnosis of recurrent KRAS-mutated, recurrent low-grade serous ovarian cancer
2. Prior therapy including platinum-based therapy
3. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
4. Patient has been treated with Mekinist or documented medical rationale has been provided explaining why it would be inappropriate treatment for the patient
5. For reauthorization, documentation showing patient does not have disease progression (defined as a greater than or equal to 20% increase in the sum of the diameters of target lesions, as per RECIST version 1.1 criteria)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

6 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **BALVERSA**

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### **MEDICATION(S)**

BALVERSA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of locally advanced or metastatic urothelial carcinoma 2. Confirmed fibroblast growth factor receptor (FGFR3) genetic alteration 3. Progression on or after at least one line of prior systemic therapy

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **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 has current active disease, 3. Pt has previous treatment with at least TWO of the following: a. Corticosteroids, b. Antimalarials, c. Immunosuppressives, 4. 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**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **BRAFTOVI**

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## **MEDICATION(S)**

BRAFTOVI, 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 binimatinib [Mektovi] 2. For encorafenib [Braftovi], dx of BRAF V600E mutation-positive metastatic colorectal cancer a. Will be used as combination therapy with cetuximab [Erbitux] 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 binimatinib [Mektovi]

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **BRONCHITOL**

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## **MEDICATION(S)**

BRONCHITOL, BRONCHITOL TOLERANCE TEST

## **PENDING CMS APPROVAL**

# **BRUKINSA**

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## **MEDICATION(S)**

BRUKINSA 160 MG TAB

## **PENDING CMS APPROVAL**

# **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**

1. Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) 2. Started inpatient in combination with plasma exchange B.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

3 months

## **OTHER CRITERIA**

Max Duration of therapy 58 days following last day of plasma exchange

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

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
4. Dx of previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET) a. Pt has failed everolimus or sunitinib
5. Dx of previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors (epNET)

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **CALQUENCE**

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### **MEDICATION(S)**

CALQUENCE 100 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 mantle cell lymphoma
  - a. Member has been previously treated:
    - i. Pt has been treated with at least one prior therapy
  - b. Member has NOT been previously treated AND are ineligible for autologous hematopoietic stem cell transplantation (HSCT):
    - i. Calquence will be used in combination with bendamustine and rituximab
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

**PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

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 caglumic 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

## **PREREQUISITE THERAPY REQUIRED**

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

### **PREREQUISITE THERAPY REQUIRED**

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

## **PREREQUISITE THERAPY REQUIRED**

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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **CRESEMBA**

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## **MEDICATION(S)**

CRESEMBA 186 MG CAP, CRESEMBA 74.5 MG CAP

## **PA INDICATION INDICATOR**

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

## **OFF LABEL USES**

Prophylaxis for Invasive fungal infection, Hematological malignancy and hemopoietic stem cell transplantation

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Pt has confirmed fungal infection with one of the following:
  - a. Invasive aspergillosis
  - b. Invasive mucormycosis
2. OR, Cresembo is being used for prophylaxis against invasive fungal infections in the setting of hematological malignancy or hematopoietic cell transplant
  - a. When used for prophylaxis, ONE of the following must be met:
    - i. Patient has tried and failed a generic antifungal (fluconazole, posaconazole, voriconazole), OR
    - ii. Patient has a contraindication to other antifungals due to QTc prolongation or drug-drug interactions

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Infectious disease specialist

## **COVERAGE DURATION**

6 months

## **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

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

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **CYSTIC FIBROSIS**

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### **MEDICATION(S)**

CAYSTON, TOBRAMYCIN 300 MG/5ML NEBU SOLN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Pt has had at least ONE positive culture for Pseudomonas aeruginosa 2. If request not for generic tobramycin: Previous trial on generic tobramycin

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

BvsD determination for tobramycin only, no BvD for Cayston

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **DANZITEN**

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### **MEDICATION(S)**

DANZITEN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of: a. newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase b. chronic phase (CP) and accelerated phase (AP) Ph+ CML i. Documented resistance, intolerance, or contraindication to imatinib (Gleevec)

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

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

### **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

YES

## **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**

BvD determination

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# 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.)
2. Drug-induced bullous pemphigoid

## REQUIRED MEDICAL INFORMATION

1. Dx of corticosteroid-dependent asthma (Please note, Dupixent is only covered for corticosteroid-dependent asthma, chronic obstructive pulmonary disease, prurigo nodularis, bullous pemphigoid, and chronic spontaneous urticaria) A. Dx of corticosteroid-dependent asthma evidenced by members requirement of at least 3 months of chronic oral corticosteroids B. 3 month failure of at least TWO of the following: i. ICS + SABA ii. ICS/LABA iii. Spiriva or Trelegy iv. LTRA C. Two provider/ER/Hospital admissions for asthma exacerbations within the last 12 months
2. Dx of prurigo nodularis (PN) A. Pt has a PP-NRS score of 7 or more B. Pt has a history of failing a 2-week course of topical corticosteroids, OR clinical presentation precludes trial of corticosteroids
3. Dx of Chronic Obstructive Pulmonary Disease (COPD) A. Diagnosis confirmed by post-bronchodilator FEV1/FVC less than 0.7 on spirometry B. Blood eosinophil count (BEC) greater than or equal to 300 cells/mcL within last 3 months C. Chronic bronchitis, defined as chronic productive cough for greater than or equal to 3 months in the past year, in absence of other known causes of chronic cough D. 2 ER/hospital admissions for COPD exacerbations within the last year despite at least 3 months treatment with inhaled LABA + LAMA + ICS triple therapy (or LABA + LAMA if ICS is contraindicated)
4. Dx of classic bullous pemphigoid (BP) confirmed with biopsy A. Bullous pemphigoid area index (BPDA) activity score greater than or equal to 24 B. Trial and failure of two of the following: i. methotrexate, azathioprine, mycopheno0late, doxycycline C. Dupixent will be initiated in combination with oral corticosteroids which will be tapered after achieving control of disease activity, OR the patient has contraindication to oral corticosteroids
5. Dx of chronic spontaneous urticaria A. Pt has previous failure on an H-1 antagonist (e.g., cetirizine, hydroxyzine) B. cont in "Other Criteria"

## AGE RESTRICTION

For PN and BP: 18 years of age or older

### **PREScriber RESTRICTION**

For corticosteroid dependent asthma: pulmonologist or allergist For COPD: pulmonologist For PN and CSU: dermatologist, allergist, or immunologist For BP: Dermatologist

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

5. B. Pt is NOT a candidate for treatment with Xolair C. Pt has NOT had a previous inadequate response to Xolair. Please note, Dupixent is not covered for patients with CSU with previous inadequate response to Xolair

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **ENBREL**

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### **MEDICATION(S)**

ENBREL 25 MG/0.5ML SOLN PRSYR, ENBREL 25 MG/0.5ML SOLUTION, ENBREL 50 MG/ML SOLN PRSYR, ENBREL MINI, ENBREL SURECLICK

### **PA INDICATION INDICATOR**

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 pediatric PsO or PsA

a. Member is 6 years of age or older:

i. Member has tried and failed ustekinumab (ie. Pyzchiva or Selarsdi)

b. Member is under 6 years of age: No additional criteria required

2. Dx of AS, RA, JIA, adult PsA, or adult PsO

A. Member has tried and failed TWO of the following: adalimumab (ie Amjevita or Hadlima), infliximab (ie renflexis), or ustekinumab (ie. Pyzchiva or Selarsdi)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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. Pt has tried and failed Uplizna or rituximab

4. Reauthorization: A. Patient is continuing to receive benefit from treatment

5. Chart notes required

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: Plan year Reauth: Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

YES

**PREREQUISITE THERAPY REQUIRED**

YES

## **ENTYVIO SQ**

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### **MEDICATION(S)**

ENTYVIO PEN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of:
  - a. moderate to severe Crohn's disease
  - b. moderate to severe Ulcerative Colitis (UC)
2. For SQ, is patient established on Entyvio IV and changing to Entyvio SQ

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Gastroenterologist

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

YES

### **PREREQUISITE THERAPY REQUIRED**

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

### **PREREQUISITE THERAPY REQUIRED**

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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# ERLEADA

