

**Network Health Insurance Corporation**

**Network Health Zero (PPO)**

**Network Health Select (PPO)**

**Network Health Choice (PPO)**

**Network Health PlusRx (PPO)**

**Network Health PremierRx (PPO)**

**Network Health Go (PPO)**

**Network Health Anywhere (PPO)**

**Prior Authorization Criteria**

**Last Updated 8/2025**

# **ABIRATERONE**

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## **MEDICATION(S)**

ABIRATERONE ACETATE, ABIRTEGA

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **ACTEMRA**

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### **MEDICATION(S)**

ACTEMRA 162 MG/0.9 ML SYRINGE, ACTEMRA ACTPEN, TYENNE 162 MG/0.9 ML SYRINGE, TYENNE AUTOINJECTOR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

### **REQUIRED MEDICAL INFORMATION**

For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved dosing and frequency. RA: diagnosis and disease severity per ACR criteria, score from objective measure/tool at baseline and continuation (e.g. CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI. pJIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. sJIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. Provider has assessed baseline disease severity utilizing an objective measure/tool such as systemic juvenile arthritis disease activity score (sJADAS) or American College of Rheumatology pediatric (ACR pedi) 30 criteria. GCA: diagnosis, pre-requisite medication trial, reauthorization: positive response. Diagnosis of large vessel arteritis that has at some point been verified with biopsy or with imaging of the large vessels (MRI, PET-CT, or CT angiography. Patient has active disease and an elevated C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR). SSc-ILD: Diagnosis, pulmonary function tests, reauth: positive response.

### **AGE RESTRICTION**

sJIA/pJIA: 2 years and older. All other indications: 18 years and older.

### **PRESCRIBER RESTRICTION**

RA/GCA/PJIA/SIJA - Prescribed by or in consultation with a Rheumatologist. Interstitial Lung disease – prescribed by or in consultation with a pulmonologist or rheumatologist (initial and continuation).

### **COVERAGE DURATION**

Initial: 6 months, Continuation: 1 year

## **OTHER CRITERIA**

RA:Initial-approve if pt has TF 2 of the following: Enbrel, a pref adalimumab product, Orencia, Rinvoq or Xeljanz/XR. Cont-approve if pt is responding positively to tx based on improvement in objective measurement/tool as compared to baseline. pJIA-Initial - approve if pt meets a, b and c:a.Dx of pJIA as evidenced by 5 or more joints with active arthritis, b. Documented baseline cJADAS-10, c. TF of TWO of the following: Enbrel, Orencia, a pref adalimumab product, Rinvoq or Xeljanz/XR. Cont-approve if pt has experienced improvement in dz response based on one a, b, c or d:a. Number of tender and swollen joint counts, b. Reduction of CRP, c.Improvement of PGA, d. Improvement in cJADAS-10 score. sJIA:Initial-approve if pt has TF one of the following conventional tx at max tolerated doses (a, b, or c):a. Min duration of 1-month trial of NSAID (e.g. ibuprofen, naproxen), b. Min duration of a 2-week trial of systemic glucocorticoid, c. One of the following biologic tx: such as Kineret, Ilaris, or a TNF-inhibitor. Cont-approve if pt had improvement in dz response based a, b, c or d: a. Number of tender and swollen joint counts, b. Decr CRP, c. Improvement of PGA, d. Improvement on a dz activity scoring tool (e.g. an improvement on a composite scoring index such as sJADAS or ACR-Pedi 30). GCA:Init-Approve if pt had a TF of at least a 12-week trial of a CS, unless intolerant or therapy is CI. Cont-Approve if pt has achieved/maintained a pos clinical response to tx as evidenced by low dz activity or improvement in s/s of the condition when there is improvement in any of the following from baseline: headaches, scalp tenderness, tenderness and/or thickening of superficial temporal arteries, constitutional sx (e.g. weight loss, fever, fatigue, night sweats), jaw and/or tongue claudication, acute visual sx (e.g. amaurosis fugax, acute visual loss, diplopia), sx of PR (e.g. shoulder and/or hip girdle pain), or limb claudication. SSc-ILD:Init-Approve if dx of SSc-ILD as documented by the following (i and ii): i. Exclusion of other known causes of ILD and ii. One of the following (1 or 2): 1. In pts not subjected to surgical lung bx, the presence of idiopathic interstitial pneumonia (e.g., NSIP, UIP and centrilobular fibrosis) pattern on HRCT revealing SSc-IL or probable SSc-ILD. 2. In pts w/ a lung bx, both HRCT and surgical lung bx pattern revealing SSc-ILD or probably SSc-ILD. Cont-Approve if pt has had pos response to tx based on both of the following: i. Decr in the rate of decline or stabilization in FVC or ppFVC as compared to pre-tx baseline, ii.Pt does not have evidence of dz-progression defined as abs decline of more than 10 percent in ppFVC within any 12-month period. Note: pref adalimumabs include: Humira (NDCs starting with -00074) and Simlandi.

## **PART B PREREQUISITE**

N/A

## **ACTIMMUNE**

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### **MEDICATION(S)**

ACTIMMUNE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ADBRY**

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### **MEDICATION(S)**

ADBRY, ADBRY AUTOINJECTOR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with other Anti-Interleukin Monoclonal Antibodies (e.g. Dupixent)

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, pre-requisite treatments, BSA and/or SCORAD index value

### **AGE RESTRICTION**

12 years of age and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an allergist, immunologist, or dermatologist

### **COVERAGE DURATION**

Initial – 6 months, Continuation - 1 year

### **OTHER CRITERIA**

Moderate-to-severe atopic dermatitis:

1.Initial Therapy. Approve if patient meets both of the following (i and ii):

i.Patient has moderate to severe atopic dermatitis involvement and meets one of the following (1 or 2):

1.Involvement of at least 10 percent body surface area (BSA)

2.SCORing Atopic Dermatitis (SCORAD) index value of at least 25

ii.Patients meets both of the following (1 and 2):

1.History of failure, contraindication, or intolerance to one of the following therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication (a or b)

a.Medium to very-high potency topical corticosteroid for 2 weeks

b.Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] for 6 weeks

2.One of the following (a or b):

- a. Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state OR
  - b. Trial and failure of one systemic treatment [e.g., oral cyclosporine, oral azathioprine, or oral mycophenolate mofetil] following a 12-week trial
2. Continuation therapy: Approve if patient meets all of the following (i, ii and iii):
- i. If patient is new to plan, meets initial criteria at time they had started the medication
  - ii. Documented dose and frequency are within the FDA approved Dosing and Frequency
  - iii. Documentation of a positive clinical response to therapy as evidenced by at least one of the following (1 or 2):
- 1. Reduction in body surface area involvement from baseline
  - 2. Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline

## **PART B PREREQUISITE**

N/A

## **ADEMPAS**

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### **MEDICATION(S)**

ADEMPAS

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis as confirmed by right heart catheterization

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2): 1. Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c): a. Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest b. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg c. Pulmonary vascular resistance (PVR) greater than 3 Wood units AND 2. Individual has WHO functional class II-IV symptoms. CTEPH: Patient meets the following (1 and 2): 1. Patient has diagnosis of CTEPH that is inoperable or persistent/recurrent after surgical treatment (i.e., pulmonary endarterectomy) AND 2. CTEPH is symptomatic.



**PART B PREREQUISITE**

N/A

## **ADSTILADRIN**

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### **MEDICATION(S)**

ADSTILADRIN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **AGENTS FOR GAUCHER DISEASE**

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### **MEDICATION(S)**

CERDELGA, CEREZYME, ELELYSO, MIGLUSTAT, VPRIV, YARGESA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, genetic tests and lab results

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a geneticist, endocrinologist, hepatologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation.

### **PART B PREREQUISITE**

N/A

## **AGENTS FOR UREA CYCLE DISORDERS**

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### **MEDICATION(S)**

SODIUM PHENYLBUTYRATE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with more than one phenylbutyrate product

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, genetic or enzymatic tests

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Urea cycle disorders – Initial: approve if genetic or enzymatic testing confirmed a urea cycle disorder. Continuation: Approve if there is confirmation of clinically significant improvement or stabilization in plasma ammonia level.