---

## MEDICATION(S)

ERLEADA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1) Diagnosis of metastatic castration sensitive prostate cancer (mCSPC) a) Patient has tried and failed abiraterone 250mg tablets AND Xtandi 2) Diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) a) Patient has PSA doubling time of less than 10 months b) Patient has failed Xtandi

## AGE RESTRICTION

N/A

## PREScriBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

## **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. Member has:

a. Forced Vital Capacity (FVC) greater than 40 percent predicted value AND carbon monoxide diffusing capacity (DLCO) greater than 30 percent predicted value OR

b. patient meets one of the following:

i. pursuing lung transplantation OR

ii. patient is being managed by a pulmonary specialist with a background in interstitial lung disease

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: 6 months, Reauth: Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

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

### **PREREQUISITE THERAPY REQUIRED**

YES

## **EULEXIN**

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### **MEDICATION(S)**

EULEXIN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

1. Severe hepatic impairment

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of:
  - a. Locally confined Stage B2-C carcinoma of the prostate
  - b. Stage D2 metastatic carcinoma of the prostate
2. Will be used in combination with LHRH-agonist

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **EVENITY**

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### **MEDICATION(S)**

EVENITY

### **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. Myocardial infarction or stroke in the last 12 months

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of osteoporosis or osteopenia
2. 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 denosumab
  - 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 denosumab

**AGE RESTRICTION**

N/A

**PREScriBER RESTRICTION**

N/A

**COVERAGE DURATION**

Plan year

**OTHER CRITERIA**

BvD Determination

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# 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

## PREREQUISITE THERAPY REQUIRED

YES

# FASENRA

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## MEDICATION(S)

FASENRA, FASENRA PEN

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Concurrent therapy with another biologic medication

## REQUIRED MEDICAL INFORMATION

1. Dx of Severe Asthma

a. Patient has tried at least 3 months on any of the following combinations:

- i. ICS/LABA
- ii. ICS/LTRA
- iii. ICS/LAMA
- iv. ICS/LABA/LAMA (Trelegy)

b. Two exacerbations requiring the use of oral corticosteroids in the previous 12 months OR one exacerbation that led to a hospitalization in the previous 12 months

c. Peripheral blood eosinophil level greater than 150 cells/mcL

2. Dx of eosinophilic granulomatosis with polyangiitis (EGPA)

a. Patient must have TWO of the following disease characteristics

i. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation

- ii. Neuropathy
- iii. Pulmonary infiltrates, non-fixed
- iv. Sino-nasal abnormality

v. Cardiomyopathy (established by echocardiography or MRI)

vi. Glomerulonephritis (hematuria, red cell casts, proteinuria)

vii. Alveolar hemorrhage

viii. Palpable purpura

ix. Anti-neutrophil cytoplasmic anti-body (ANCA) positive

c. Patient has a history of eosinophil level greater than 100 cells/mcL or blood eosinophil level

greater than 10%

d. Patient has a history of relapse or refractory disease despite current use of oral glucocorticoids unless contraindicated or not tolerated

#### **AGE RESTRICTION**

N/A

#### **PREScriber RESTRICTION**

For EGPA: allergist, immunologist, rheumatologist, or pulmonologist

#### **COVERAGE DURATION**

Plan Year

#### **OTHER CRITERIA**

BvsD Determination

#### **PART B PREREQUISITE**

N/A

#### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **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

**PREREQUISITE THERAPY REQUIRED**

YES

## **FILSUEZ**

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### **MEDICATION(S)**

FILSUEZ

### **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 or wound care specialist

### **COVERAGE DURATION**

Initial: 6 months Reauth: Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **FIRAZYR**

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## **MEDICATION(S)**

ICATIBANT ACETATE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. For HAE type I and II and acquired angioedema:

a. Dx has been verified by low C1-INH and/or low C1-INH function levels

2. For HAE with normal C1-INH:

a. Pt has a history of recurrent angioedema in the absence of urticaria and no use of medications known to cause angioedema

b. The pt has documented normal or near normal C4, C1-INH antigen, and C1-INH function

c. The patient has ONE of the following:

i. documentation showing a mutation associated with the disease OR

ii. a positive family history of recurrent angioedema and documented lack of efficacy of high-dose antihistamine therapy for at least 1 month or an interval expected to be associated with 3 or more attacks of angioedema (whichever is longer)

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

**COVERAGE DURATION**

1. Initial: 6 months, 2. Reauth: Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **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: 6 months Reauthorization: Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

YES

## **GATTEX**

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### **MEDICATION(S)**

GATTEX

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of short bowel syndrome
2. The patient is currently receiving parenteral nutrition/intravenous fluids at least 3 days per week
3. Dosing within FDA-approved dosage
3. Member has documented treatment failure, intolerance, or contraindication to octreotide therapy (octreotide treatment failure defined as lack of reduction in stool output within the first 4 weeks of treatment)
4. For adults, patient has had a colonoscopy in the last year and has had polyps removed if identified
5. For pediatric patients, a fecal occult blood test was performed and there was no new or unexplained blood in the stool OR a colonoscopy/sigmoidoscopy and upper GI endoscopy was performed if new or unexplained blood was identified in a fecal occult blood test
6. Reauthorization: Member has documented reduction in parenteral nutrition or intravenous support

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

Gastroenterologist

### **COVERAGE DURATION**

6 months

### **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **GAVRETO**

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### **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-smallcell 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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# GILOTRIF

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## 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

## PREREQUISITE THERAPY REQUIRED

YES

# **GLEOSTINE**

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## **MEDICATION(S)**

LOMUSTINE

## **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **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)

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **GOMEKLI**

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### **MEDICATION(S)**

GOMEKLI

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

1. Previous treatment with prior MEK inhibitor

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of documented NF1 mutation or diagnosis of NF1 using NIH Consensus Conference criteria inclusive of presence of a plexiform neurofibromas (PN)
2. The PN is inoperable- defined as a PN that cannot be completely surgically removed without risk for substantial morbidity due to encasement of or close proximity to vital structures, invasiveness, or high vascularity of the PN
3. Intolerance, contraindication or documentation explaining why treatment with Koselugo is inappropriate.
4. Reauthorization: Patient must not have centrally confirmed radiographic disease progression

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

6 months

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **GROWTH HORMONE**

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### **MEDICATION(S)**

GENOTROPIN, GENOTROPIN MINIQUICK, OMNITROPE

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

1. All medically accepted indications not otherwise excluded from Part D

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1)Adult Growth Hormone Deficiency a)Patient has failed two of the following stimulation tests:  
i)Arginine, Clonidine, Glucagon, Insulin, Levodopa, Gonadotropin ii)OR patient has at least two other pituitary hormone deficiencies in addition to low insulin-like growth factor 1 measurement below the age appropriate level (e.g. below 2.5th percentile or Z-score less than -2 iii)OR the patient has already been established on growth hormone at a pediatric age (under 18) 2)Pediatric growth hormone deficiency (Ped GHD) or idiopathic short stature (ISS) 3)Chronic Renal Insufficiency: a)Meet ALL of the following: i)Pt dxed with CRI AND has not yet received renal transplant, ii)Existing metabolic disorders have been corrected, iii)Ht more than 2 SD below the population mean OR less than 3rd percentile, iv)Height velocity less than 4cm/yr or less than 10th percentile of normal for age and gender, 4)Turner Syndrome: a)Meet ALL of the following: i)Dx of TS confirmed by blood karotype or fibroblast studies, ii)Ht of female pt plotted on TS-specific growth curve AND pt is less than 5th percentile of normal growth curve for girls, 5)Prader-Willi Syndrome: a)Meet ALL of the following: i)Dx of PWS confirmed by appropriate genetic testing, ii)Ht more than 2 SD below the pop mean OR less than 3rd percentile, iii)Ht velocity less than 3cm/yr or less than 10th percentile of normal for age and gender, 6)Small for Gestational Age: a)Meet ALL of the following: i)Dx of SGA as defined as one of the following: (1)Birth weight of less than 2,500g at gestational age of greater than 37 weeks, (2)OR birth weight or length less than 3rd percentile for gestational age, ii)Pt has failed to catch up in ht by 2 yo,