### **PART B PREREQUISITE**

N/A

## **AIMOVIG**

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### **MEDICATION(S)**

AIMOVIG AUTOINJECTOR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

18 years of age and older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

For Initial approval: The member must have a diagnosis of Chronic migraine or Episodic migraine.

### **PART B PREREQUISITE**

N/A

## AJOVY

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### **MEDICATION(S)**

AJOVY AUTOINJECTOR, AJOVY SYRINGE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

18 years of age and older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

The member must have a diagnosis of migraine.

### **PART B PREREQUISITE**

N/A

## **AKEEGA**

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### **MEDICATION(S)**

AKEEGA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ALECENSA**

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### **MEDICATION(S)**

ALECENSA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **ALOSETRON**

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### **MEDICATION(S)**

ALOSETRON HCL

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Exclude if patient is biologically male

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, Reauth: positive clinical response

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 6 months, continuation: 1 year

### **OTHER CRITERIA**

Severe diarrhea-predominant Irritable bowel syndrome (IBS): 1.Initial: Approve if the patient meets the following (a, b, c and d):

a. Patient has experienced chronic IBS symptoms for 6 months or longer, b. Patient had anatomic or biochemical abnormalities of the gastrointestinal track excluded, c. Patient has tried and failed one anti-diarrheal agent (e.g. loperamide), d. Patient has tried and failed one antispasmodic agent (e.g. dicyclomine). 2. Continuation: Approve if the patient meets the following (a, b and c):

a. If patient is new to plan, meets initial criteria at time they had started the medication, b. Documented dose and frequency are within the FDA approved dosing and frequency, c. Patient is experiencing a positive clinical response to therapy

### **PART B PREREQUISITE**

N/A

## **ALPHA 1 PROTEINASE INHIBITORS**

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### **MEDICATION(S)**

ARALAST NP, GLASSIA, PROLASTIN C, ZEMAIRA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

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

### **PART B PREREQUISITE**

N/A

## **ALUNBRIG**

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### **MEDICATION(S)**

ALUNBRIG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **AMBRISANTAN**

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### **MEDICATION(S)**

AMBRISANTAN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis as confirmed by right heart catheterizations

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, a cardiologist or pulmonologist.

### **COVERAGE DURATION**

Lifetime

### **OTHER CRITERIA**

Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2): 1. Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c): a. Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest b. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg c. Pulmonary vascular resistance (PVR) greater than 3 Wood units AND 2. Individual has WHO functional class II-IV symptoms.

### **PART B PREREQUISITE**

N/A

## **AMPYRA**

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### **MEDICATION(S)**

DALFAMPRIDINE ER

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

The member has sustained walking impairment AND the member is able to walk.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Neurologist or MS specialist.

### **COVERAGE DURATION**

Initial: 3 months. Continuation: 3 years

### **OTHER CRITERIA**

For continuation, authorization will be granted to members with multiple sclerosis for improvement in walking if the member has experienced an improvement in walking speed OR another objective measure of walking ability since starting dalfampridine.

### **PART B PREREQUISITE**

N/A

## **ANKTIVA**

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### **MEDICATION(S)**

ANKTIVA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ANTICONVULSANT THERAPY**

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### **MEDICATION(S)**

APTOM, BRIVIACT 10 MG TABLET, BRIVIACT 10 MG/ML ORAL SOLN, BRIVIACT 100 MG TABLET, BRIVIACT 25 MG TABLET, BRIVIACT 50 MG TABLET, BRIVIACT 75 MG TABLET, DIACOMIT, DILANTIN 30 MG CAPSULE, EPRONTIA, EQUETRO, ESLICARBAZEPINE ACETATE, FYCOMPA, METHSUXIMIDE, MOTPOLY XR, OXCARBAZEPINE ER, PERAMPANEL, RUFINAMIDE, SPRITAM, VIGAFYDE, XCOPRI, ZONISADE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

Carbamazepine, Epitol, Divalproex, ethosuximide, felbamate, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, primidone, Roweepra, tiagabine, topiramate, valproic acid, and zonisamide oral products are the preferred products. The drug must be prescribed within the manufacturers



published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to one preferred formulary alternative OR the member has had an adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternatives OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