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

7)AIDS-Related Wasting: a)Meet ALL of the following: i)Involuntary weight loss of more than 5% pre-illness body weight or a BMI less than 20, ii) Chronic diarrhea (defined as more than 3 loose stools/day for more than 30 days) OR Chronic weakness and documented fever (30 days, intermittent or constant) in the absence of concurrent illness or condition other than HIV infection that would otherwise explain the symptoms.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# HAEGARDA

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## MEDICATION(S)

HAEGARDA, ORLADEYO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

### 1. Initial

#### a. For HAE type I and II and acquired angioedema:

i. Dx has been verified by low C1-INH and/or low C1-INH function levels

ii. The patient has a history of facial, laryngeal, and/or gastrointestinal HAE attacks

#### b. For HAE with normal C1-INH:

i. Pt has a history of recurrent angioedema in the absence of urticaria and no use of medications known to cause angioedema

ii. The pt has documented normal or near normal C4, C1-INH antigen, and C1-INH function

iii. The patient has ONE of the following: documentation showing a mutation associated with the disease OR a positive family history of recurrent angioedema and documented lack of efficacy of high-dose antihistamine therapy for at least 1 month or an interval expected to be associated with 3 or more attacks of angioedema (whichever is longer)

iv. The patient has a history of facial, laryngeal, and/or gastrointestinal HAE attacks

2. Reauthorization:

- a. Pt has had a decrease in frequency, severity, and/or duration of attacks.

**AGE RESTRICTION**

N/A

**PREScriber RESTRICTION**

N/A

**COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# **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

**PREREQUISITE THERAPY REQUIRED**

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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **HERNEXEOS**

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### **MEDICATION(S)**

HERNEXEOS

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations as detected by an FDA-approved test
2. Patient has tried and failed prior systemic therapy that included platinum-based chemotherapy
3. For reauthorization:
  - A. Lack of disease progression/unacceptable toxicity

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

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, AMJEVITA-PED 15KG TO <30KG 20 MG/0.2ML SOLN PRSYR, 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, CD, or PsA 2. Dx of RA or JIA 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

**PREREQUISITE THERAPY REQUIRED**

YES

# 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

## PREREQUISITE THERAPY REQUIRED

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
2. Dx of endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer
  - a. Ibrance used following recurrence on or after completing adjuvant endocrine therapy
    - i. used in combination with inavolisib and fulvestrant

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **IBTROZI**

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### **MEDICATION(S)**

IBTROZI

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

1. Patients with interstitial fibrosis or interstitial lung disease
2. Ongoing cardiac dysrhythmias of NCI CTCAE (v5.0) Grade greater than or equal to 2, uncontrolled atrial fibrillation of any grade, or QTc interval greater than 470 microsec
3. Patients taking strong CYP3A inhibitors (ie. atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, troleandomycin, voriconazole)
4. Patients taking strong CYP3A4 inducers (i.e. carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, and St John's Wort)
5. Patient taking strong CYP3A4 substrates with narrow therapeutic indices (i.e. dihydroergotamine, ergotamine, pimozide, astemizole, cisapride, and terfenadine)
6. Patient is taking any medication that is known to induce QTc prolongation

### **REQUIRED MEDICAL INFORMATION**

1. Patient has locally advanced or metastatic NSCLC
2. Patient has documented ROS1+ fusion
3. Patient has Eastern Cooperative Oncology Group Performance Status of 0–1
4. Patient has documented failure/contraindication of Rozlytrek

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **ICLUSIG**

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### **MEDICATION(S)**

ICLUSIG

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Chronic Phase CML dx a. Resistance or intolerance to at least two prior kinase inhibitors. 2. Accelerated or Blast phase CML OR Ph+ ALL a. No other TKI is indicated 3. T315I-positive CML or T315I-positive ALL 4. Newly diagnosed Ph+ ALL

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **IDHIFA**

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### **MEDICATION(S)**

IDHIFA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Cancer has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by a FDA-approved test,
2. Pt has relapsed or is refractory to one or more prior anticancer regimens

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **IMKELDI**

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### **MEDICATION(S)**

IMKELDI

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Pt is unable to swallow tablets

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

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

### **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **INLURIYO**

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### **MEDICATION(S)**

INLURIYO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of advanced or metastatic ER+, HER2- breast cancer
2. Confirmation of ESR1-mutated breast cancer
3. The patient 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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# 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

## PREREQUISITE THERAPY REQUIRED

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

N/A

## REQUIRED MEDICAL INFORMATION

A. Diagnosis of intermediate or high-risk primary or secondary myelofibrosis B. Platelet count greater than or equal to 50x10<sup>9</sup>/L

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# IRESSA

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## 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

## PREREQUISITE THERAPY REQUIRED

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 Endogenous hypercortisolemia in adults with Cushing's Syndrome 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. Trial and failure, intolerance, or contraindication, to two of the following: Signifor, cabergoline, or ketoconazole) 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

**PREREQUISITE THERAPY REQUIRED**

YES

# ITOVEBI

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## MEDICATION(S)

ITOVEBI

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Disease progression on or following other PI3k inhibitors

## REQUIRED MEDICAL INFORMATION

1. Pt must have advanced or metastatic HR-positive, HER2-negative breast cancer with documented PIK3CA mutation via specified testing
2. Pt must have disease progression following at least one line of endocrine therapy in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy
3. Itovebi will be given in combination with Ibrance (palbociclib) and fulvestrant 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

## PREREQUISITE THERAPY REQUIRED

YES

# IVIG

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## MEDICATION(S)

BIVIGAM, GAMMAGARD 1 GM/10ML SOLUTION, GAMMAGARD 2.5 GM/25ML SOLUTION, GAMMAGARD 20 GM/200ML SOLUTION, GAMMAGARD 30 GM/300ML SOLUTION, 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

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# IWILFIN

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## 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

## PREREQUISITE THERAPY REQUIRED

YES

# 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

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. For blood transfusion dx: a. Pt's serum ferritin is greater than 1000 mcg/L, b. Pt has failed subcutaneous deferoxamine through an inability to achieve desired goals of therapy or been intolerant to therapy, 2. For non-transfusion-dependent thalassemia dx: a. Pt's liver iron concentration is at least 5 mg Fe per gram of dry weight, b. Pt's serum ferritin is greater than 300 mcg/L, c. Pt has failed subcutaneous deferoxamine through an inability to achieve desired goals of therapy or been intolerant to therapy

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

Part B before Part D step therapy

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **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-polychythemia vera myleofibrosis, 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 50X10(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

**PREREQUISITE THERAPY REQUIRED**

YES

# **JAYPIRCA**

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## **MEDICATION(S)**

JAYPIRCA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of relapsed/refractory MCL    a. Previous treatment with at least two lines of systemic therapy, including a BTK inhibitor
2. Diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)    a. Previous treatment with at least two prior lines of therapy including a BTK inhibitor and a BCL-2 inhibitor

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **JYNARQUE**

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### **MEDICATION(S)**

TOLVAPTAN 15 MG TAB THPK, TOLVAPTAN 30 & 15 MG TAB THPK, TOLVAPTAN 45 & 15 MG TAB THPK, TOLVAPTAN 60 & 30 MG TAB THPK, TOLVAPTAN 90 & 30 MG TAB THPK

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

eGFR less than 25ml/min

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of autosomal dominant polycystic kidney disease   a) Diagnosis has been confirmed by radiology

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

Endocrinologist, nephrologist, cardiologist and hepatologist.