**PART B PREREQUISITE**

N/A

## **ANTIFUNGALS (IV)**

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### **MEDICATION(S)**

VORICONAZOLE 200 MG VIAL

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ARANESP**

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### **MEDICATION(S)**

ARANESP 10 MCG/0.4 ML SYRINGE, ARANESP 100 MCG/0.5 ML SYRINGE, ARANESP 100 MCG/ML VIAL, ARANESP 150 MCG/0.3 ML SYRINGE, ARANESP 200 MCG/0.4 ML SYRINGE, ARANESP 200 MCG/ML VIAL, ARANESP 25 MCG/0.42 ML SYRING, ARANESP 25 MCG/ML VIAL, ARANESP 300 MCG/0.6 ML SYRINGE, ARANESP 40 MCG/0.4 ML SYRINGE, ARANESP 40 MCG/ML VIAL, ARANESP 500 MCG/1 ML SYRINGE, ARANESP 60 MCG/0.3 ML SYRINGE, ARANESP 60 MCG/ML VIAL

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Anemia due to myelodysplastic syndrome (MDS)

### **EXCLUSION CRITERIA**

Uncontrolled hypertension. Anemic patients willing to donate autologous blood. Anemia due to factors other than diagnoses noted (iron or folate deficiency, hemolysis, GI bleeding). Patients receiving hormonal agents, therapeutic biological products, or radiotherapy UNLESS also receiving concomitant myelosuppressive chemotherapy. For immediate anemia correction or as a substitute for emergency transfusion. Prophylactic use to prevent chemotherapy included anemia.

### **REQUIRED MEDICAL INFORMATION**

Chronic renal failure patients not on dialysis must have symptomatic anemia with a HGB of 10g/dl or less. Non myeloid malignancy chemotherapy induced anemia must have HGB of 10g/dl or less to start AND serum ferritin greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% or patient is receiving supplemental iron - if previously receiving Aranesp or epoetin alfa, Hgb must be 12 g/dl or less and the patient has had a response to therapy. For Myelodysplastic Syndrome refractory anemia diagnosis must include excess blasts, or excess blasts in transformation to leukemia when, for medical reasons, the patient is not a candidate for active treatment of active leukemia. For Myelodysplastic Syndrome the patient must have endogenous EPO serum level less than 500mu/ml AND serum ferritin greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% or patient is receiving supplemental iron. For MDS, if previously receiving Aranesp or epoetin alfa, Hgb must be 12 g/dl or less and the patient has had a response to therapy.

### **AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.

**COVERAGE DURATION**

Chemo-induced anemia: 6 months. All other indications - 1 year.

**OTHER CRITERIA**

For non myeloid malignancy anemia related to chemotherapy, the member must have received chemotherapy in past 8 weeks and will be receiving chemo for a minimum of 2 months. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.

**PART B PREREQUISITE**

N/A

# ARCALYST

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## MEDICATION(S)

ARCALYST

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Concurrent use a biologic drug or targeted synthetic drug

## REQUIRED MEDICAL INFORMATION

Diagnosis, Reauth: documentation of positive clinical response

## AGE RESTRICTION

CAPS, Pericarditis - 12 years or greater.

## PRESCRIBER RESTRICTION

CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA - prescribed by, or in consultation with, a rheumatologist, geneticist, dermatologist or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis - prescribed by, or in consultation with, a rheumatologist or cardiologist.

## COVERAGE DURATION

CAPS, DIRA: Initial: 6 months, cont 1 year. Pericarditis: Initial 3 months, cont 1 year

## OTHER CRITERIA

1. Cryopyrin-Associated Periodic Syndrome: a. Initial: Approve if patient meets all of the following (i, ii and iii): i. Patient has a diagnosis of Familial Cold Autoinflammatory Syndrome (FCAS) with classic signs and symptoms (i.e. recurrent, intermittent fever and rash that are often exacerbated by exposure to generalized cool ambient temperature), Muckle-Wells Syndrome (MWS) with classic signs and symptoms (i.e. chronic fever and rash of waxing and waning intensity, sometimes exacerbated by exposure to generalized cool ambient temperature), ii. Patient must be up to date and have received all recommended vaccines or must receive all recommended vaccinations prior to initiation of therapy, iii. Patient has functional impairment limiting the activities of daily living. b. Continuation: Approve if

patient meets all of the following (i and ii): i. For patients new to plan, must have met initial criteria at time of starting medication, ii. Documentation of positive clinical response (low disease activity or improvement in signs and symptoms of the condition).

2. Deficiency of the Interleukin-1 Receptor Antagonist (DIRA) a. Initial: Approve if patient meets all of the following (i, ii, iii and iv): i. Weighs at least 10 kg, ii. Genetic test confirms a mutation in the IL1RN gene, iii. Patient has demonstrated clinical benefit with anakinra subcutaneous infusion, iv. Patient must be up to date and have received all recommended vaccines or must receive all recommended vaccinations prior to initiation of therapy, b. Continuation: Approve if patient meets all of the following (i and ii): i. For patients new to plan, must have met initial criteria at time of starting medication, ii. Documentation of positive clinical response (low disease activity or improvement in signs and symptoms of the condition),

3. Pericarditis: a. Initial: Approve if the patient meets all of the following (i, ii and iii): i. Patient has recurrent pericarditis, ii. Tried and failed at least two agents of standard therapy (e.g. colchicine, non-steroidal anti-inflammatory drugs, corticosteroids) iii. Patient must be up to date and have received all recommended vaccines or must receive all recommended vaccinations prior to initiation of therapy. b. Continuation: Approve if the patient meets all of the following: i. For patients new to plan, must have met initial criteria at time of starting medication, ii. Documentation of positive clinical response (decreased recurrence, improvement of signs and symptoms [e.g. improvement in pericarditic or pleuritic chest pain, pericardial or pleural rubs, ECG, pericardial effusion, or c-reactive protein]).

## **PART B PREREQUISITE**

N/A

## **ARIKAYCE**

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### **MEDICATION(S)**

ARIKAYCE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, Amikacin MIC

### **AGE RESTRICTION**

MAC-18 years and older

### **PRESCRIBER RESTRICTION**

MAC-prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections.

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

MAC Lung disease: Initial-approve if the patient has NOT achieved negative sputum cultures for MAC since completion of most recent background multidrug regimen AND Arikayce will be used in conjunction to a background multidrug regimen AND the MAC isolate is susceptible to amikacin with minimum inhibitor concentration (MIC) of less than or equal to 64 microgram/mL. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin). Continuation: Patient has not achieved negative sputum cultures for MAC OR patient has achieved negative sputum cultures for MAC for less than 12 months.

### **PART B PREREQUISITE**

N/A





## **ATYPICAL ANTIPSYCHOTICS**

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### **MEDICATION(S)**

ASENAPINE MALEATE, CAPLYTA, CLOZAPINE ODT, FANAPT 1 MG TABLET, FANAPT 10 MG TABLET, FANAPT 12 MG TABLET, FANAPT 2 MG TABLET, FANAPT 4 MG TABLET, FANAPT 6 MG TABLET, FANAPT 8 MG TABLET, FANAPT TITRATION PACK A, OLANZAPINE-FLUOXETINE HCL, OPIPZA, PALIPERIDONE ER, PERSERIS, QUETIAPINE FUMARATE ER, REXULTI 0.25 MG TABLET, REXULTI 0.5 MG TABLET, REXULTI 1 MG TABLET, REXULTI 2 MG TABLET, REXULTI 3 MG TABLET, REXULTI 4 MG TABLET, SECUADO, VERSACLOZ

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

For Fanapt, Caplyta, and Rexulti: The drug must be prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current

literature AND one of the following: The member has demonstrated a failure of or intolerance Lybalvi and Vraylar OR the member has a documented contraindication to Lybalvi and Vraylar OR the member has had an adverse reaction or would be reasonably expected to have an adverse reaction to Lybalvi and Vraylar OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

For clozapine ODT, olanzapine/fluoxetine, paliperidone ER, Secuado, Versacloz suspension, asenapine, Perseris ER and quetiapine ER: The drug must be prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to two preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to two preferred formulary alternative OR the member has had an adverse reaction or would be reasonably expected to have an adverse reaction to two preferred formulary alternatives OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature. Preferred formulary alternatives include: aripiprazole (tablet, odt, solution), clozapine (tablet), fluphenazine decanoate/fluphenazine hydrochloride (tablet, oral solution, injectable vial), Haloperidol (tablet, oral solution, injectable vial), loxapine, lurasidone, molindone, olanzapine (tablet, ODT), perphenazine, pimozide, quetiapine (IR tablet), risperidone (tablet, ODT, oral solution), thioridazine, thiothixene, trifluoperazine and ziprasidone are the preferred products.