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **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: 6 months Reauth: Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

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
2. Diagnosis of HF with documented LVEF greater than or equal to 40%
  - 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

**PREREQUISITE THERAPY REQUIRED**

YES

# **KEVEYIS**

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## **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, electromyography, 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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **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)

## **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, must meet ONE of the following: a. Pt will receive an aromatase inhibitor in combination with Kisqali as initial endocrine based therapy for advanced or metastatic disease, b. Pt will receive fulvestrant in combination with Kisqali 2. Dx of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II or stage III early breast cancer at high risk of recurrence a. Pt will receive an aromatase inhibitor in combination with Kisqali

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# **KORLYM**

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## **MEDICATION(S)**

MIFEPRISTONE 300 MG TAB

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

PENDING CMS APPROVAL

## **EXCLUSION CRITERIA**

PENDING CMS APPROVAL

## **REQUIRED MEDICAL INFORMATION**

PENDING CMS APPROVAL

## **AGE RESTRICTION**

PENDING CMS APPROVAL

## **PREScriBER RESTRICTION**

PENDING CMS APPROVAL

## **COVERAGE DURATION**

PENDING CMS APPROVAL

## **OTHER CRITERIA**

PENDING CMS APPROVAL

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# KOSELUGO

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## MEDICATION(S)

KOSELUGO 10 MG CAP, KOSELUGO 25 MG CAP

## 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

## PREREQUISITE THERAPY REQUIRED

N/A

## **KYNMOBI**

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### **MEDICATION(S)**

APOMORPHINE HCL

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of Parkinson's disease A. Experiencing off episodes 2. Currently taking an oral formulation of carbidopa/levodopa or there is documentation of an inability to take an oral formulation of carbidopa/levodopa 3. Previous use of an immediate release or oral disintegrating carbidopa/levodopa as a rescue for off episodes 4. Previous use of at least one of: a. COMT inhibitor (tolcapone, entacapone), b. Dopamine agonist (ropinirole, pramipexole), c. MAO-B inhibitor (selegiline, rasagiline, safinamide) 5. Prescribed in combination with antiemetic therapy (Not a 5HT3)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **LAZCLUZE**

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### **MEDICATION(S)**

LAZCLUZE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

1. Prior systemic treatment for locally advanced Stage III or metastatic Stage IV disease
2. Symptomatic or previously treated unstable brain metastases

### **REQUIRED MEDICAL INFORMATION**

1. Initial A. Patient must have confirmed NSCLC that is metastatic or unresectable with EGFR exon 19 deletions or 21 L858R substitution mutations. B. Patient must receive anticoagulant prophylaxis to prevent VTE events for the first 4 months of treatment. C. Patients must have an ECOG of 0 or 1 D. Clinical rational why Tagrisso with /without chemotherapy is not appropriate for use in the patient.
2. Reauthorization A. Tumor assessment does not show new growth, activity or mutations

### **AGE RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

6 months

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **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

**PREREQUISITE THERAPY REQUIRED**

YES

# **LEUKERAN**

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## **MEDICATION(S)**

LEUKERAN

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of:
  - a. chronic lymphatic (lymphocytic) leukemia
  - b. malignant lymphomas including lymphosarcoma,
  - c. giant follicular lymphoma
  - d. Hodgkins disease

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **LEUKINE**

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## **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

**PREREQUISITE THERAPY REQUIRED**

YES

## **LIVTENCITY**

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### **MEDICATION(S)**

LIVTENCITY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

1. Combination use with valganciclovir or ganciclovir

### **REQUIRED MEDICAL INFORMATION**

1. Pt weighs at least 35 kg or more 2. History of hematopoietic stem cell transplant (HSCT) or solid organ transplant (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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **LUCEMYRA**

---

### **MEDICATION(S)**

LOFEXIDINE HCL

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Mitigation of opioid withdrawal symptoms
2. Provider submitted documentation that the patient has been counseled on the risks of taking lofexidine with alcohol, benzodiazepines, and/or barbituates
3. Patient has failed clonidine as part of this opioid discontinuation attempt

### **AGE RESTRICTION**

18 years of age or older

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

14 Days

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# LUMAKRAS

---

## MEDICATION(S)

KRAZATI, LUMAKRAS

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Previous KRAS G12C-targeted therapy (other than current)
  - a. Krazati and Lumakras have similar mechanisms of action and it is not recommended to switch between agents upon progression

## REQUIRED MEDICAL INFORMATION

1. Lumakras:
  - a. Diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC)
    - i. At least one prior systemic therapy
  - b. Diagnosis of KRAS G12C-mutated Metastatic Colorectal Cancer (mCRC)
    - i. Received prior treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy
    - ii. Used in combination with panitumumab
3. Krazati:
  - a. Diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC)
    - i. At least one prior systemic therapy
  - b. Diagnosis of KRAS G12C-mutated locally advanced or metastatic colorectal cancer (CRC)
    - i. Received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
    - ii. Used in combination with cetuximab

## 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

**PREREQUISITE THERAPY REQUIRED**

YES

# **LUPKYNIS**

---

## **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

## **PREREQUISITE THERAPY REQUIRED**

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

**PREREQUISITE THERAPY REQUIRED**

YES

# LYTGOBI

---

## MEDICATION(S)

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

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

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

## PREREQUISITE THERAPY REQUIRED

YES

# MAVYRET

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## 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

## PREREQUISITE THERAPY REQUIRED

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. Will be used as monotherapy for:

a. Dx of unresectable or metastatic melanoma with BRAF V600E or V600K mutations in BRAF-inhibitor treatment-naïve patients

2. Will be used in combination with dabrafenib for:

a. Dx of unresectable or metastatic melanoma with BRAF V600E or V600K mutations

b. The adjuvant treatment of patients with dx of melanoma with BRAF V600E or V600K mutations and involvement of lymph node(s), following complete resection.

c. Dx of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation

d. Dx of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.

e. Dx of unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

f. Dx of low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

3. For 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

**PREREQUISITE THERAPY REQUIRED**

N/A

# **MIGRANAL**

---

## **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **MODEYSO**

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### **MEDICATION(S)**

MODEYSO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of diffuse midline glioma
2. Confirmation of H3 K27M mutation via tumor tissue-based testing performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory using immunohistochemistry (IHC) or DNA sequencing
3. Patient has had disease progression after a trial and failure of previous therapy
4. Chart notes required with current body weight documented

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **MULPLETA**

---

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **MYALEPT**

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### **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-metreleptin antibodies, b. If presence of anti-metreleptin 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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **NARCOLEPSY**

---

## **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

# NERLYNX

---

## MEDICATION(S)

NERLYNX

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

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

## PREREQUISITE THERAPY REQUIRED

YES

# **NEULASTA**

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## **MEDICATION(S)**

FYLNTRA, 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 Fylnetra, 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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **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. Dx of Unresectable hepatocellular carcinoma
2. Dx of Advanced renal cell carcinoma
3. Dx of Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) refractory to radioactive iodine treatment

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **NEXLETOL**

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### **MEDICATION(S)**

NEXLETOL

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. The patient has one of the following:
  - a. A diagnosis of familial hypercholesterolemia
  - b. Established atherosclerotic cardiovascular disease (ASCVD)
  - c. The patient is considered high risk for cardiovascular disease without established ASCVD and meets the following:
    - i. Has documented intolerance to statin therapy
    - ii. Has failed to achieve an LDL-C goal of less than 55 mg/dL after two separate trials of maximally tolerated statins OR one high-intensity statin
  - d. The patient has primary hyperlipidemia and meets the following:
    - i. Has documented intolerance to statin therapy
    - ii. Has failed to achieve an LDL-C goal of less than 70 mg/dL after two separate trials of maximally tolerated statins OR one high-intensity statin

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **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. The patient has one of the following:
  - a. A diagnosis of familial hypercholesterolemia
  - b. Established atherosclerotic cardiovascular disease (ASCVD)
  - c. The patient is considered high risk for cardiovascular disease without established ASCVD and meets the following:
    - i. Has documented intolerance to statin therapy
    - ii. Has failed to achieve an LDL-C goal of less than 55 mg/dL after two separate trials of maximally tolerated statins OR one high-intensity statin
  - d. The patient has primary hyperlipidemia and meets the following:
    - i. Has documented intolerance to statin therapy
    - ii. Has failed to achieve an LDL-C goal of less than 70 mg/dL after two separate trials of maximally tolerated statins OR one high-intensity statin

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **NICOTROL**

---

### **MEDICATION(S)**

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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **NINLARO**

---

## **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

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

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**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **NOXAFIL**

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## **MEDICATION(S)**

NOXAFIL 300 MG PACKET

## **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **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 either as monotherapy or 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

### **PREREQUISITE THERAPY REQUIRED**

YES

## **NUPLAZID**

---

### **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: 6 months, Reauth: Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **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, 2. Dx of metastatic carcinoid tumors: c. Dx of vasoactive intestinal peptide secreting tumors (VIPoma)

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

BvsD determination

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **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
- b. idiopathic pulmonary fibrosis (IPF)
- c. 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. Member has:

- a. Forced Vital Capacity (FVC) greater than 40 percent predicted value AND carbon monoxide diffusing capacity (DLCO) greater than 30 percent predicted value OR
- b. patient meets one of the following:
  - i. pursuing lung transplantation or
  - ii. patient is being managed by a pulmonary specialist with background in interstitial lung disease

4. Liver function tests (ALT, AST, and bilirubin) completed prior to initiating therapy

5. 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: 6 months, Reauth: Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

## **OGSIVEO**

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### **MEDICATION(S)**

OGSIVEO 100 MG TAB, OGSIVEO 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 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

### **PREREQUISITE THERAPY REQUIRED**

YES

# 0JEMDA

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## MEDICATION(S)

0JEMDA

## 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 Tafinlar 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

## PREREQUISITE THERAPY REQUIRED

YES

# OJJAARA

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## MEDICATION(S)

OJJAARA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF (postpolycythemia vera (PV) and post-essential thrombocythemia (ET))
2. Hemoglobin less than 10g/dL
3. Member has tried and failed or has intolerance to Jakafi

## AGE RESTRICTION

N/A

## PREScriBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# 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 trial 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

## PREREQUISITE THERAPY REQUIRED

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

YES

# 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
  - i. Pt had a baseline succinylacetone (SA) level drawn
  - ii. Pt had a baseline liver function testing performed
- b. Diagnosis of alkaptonuria based upon urinary HGA excretion greater than 0.4 g/24 hours
  - i. At least one hip joint remaining
  - ii. Some evidence of hip involvement (e.g. pain or decreased range of motion)
  - iii. Will be used in combination with dietary restriction of tyrosine and phenylalanine
- d. For Nityr tablets: Patient has a trial, intolerance, or contraindication to 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

**PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

YES

# 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

## PREREQUISITE THERAPY REQUIRED

YES

# **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: 6 months Reauth: Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **OSTEOPOROSIS**

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## **MEDICATION(S)**

TERIPARATIDE, 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

## **REQUIRED MEDICAL INFORMATION**

1. For teriparatide:

- A. Member must fail Tymlos OR
- B. Member has glucocorticoid-associated osteoporosis

2. Diagnosis of osteoporosis or osteopenia

3. 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 denosumab

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 denosumab

**AGE RESTRICTION**

N/A

**PREScriBER RESTRICTION**

N/A

**COVERAGE DURATION**

Plan year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **PALYNZIQ**

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## **MEDICATION(S)**

PALYNZIQ

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. If PKU dx:

a. Pt has trial on sapropterin therapy

2. All dx:

a. Pt has a blood phenylalanine (Phe) concentration of greater than 600 micromol/L

3. For dose increase to 60mg/day

a. Patient has had two consecutive blood phenylalanine (Phe) concentrations greater than 360 micromol/L on existing management as recommended by the American College of Medical Genetics and Genomics (ACMG) guidelines

4. Palynziq will be used in combination with a dietary phenylalanine restriction (documentation of compliance with dietary phenylalanine restriction provided with request)

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

**COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# **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 Karposi'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

## **PREREQUISITE THERAPY REQUIRED**

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, APREPITANT, ARANESP (ALBUMIN FREE), ARFORMOTEROL TARTRATE, ARISTADA, ARISTADA INITIO, ASTAGRAF XL, AZATHIOPRINE, BILDYOS, BILPREVDA, 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, ELIGARD 22.5 MG KIT, ELIGARD 30 MG KIT, ELIGARD 7.5 MG KIT, ENGERIX-B, ENVARSUS XR, EPOGEN, ERZOFRI, 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 100 MG CAP, GENGRAF 25 MG CAP, GRANISETRON HCL 1 MG TAB, GRANIX 300 MCG/0.5ML SOLN PRSYR, GRANIX 300 MCG/ML SOLUTION, GRANIX 480 MCG/0.8ML SOLN PRSYR, HALOPERIDOL DECANOATE, HALOPERIDOL LACTATE 5 MG/ML SOLUTION, HEPLISAV-B, INVEGA HAFYERA, INVEGA SUSTENNA, INVEGA TRINZA, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, JUBBONTI, LEUPROLIDE ACETATE (3 MONTH), 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 250 MG/10ML SOLUTION, METHOTREXATE SODIUM 50 MG/2ML SOLUTION, METHOTREXATE SODIUM (PF), MICAFUNGIN SODIUM, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE SODIUM, MYCOPHENOLIC ACID, NIVESTYM, 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, PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PULMOZYME, RECOMBIVAX HB, RETACRIT, RISPERIDONE MICROSPHERES ER, SIROLIMUS, SODIUM CHLORIDE 0.9 % SOLUTION, STREPTOMYCIN SULFATE, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TESTOSTERONE CYPIONATE, TESTOSTERONE ENANTHATE, TRELSTAR MIXJECT, TWINRIX, UDENYCA, UZEDY, VARUBI (180 MG DOSE), WYOST,

## ZIPRASIDONE MESYLATE

### 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 SURECLICK

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. The patient meets one of the following: A. The patient has tried one high-intensity statin(e.g. atorvastatin 40-80mg, rosuvastatin 20-40mg) or a maximally tolerated statin without achieving the LDL-C goal B. The patient experienced statin-related rhabdomyolysis with documented CK elevations greater than 10x ULN C. The patient experienced muscle-related symptoms such as myopathy or myalgia while on two separate trials of different statin therapy that both resolved upon discontinuation of statin therapy 2. AND meets 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

**PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# PIQRAY

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## MEDICATION(S)

PIQRAY (200 MG DAILY DOSE), PIQRAY (250 MG DAILY DOSE), PIQRAY (300 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 hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer    a. PIK3CA-mutation positive    b. Receiving or previous use of an endocrine-based regimen

## AGE RESTRICTION

N/A

## PREScriBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **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. bortezomib, 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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **PREVYMIS**

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## **MEDICATION(S)**

PREVYMIS 120 MG PACKET, PREVYMIS 20 MG PACKET, 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

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **PROLASTIN**

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## **MEDICATION(S)**

PROLASTIN-C

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Pt has severe congenital alpha-1 proteinase inhibitor (A1PI) deficiency, defined as either nephelometry (levels less than 50mg/dL or less than 9micromol/L) or by radial immunodiffusion (levels less than 80mg/dL or less than 15micromol/L). Laboratory results must be submitted
2. Patient has either PiZZ or PiSZ genotype

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

BvD determination required

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **PROMACTA**

---

## **MEDICATION(S)**

ELTROMBOPAG OLAMINE

## **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **PURIXAN**

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## **MEDICATION(S)**

MERCAPTOPURINE 2000 MG/100ML SUSPENSION

## **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 is unable to swallow mercaptopurine tablets

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **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. Initial:

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

2. Reauth:

- a. Member has increase in Hb compared to baseline and/or reduction in transfusion burden

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **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. Reauthorization Criteria: A. 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

### **PREREQUISITE THERAPY REQUIRED**

YES

**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 exemestane, tamoxifen, or fulvestrant

**AGE RESTRICTION**

N/A

**PREScriBER RESTRICTION**

N/A

**COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **RETEVMO**

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### **MEDICATION(S)**

RETEVMO 120 MG TAB, RETEVMO 160 MG TAB, RETEVMO 40 MG TAB, RETEVMO 80 MG TAB

### **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
  - d. Locally advanced or metastatic solid tumors with a RET gene fusion, that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options
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

**PREREQUISITE THERAPY REQUIRED**

YES

# REVCOV

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## MEDICATION(S)

REVCOV

## 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 50,000 cell/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

**PREREQUISITE THERAPY REQUIRED**

N/A

## **REVLIMID**

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### **MEDICATION(S)**

LENALIDOMIDE

### **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 imitediate-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

**PREREQUISITE THERAPY REQUIRED**

YES

# **REVUFORJ**

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## **MEDICATION(S)**

REVUFORJ

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

1. Patients with an 11q23 partial tandem duplication
2. Active acute promyelocytic leukemia
3. Concomitant use with strong CYP3A4 inducers