Requests for Rexulti, quetiapine extended release and fluoxetine-olanzapine will be authorized if using for treatment of Major Depressive Disorder. Fluoxetine-olanzapine or quetiapine extended release will be authorized for bipolar depression. Requests for Rexulti will be authorized if using for treatment of agitation associated with dementia due to Alzheimer's disease. Member will not need to try preferred products.

## **PART B PREREQUISITE**

N/A

## **AUGTYRO**

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### **MEDICATION(S)**

AUGTYRO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## AUSTEDO

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### MEDICATION(S)

AUSTEDO, AUSTEDO XR, AUSTEDO XR TITRATION KT(WK1-4)

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

Impaired hepatic function, concomitant use of monoamine oxidase inhibitors (minimum of 14 days should elapse after stopping MAOI and starting Austedo), Concomitant use of reserpine (minimum of 20 days should elapse after stopping reserpine and before starting Austedo), Concomitant use of tetrabenazine or Ingrezza, current suicidality, untreated or inadequately treated depression, Non-Huntington's disease related chorea

### REQUIRED MEDICAL INFORMATION

Diagnosis, TD: AIMS or DISCUS score, HD reauth: positive clinical response

### AGE RESTRICTION

18 years of age or older

### PRESCRIBER RESTRICTION

Chorea - prescribed by, or in consultation with, a neurologist. Tardive dyskinesia - prescribed by, or in consultation with, a psychiatrist or neurologist.

### COVERAGE DURATION

HD: 1 year, TD – initial 4 months, continuation 1 year.

### OTHER CRITERIA

1.Chorea associated with Huntington's Disease: a.Initial: Approve if patient meets both of the following (i and ii): i. Diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36), ii. Patient has tried and failed or has intolerance to tetrabenazine b. Continuation: Approve if patient meets both of the following (i and ii): i.If new to plan, patient met initial criteria at time of starting medication, ii. Patient has had positive clinical response to therapy. 2. Tardive Dyskinesia: a. Initial use: Approve if patient meets all of the following (i, ii, and iii): i.Patient has had at

least 60 days of stable (drug and dose) medication exposure to one of the following (1, 2 or 3):

1. Typical or first generation antipsychotic agents (e.g. chlorpromazine, haloperidol, fluphenazine),
2. Atypical or second-generation antipsychotic agents (e.g. clozapine, risperidone, olanzapine)
3. Dopamine receptor-blocker used in treatment of nausea and gastroparesis (e.g. prochlorperazine, promethazine, metoclopramide)

ii. Symptoms persist despite one of the following (1 or 2):

1. Discontinuation or reduction in dose of offending agent(s),
2. Discontinuation or reduction in dose of offending agent(s) is not possible,
- iii. Patient has presence of involuntary athetoid or choreiform movements lasting at least 30 days

b. Continuation: Approve if patient meets all of the following (i and ii):

- i. If new to plan, patient met initial criteria at time of starting medication,
- ii. Following at least 3 months of therapy, patient has experienced an improvement or maintenance of symptoms while on Austedo based on reduction in abnormal involuntary movement scale (AIMS) or Dyskinesia Identification System: Condensed User Scale (DISCUS) from baseline.

## **PART B PREREQUISITE**

N/A

## **AYVAKIT**

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### **MEDICATION(S)**

AYVAKIT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **BALVERSA**

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### **MEDICATION(S)**

BALVERSA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **BASAL INSULIN**

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### **MEDICATION(S)**

BASAGLAR KWIKPEN U-100, BASAGLAR TEMPO PEN U-100, INSULIN DEGLUDEC, INSULIN DEGLUDEC PEN (U-100), INSULIN DEGLUDEC PEN (U-200), INSULIN GLARGINE, INSULIN GLARGINE MAX SOLOSTAR, INSULIN GLARGINE SOLOSTAR, LEVEMIR, LEVEMIR FLEXPEN, LEVEMIR FLEXTOUCH, REZVOGLAR KWIKPEN, SEMGLEE (YFGN), SEMGLEE (YFGN) PEN, TRESIBA, TRESIBA FLEXTOUCH U-100, TRESIBA FLEXTOUCH U-200

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Previous therapies

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

For Basaglar, Basaglar Tempo, Rezvoglar, Semglee, Semglee-YFGN, or insulin glargine-YFGN approval, the member must meet one of the following criteria (A), (B), (C), OR (D): (A) The member has demonstrated a failure of or intolerance to the preferred product, Lantus (brand), for the given diagnosis, (B) The member has a documented contraindication to the Lantus (brand), (C) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to Lantus (brand), OR (D) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to Lantus (brand) for the requested indication. For insulin degludec and Tresiba, the



member must meet one of the following criteria (A), (B), (C), OR (D): (A) The member has demonstrated a failure of or intolerance to one of the preferred products, Lantus or Toujeo, for the given diagnosis, (B) The member has a documented contraindication to one of the preferred products, Lantus or Toujeo, (C) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Lantus or Toujeo, OR (D) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Lantus or Toujeo for the requested indication.

#### **PART B PREREQUISITE**

N/A

## **BENLYSTA**

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### **MEDICATION(S)**

BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent Use with Other Biologics, Lupkynis or Saphnelo, patients with active central nervous system lupus

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, ANA or anti-dsDNA level, SLE: SELENA-SLEDAI score, LN: biopsy proven lupus nephritis

### **AGE RESTRICTION**

5 years and older

### **PRESCRIBER RESTRICTION**

SLE-prescribed by, or in consultation with, a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation). Lupus nephritis nephrologist or rheumatologist (initial and continuation).

### **COVERAGE DURATION**

SLE: 4 mo. initial, 1 yrs cont. Lupus Nephritis 6 mo. initial, 1 year cont.

### **OTHER CRITERIA**

Lupus Nephritis: 1) Initial: Approve if patient meets all of the following (a, b and c): a) The patient is autoantibody-positive in the absence of any drugs for SLE as defined as one of the following (1 or 2): (1) ANA titer greater than or equal to 1:80 OR, (2) Anti-dsDNA level greater than or equal to 30 I/ml, b) The patient has biopsy-proven lupus nephritis Class III, IV and/or V, c) The patient has active renal disease requiring standard therapy of corticosteroids with mycophenolate for induction and maintenance or cyclophosphamide for induction followed by azathioprine for maintenance, 2) Continuation: Approve if patient meets all of the following (a and b): a) If patient is new to plan, must have met initial criteria at time of starting medication, b) According to the prescriber, patient has

experienced improvement with therapy. SLE 1) Initial: Approve if patient meets all of the following (a, b and c): a) The patient is autoantibody-positive in the absence of any drugs for SLE as defined as one of the following (1 or 2): (1) ANA titer greater than or equal to 1:80 OR (2) Anti-dsDNA level greater than or equal to 30 I/ml. b) The patient has active SLE with a score of 6 or greater (as documented by a SELENA-SLEDAI or as scored by a comparable standardized rating scale that reliably measures SLE disease activity) while on treatment with corticosteroid, anti-malarial, or immunosuppressant therapy (alone or as combination), c) Benlysta will be used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) d) Continuation: Approve if patient meets all of the following (a, b and c): a. If patient is new to plan, must have met initial criteria at time of starting medication, b. According to the prescriber, patient has experienced improvement in therapy, c. Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate])

## **PART B PREREQUISITE**

N/A

## **BESREMI**

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### **MEDICATION(S)**

BESREMI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **BIMZELX**

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### **MEDICATION(S)**

BIMZELX, BIMZELX AUTOINJECTOR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

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

### **REQUIRED MEDICAL INFORMATION**

Plaque Psoriasis: Diagnosis, PASI score, reauth: positive response. Non-radiographic axial spondyloarthritis: Diagnosis, pre-requisite medication trials, objective signs of inflammation, reauth: positive clinical response. AS: Diagnosis, pre-requisite medication trials, objective measure at initiation and continuation (examples outlined in other criteria). PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. HS: Diagnosis, pre-requisite medication trials, reauth: When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested medication). Note: Examples of objective measures include Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity Index. For all: If patient is new to plan, meets initial criteria at time they had started the medication, documented dose and frequency is within the FDA approved Dosing and Frequency.