## **REQUIRED MEDICAL INFORMATION**

1. Dx of relapsed or refractory (R/R) acute leukemia with a KMT2A translocation defined as bone marrow blasts greater than or equal to 5% of reappearance of blasts in peripheral blood
2. Pt has a QTcF less than 450msec
3. For AML and ALL, patient has been treated with greater than or equal to 1 previous therapy

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

# REZDIFFRA

---

## MEDICATION(S)

REZDIFFRA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Patient consumes more than 2 glasses (30g) of alcohol per day
2. Patients TSH is greater than 7

## REQUIRED MEDICAL INFORMATION

1. Patient must have a diagnosis of MASH with stage F2 or F3 fibrosis confirmed by transient elastography (FibroScan) CAP OR liver biopsy
2. Trial of a GLP-1 agonist at the maximumally tolerated dose for at least 90 days without resolution of NASH/MASH, or a documented contraindication or inability to use a GLP-1 agonist

## AGE RESTRICTION

18 years of age or older

## PREScriBER RESTRICTION

Hepatologist or Gastroenterologist

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

## **REZLIDHIA**

---

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# REZUROCK

---

## 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 Reauthorization 2. 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

## PREREQUISITE THERAPY REQUIRED

YES

# **ROMVIMZA**

---

## **MEDICATION(S)**

ROMVIMZA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of symptomatic TGCT
2. Patient is not a surgical candidate
3. Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1
4. Intolerance, contraindication or medical rationale explaining why patient is unable to be treated with Turalio

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# 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

## PREREQUISITE THERAPY REQUIRED

N/A

## **RUBRACA**

---

### **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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **SABRIL**

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## **MEDICATION(S)**

VIGABATRIN, VIGADRONE 500 MG PACKET, VIGAFYDE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. For infantile spasms (solution only)
  - a. Must be used as monotherapy
2. For refractory complex partial seizures
  - a. For oral solution requests, patient has inability to swallow tablets
  - b. Must be used as adjunctive therapy,
  - c. 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**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **SCEMBLIX**

---

## **MEDICATION(S)**

SCEMBLIX

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP)
2. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP):
  - A. Trial and failure of at least 1 TKI
  3. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with T315I mutation:
    - A. Documentation of testing for mutation
    - B. 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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **SIGNIFOR**

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### **MEDICATION(S)**

SIGNIFOR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. For Cushing's: a. Pt is NOT a candidate for pituitary surgery, b. If pt previously had pituitary surgery: Pt continues to have high 24-hour urinary free cortisol levels c. Patient has tried at least one of the following: i. ketoconazole ii. metyrapone 2. For acromegaly a. Pt has had surgical resection of the pituitary gland OR is not a candidate for surgery/radiation therapy b. Pt has tried at least one of the following: i. bromocriptine ii. cabergoline iii. octreotide acetate c. Pt has tried at least one of the following: octreotide depot or lanreotide

### **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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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. Dx of active multi-drug resistant tuberculosis (resistant to both isoniazid and rifampin)
2. Sirturo will be given in combination with at least 3 medications that are active against the patient's TB isolate

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

6 Months

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **SOHONOS**

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## **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **SOMAVERT**

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## **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 at least ONE of the following: octreotide depot or lanreotide

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# SPRYCEL

---

## MEDICATION(S)

DASATINIB

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. Dx of newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
2. Treatment for adults with dx of chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib.
3. Treatment for adults with dx of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.
4. Treatment of pediatric patients 1 year of age and older with dx of Ph+ CML in chronic phase.
5. Treatment of pediatric patients 1 year of age and older with dx of newly diagnosed Ph+ ALL in combination with chemotherapy.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **STELARA**

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## **MEDICATION(S)**

STELARA 45 MG/0.5ML SOLN PRSYR, STELARA 45 MG/0.5ML SOLUTION, STELARA 90 MG/ML SOLN PRSYR, USTEKINUMAB 45 MG/0.5ML SOLN PRSYR, USTEKINUMAB 45 MG/0.5ML SOLUTION, USTEKINUMAB 90 MG/ML SOLN PRSYR

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

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

## **REQUIRED MEDICAL INFORMATION**

1. Dx of:
  - a. Crohn's disease
  - b. Ulcerative Colitis
  - c. Plaque Psoriasis
  - d. Psoriatic arthritis
2. For pediatric PsO and pediatric PsA:
  - a. Pt has a trial, intolerance, or contraindication to ustekinumab (ie. Pyzchiva or Selarsdi)
3. For CD, UC, adult PsO, and adult PsA:
  - a. Pt has a trial, intolerance, or contraindication TWO of adalimumab (ie Amjevita or Hadlima), infliximab (ie renflexis), or ustekinumab (ie. Pyzchiva or Selarsdi)

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

YES

**PREREQUISITE THERAPY REQUIRED**

YES

# 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. Diagnosis of metastatic colorectal cancer (CRC)
  - A. Patient has been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy.
2. Diagnosis of locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST)
  - A. Patient has been previously treated with imatinib mesylate and sunitinib malate.
3. Diagnosis of hepatocellular carcinoma (HCC)
  - A. Patient has been previously treated with sorafenib

## AGE RESTRICTION

N/A

## PREScriBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

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. Treatment of adult patients with gastrointestinal stromal tumor (GIST)

a. Patient had disease progression on or intolerance to imatinib mesylate.

2. Treatment of adult patients with advanced renal cell carcinoma (RCC).

3. Adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy.

4. Treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in adult patients 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

**PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# 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

**PREREQUISITE THERAPY REQUIRED**

YES

## **TABLOID**

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### **MEDICATION(S)**

TABLOID

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

1. Use for chronic lymphocytic leukemia, Hodgkins lymphoma, multiple myeloma, or solid tumors
2. Use in patients whose disease has demonstrated prior resistance to thioguanine

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of a. Acute Myeloid Leukemia

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **TABRECTA**

---

## **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **TADALAFIL**

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### **MEDICATION(S)**

TADALAFIL 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 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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **TAFINLAR**

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## **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**

N/A

**PREREQUISITE THERAPY REQUIRED**

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. Diagnosis of metastatic non-small cell lung cancer (NSCLC) and will be used as one of the following:
  - a. adjuvant therapy after tumor resection, whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations
  - b. locally advanced, unresectable (stage III) NSCLC whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations
  - c. first-line treatment of metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations
  - d. first-line treatment of locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations in combination with pemetrexed and platinum-based chemotherapy
  - e. treatment of adult patients with metastatic EGFR T790M mutation positive NSCLC, whose disease has progressed on or after EGFR TKI therapy

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **TALTZ**

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## **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 TWO of: adalimumab (ie Amjevita, Hadlima, etc), Enbrel, or infliximab (ie. Renflexis)

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

YES

## **PREREQUISITE THERAPY REQUIRED**

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

## **PREREQUISITE THERAPY REQUIRED**

YES

# 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

## PREREQUISITE THERAPY REQUIRED

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. Interleukin-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

## PREREQUISITE THERAPY REQUIRED

YES

# **TARPEYO**

---

## **MEDICATION(S)**

FILSPARI, TARPEYO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **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 0.5 g/day

## **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **TASIGNA**

---

### **MEDICATION(S)**

NILOTINIB HCL

### **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

### **PREREQUISITE THERAPY REQUIRED**

YES

## **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/micL
2. Reauth: a. Platelet count is greater than 50000/micL

### **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

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# 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

## PREREQUISITE THERAPY REQUIRED

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **TIBSOVO**

---

### **MEDICATION(S)**

TIBSOVO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Treatment of newly diagnosed AML in adults 75 years or older, or who have comorbidities that preclude the use of intensive induction chemotherapy and will be used either in combination with azacitidine or as monotherapy
2. Diagnosis of relapsed or refractory AML.
3. Diagnosis of relapsed or refractory myelodysplastic syndromes.
4. Diagnosis of locally advanced or metastatic cholangiocarcinoma who have been previously treated

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# **TRIKAFTA**

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## **MEDICATION(S)**

TRIKAFTA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

1. Clinically significant cirrhosis

## **REQUIRED MEDICAL INFORMATION**

1. Initial: a. Pt has been genotyped by a FDA-approved CF mutation test and the mutation is responsive to Trikafta C. Pt has FEV1 between 40-90% 2. Reauthorization: a. Pt has been reassessed b. Pt's FEV1 has increased since initiation of Trikafta

## **AGE RESTRICTION**

Granules: 2 to 5 years of age Tablets: 6 years of age and older

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months Reauthorization: Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **TRUQAP**

---

## **MEDICATION(S)**

TRUQAP

## **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.
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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **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. Diagnosis of advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases:
  - a. Pt has received one or more prior anti-HER2-based regimens in the metastatic setting
  - b. Tukysa will be used in combination with trastuzumab and capecitabine.
2. Diagnosis of RAS wild-type HER2-positive unresectable or metastatic colorectal cancer
  - a. Cancer has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy,
  - b. Tukysa will be used in combination with trastuzumab

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **TURALIO**

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## **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

# TYENNE

---

## MEDICATION(S)

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

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

1. Combination use with another biologic medications, janus kinase inhibitor (JAK), or Otezla

## REQUIRED MEDICAL INFORMATION

1. Dx of: A. Cytokine release syndrome (CRS) B. Giant cell arteritis (GCA) C. Systemic juvenile idiopathic arthritis (JIA) D. Moderate to severe rheumatoid arthritis (RA) E. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) F. Covid-19 2, For RA or JIA A. Pt has failed at least three months therapy on at least ONE of the following: i. methotrexate, ii. leflunomide, iii. hydroxychloroquine, iv. 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

## AGE RESTRICTION

N/A

## PREScriBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# TYKERB

---

## MEDICATION(S)

LAPATINIB DITOSYLATE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

1. For advanced or metastatic HER-2 positive breast cancer dx: a. Previous failure on anthracycline, taxane, and trastuzumab AND b. Combination therapy with capecitabine
2. For postmenopausal HER-2 receptor hormone receptor positive breast cancer dx: a. Combination therapy with aromatase inhibitor

## AGE RESTRICTION

N/A

## PREScriBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

YES

## PREREQUISITE THERAPY REQUIRED

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# UPTRAVI

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## MEDICATION(S)

UPTRAVI 1000 MCG TAB, UPTRAVI 1200 MCG TAB, UPTRAVI 1400 MCG TAB, UPTRAVI 1600 MCG TAB, UPTRAVI 200 & 800 MCG TAB THPK, UPTRAVI 200 MCG TAB, UPTRAVI 400 MCG TAB, UPTRAVI 600 MCG TAB, UPTRAVI 800 MCG TAB

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

### 1. Initial:

- a. If pt has a positive vasoreactivity test:
  - i. Pt has failed maximum tolerated doses of calcium channel blockers,
  - b. Pt has previous trial on at least ONE of the following:
    - i. ambrisentan, ii. bosentan iii. Opsumit iv. Adempas

### 2. Reauth:

- a. Pt has been reassessed within the past 6 months.

## AGE RESTRICTION

N/A

## PREScriBER RESTRICTION

Pulmonologist or Cardiologist

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **USTEKINUMAB**

---

### **MEDICATION(S)**

PYZCHIVA 45 MG/0.5ML SOLN PRSYR, PYZCHIVA 45 MG/0.5ML SOLUTION, PYZCHIVA 90 MG/ML SOLN PRSYR, SELARSDI 45 MG/0.5ML SOLN PRSYR, SELARSDI 90 MG/ML SOLN PRSYR

### **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. 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

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **VAXCHORA**

---

## **MEDICATION(S)**

VAXCHORA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Member is traveling to area of active cholera transmission (Please note, the dates and location of active cholera transmission area member is going to need to be documented in request) 2. Member is between the ages of 2 and 64

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## VELTASSA

---

### MEDICATION(S)

VELTASSA

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

1. Initial: a. If patient is on a ACE or ARB must meet BOTH of the following: i. Pt has been tried on a loop or thiazide diuretic or has a contraindication to one of these diuretics, ii. The dose of the ACE or ARB has been reduced in an attempt to lower serum potassium levels, b. Serum potassium levels above upper limit of normal on two separate screenings, c. If patient is 18 years or older: Pt has failed Lokelma

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Plan Year

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

### PREREQUISITE THERAPY REQUIRED

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **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

### **PREREQUISITE THERAPY REQUIRED**

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

## **PREREQUISITE THERAPY REQUIRED**

YES

# 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. Adjuvant treatment of HR-positive, HER-2 negative, node positive early breast cancer at high risk of recurrence in combination with tamoxifen or aromatase inhibitor 2. Dx of HR-positive, HER2-negative 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 as initial endocrine-based therapy b. Pt with disease progression following endocrine therapy in combination with fulvestrant, c. Pt with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Plan Year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# 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/documentated 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

## PREREQUISITE THERAPY REQUIRED

N/A

## **VIMKUNYA**

---

### **MEDICATION(S)**

VIMKUNYA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Documentation that confirms that the patient is at increased risk of exposure to chikungunya virus

### **AGE RESTRICTION**

12 years of age or older

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 month

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **VITRAKVI**

---

## **MEDICATION(S)**

VITRAKVI

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **VIVJOA**

---

## **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **VIVOTIF**

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### **MEDICATION(S)**

VIVOTIF

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Member meets one of the following:

- A. Traveling to an area with recognized risk of exposure to *S. typhi* (dates and location of the area member is going to need to be documented in request)
- B. Has intimate exposure to a *S. typhi* carrier (documentation must be provided with request)
- C. a microbiology laboratorian frequently working with *S. typhi* (documentation must be provided with request)

2. Member has not received vaccination for *S. typhi* in the last 5 years

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 Month

### **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

## **VIZIMPRO**

---

### **MEDICATION(S)**

VIZIMPRO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1) First line therapy 2) EGFR exon 19 deletion or EGFR 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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **VONJO**

---

## **MEDICATION(S)**

VONJO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of intermediate or high-risk primary or secondary myelofibrosis (MF) a. For secondary MF: post-polycythemia vera or post-essential thrombocythemia 2. Documentation showing platelet counts below 50,000/mm<sup>3</sup> within the last 30 days 3. For intermediate risk: Inadequate response or intolerance to hydroxyurea, Pegasys, or Jakafi 4. For high risk: patient is not a candidate for transplant 5. Reauthorization: CBC and platelet count required. If above 50,000/mm<sup>3</sup>, Vonjo is no longer indicated. Jakafi is approved for use in patients with platelet counts above 50,000/mm<sup>3</sup>

## **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

## **PREREQUISITE THERAPY REQUIRED**

YES

# **VORANIGO**

---

## **MEDICATION(S)**

VORANIGO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Initial: A. Patient has Grade 2 oligodendrogloma or astrocytoma per WHO criteria B. Patient has confirmed IDH1 or IDH2 gene mutation C. Patient has had at least 1 prior surgery for glioma (biopsy, sub-total resection, gross-total resection) D. One of: i. Patient has not received other prior anticancer therapy, including chemotherapy and radiotherapy ii. Patient has received both RT and chemotherapy AND a. patient has KPS greater than or equal to 60 E. Patient has MRI evaluable, measurable, non-enhancing disease
2. Reauthorization A. Patient does not have imaging-based (MRI) disease progression

## **AGE RESTRICTION**

N/A

## **PREScriBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# VOSEVI

---

## 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

## PREREQUISITE THERAPY REQUIRED

N/A

# **VOTRIENT**

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## **MEDICATION(S)**

PAZOPANIB HCL 200 MG TAB

## **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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **VOXZOGO**

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### **MEDICATION(S)**

VOXZOGO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of achondroplasia, confirmed by genetic testing 2. Ambulatory and able to stand without assistance 3. Member has open epiphyses 4. Reauthorization a) No evidence of growth plate closure (proximal tibia, distal femur)

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **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**

1. Diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) is established through one of the following:
  - a. Documented genetic testing showing pathogenic transthyretin (TTR) (e.g., V39, V122I)
  - b. Cardiac tissue biopsy documenting histological confirmation of ATTR amyloid deposits
  - c. Echocardiogram (ECHO) or cardiac magnetic resonance (MRI) suggestive of amyloidosis AND radionuclide imaging (e.g., technetium-99m) showing grade 2 or 3 cardiac uptake AND absence of light chain proteins
2. New York Heart Association (NYHA) class I to III heart failure
3. Signs and symptoms of cardiomyopathy (e.g., heart failure, edema, dyspnea, etc.)
4. Pro-B-type natriuretic peptide (NT-proBNP) level is greater than 300 pg/mL

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

## **WELIREG**

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### **MEDICATION(S)**

WELIREG

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

1. Requires immediate surgery

### **REQUIRED MEDICAL INFORMATION**

1. Dx von Hippel-Lindau (VHL) disease who require therapy for associated:

- a. renal cell carcinoma (RCC)
- b. central nervous system (CNS) hemangioblastomas
- c. pancreatic neuroendocrine tumors (pNET)

2. Dx of advanced renal cell carcinoma (RCC)

a. Will be used following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)

3. Dx of locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL)

4. Reauthorization: Patient is stable on therapy

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## WINREVAIR

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### MEDICATION(S)

WINREVAIR 2 X 45 MG KIT

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

1. Diagnosis or 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 2 background PAH medications including: a. PDE-5 inhibitor (tadalafil, sildenafil), plus endothelin receptor antagonist (ambrisentan, bosentan, Opsumit), and a prostacyclin agonist (treprostинil or epoprostenol, or selexipag) 6. Patient has a documented intolerance or disease progression on a two-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

**PREREQUISITE THERAPY REQUIRED**

YES

# **XALKORI**

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## **MEDICATION(S)**

XALKORI

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1) Dx with: a) metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) b) metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive c) relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive d) unresectable, recurrent, or refractory ALK-positive inflammatory myofibroblastic tumor 2) For NSCLC and ALK-positive inflammatory myofibroblastic tumor: 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

## **PREREQUISITE THERAPY REQUIRED**

YES

## **XDEMVY**

---

### **MEDICATION(S)**

XDEMVY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Dx of Demodex blepharitis

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

Ophthalmologist

### **COVERAGE DURATION**

6 weeks

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **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 and JIA: 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

**PREREQUISITE THERAPY REQUIRED**

YES

# **XENAZINE**

---

## **MEDICATION(S)**

TETRABENAZINE

## **PA INDICATION INDICATOR**

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

## **OFF LABEL USES**

Tardive Dyskinesia

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of chorea due to Huntington's Disease OR 2. Diagnosis of Tardive Dyskinesia

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **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 ocreotide depot or lanreotide

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

**PREREQUISITE THERAPY REQUIRED**

YES

## **XHANCE**

---

### **MEDICATION(S)**

XHANCE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

1. Diagnosis of Chronic Rhinosinusitis with or without Nasal Polyps. 2. Previous use of mometasone intranasal spray

### **AGE RESTRICTION**

N/A

### **PREScriBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Plan Year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **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

**PREREQUISITE THERAPY REQUIRED**

YES

# **XOLAIR**

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## **MEDICATION(S)**

XOLAIR

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

1. Concurrent therapy with another biologic medication 2. Combination use with Palforzia

## **REQUIRED MEDICAL INFORMATION**

1. For allergic asthma dx: a. Patient has tried at least 3 months on any of the following combinations:  
i. ICS/LABA    ii. ICS/LTRA    iii. ICS/LAMA    iv. ICS/LABA/LAMA (Trelegy)    b. Pt has failed had two or more exacerbations requiring oral corticosteroids OR one exacerbation that led to a hospitalization within the past 12 months    c. Pt's IgE level is greater than or equal to 30 IU/mL    d. Pt is less than 330 lbs. (150 kg), 2. For Chronic Spontaneous Urticaria (CSU) dx: a. Pt has previous failure on a H-1 antagonist, (e.g., cetirizine, hydroxyzine) 3. Dx of Nasal Polyps a. Previous use of systemic corticosteroid therapy    b. Patient has had previous failure of and will be used in combination with nasal corticosteroids 4. IgE-mediated Food Allergy a. Documentation supports that the patient has a history of Type 1 (IgE-mediated) food allergy    b. Diagnosis is confirmed through positive skin prick test or positive serum IgE    c. Body weight and documented pretreatment IgE levels are within the dosing recommendations based on the FDA prescribed information    d. Patient will continue with food allergen avoidance where appropriate    e. For reauthorization:    i. Documentation must show the patient has experienced a significant reduction in frequency or severity of incidental exposure reactions

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

For Food Allergy: Allergist or Immunologist

## **COVERAGE DURATION**

For Food Allergy: 6 months, Reauth: Plan Year For other indications: Plan Year

**OTHER CRITERIA**

BvsD Determination

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **XPOVIO**

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## **MEDICATION(S)**

XPOVIO (100 MG ONCE WEEKLY), XPOVIO (40 MG ONCE WEEKLY), XPOVIO (40 MG TWICE WEEKLY), XPOVIO (60 MG ONCE WEEKLY), XPOVIO (60 MG TWICE WEEKLY), XPOVIO (80 MG ONCE WEEKLY) 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. Diagnosis of multiple myeloma:

A. Patient has received at least one prior therapy

B. Xpovio will be used in combination with bortezomib and dexamethasone

2. Diagnosis of relapsed or refractory multiple myeloma:

A. Patient has received at least four prior therapies

B. Patient's disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody

C. Xpovio will be used in combination with dexamethasone.

3. Diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma

A. Patient has previous use of at least 2 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

**PREREQUISITE THERAPY REQUIRED**

YES

# XTANDI

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## 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 castration-resistant prostate cancer (CRPC) 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

## PREREQUISITE THERAPY REQUIRED

YES

# **YORVIPATH**

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## **MEDICATION(S)**

YORVIPATH

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

1. Impaired responsiveness to PTH (pseudohypoparathyroidism) 2. Any disease that might affect calcium metabolism or calcium-phosphate homeostasis or PTH levels other than HP (e.g active hyperthyroidism, Paget disease of bone, severe hypomagnesemia, uncontrolled diabetes, active pancreatitis, malnutrition, rickets, recent prolonged immobility, active malignancy)

## **REQUIRED MEDICAL INFORMATION**

1. Pt has chronic hypoparathyroidism of postsurgical, autoimmune, genetic, or idiopathic etiologies for a duration of at least 26 weeks 2. Pt has tried and failed active vitamin D (calcitriol) 3. Recent serum 25 (OH) vitamin D in normal range (20 – 80 ng/mL) and albumin-adjusted serum calcium greater than 7.8mg/dL 4. Reauthorization: A. Patient has shown improvement in their albumin-adjusted calcium while on therapy

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an Endocrinologist or Nephrologist

## **COVERAGE DURATION**

Initial: 6 months Reauth: Plan Year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# 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:
  - A. Neutropenia
  - B. Autologous Peripheral Blood Progenitor Cell Collection and Therapy
  - C. Hematopoietic Syndrome of Acute Radiation Syndrome
2. For Neutropenia: pt has trial on BOTH of the following: a. Nivestym, b. Granix
3. For Autologous Peripheral Blood Progenitor Cell Collection and Therapy: pt has trial on Nivestym

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Plan year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## 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. First-Line Maintenance Treatment of HRD-Positive Advanced Ovarian Cancer
  - a. Pt has had complete or partial response to first-line platinum-based chemotherapy
  - b. Cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
    - i. a deleterious or suspected deleterious BRCA mutation, and/or
    - ii. genomic instability.
2. Maintenance Treatment of Recurrent Germline BRCA-Mutated Ovarian Cancer
  - a. Pt has had 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

**PREREQUISITE THERAPY REQUIRED**

YES

## **ZELBORAF**

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### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **ZOLINZA**

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### **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

### **PREREQUISITE THERAPY REQUIRED**

YES

## **ZONISADE**

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### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **ZTALMY**

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### **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

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **ZURZUVAE**

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### **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 Postpartum Depression (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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# ZYDELIG

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## 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

## PREREQUISITE THERAPY REQUIRED

N/A

# **ZYKADIA**

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## **MEDICATION(S)**

ZYKADIA

## **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

## **PREREQUISITE THERAPY REQUIRED**

YES