### **AGE RESTRICTION**

18 years of age and older

### **PRESCRIBER RESTRICTION**

HS, PP: Prescribed by or in consultation with a dermatologist. Nr-asXpA, AS: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed by or in consultation with a Rheumatologist or Dermatologist.

### **COVERAGE DURATION**

Initial: 6 months, Continuation 1 year

## OTHER CRITERIA

PP-Init- Approve if the pt meets all of the following (a and b): a. Has a dx of mod to severe PP with a PASI score of 10 or more, b. Pt has tried 2 of the following: Enbrel, a pref adalimumab, Skyrizi, pref ustekinumab (SC), Otezla, or Cosentyx. Note: If the pt does not meet this requirement, a trial of a non-pref adalimumab or ustekinumab will also count. Cont-Approve if the pt meets the following: a. Has evidence of a pos response based on 1 of the following (i or ii): i. Achieved or maintained clear or minimal dz, ii. A decr in PASI score compared to baseline. nr-asXpA:Initial-approve if the pt meets a and b: a. Has objective signs of inflammation, defined as at least one of the following (1 or 2): 1. CRP elevated beyond the ULN for the reporting lab, 2. Sacroiliitis reported on MRI, b. Has T/F both of the following: Cosentyx and Rinvoq. Cont-approve if pt has experienced a pos clinical response to tx as evidenced by improvement from baseline for at least one of the following (1, 2, 3 or 4): 1. Dz activity (e.g. pain, fatigue, inflammation, stiffness), 2. Lab values (CRP), 3. Axial status (e.g. lumbar spine motion, chest expansion), 4. Total active (swollen and tender) joint count. AS-Init-approve if the pt meets all of the following (i and ii): i. Confirmed dx of AS as defined by presence of active dz for at least 4 wks defined by any dz specific functional scoring tool (i.e. a BASDAI Index of at least 4, HAQ, MHAQ, etc.) and expert opinion based on clinical features, acute phase reactants and imaging modalities. ii. Pt has T/F TWO of the following: Enbrel, a pref adalimumab product, Cosentyx, Rinvoq or Xeljanz/Xeljanz XR. Cont-approve if the pt meets the following: i. Has experienced a pos clinical response to tx as evidenced by at least 1 objective measure compared to baseline. Ex. of objective measures include ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI, DFI, HAQ-S, and/or serum markers (e.g. CRP, ESR). PsA: Init-approve if the pt meets the following (a and b): a. Currently experiencing 1 of the following (i, ii, iii, iv or v): i. Actively inflamed joints, ii. Dactylitis, iii. Enthesitis, iv. Axial dz v. Active skin and/or nail involvement, b. Pt has active PsA and pt has tried TWO of the following: Enbrel, a pref adalimumab, a pref ustekinumab (SC), Otezla, Orencia, Xeljanz/XR, Cosentyx, Rinvoq or Skyrizi. Cont-approve if the pt meets the following from baseline (i, ii, iii, iv or v): i. Number of swollen joints, ii. Number of tender joints, iii. Dactylitis, iv. Enthesitis, v. Axial dz. HS: Approve if the patient has tried both of the following meds for tx of HS: A pref adalimumab product and Cosentyx SC. Where applicable, please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Preferred ustekinumabs include Stelara and Yesintek.

## PART B PREREQUISITE

N/A

## **BIZENGRI**

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### **MEDICATION(S)**

BIZENGRI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **BOSENTAN**

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### **MEDICATION(S)**

BOSENTAN 125 MG TABLET, BOSENTAN 62.5 MG TABLET

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Chronic thromboembolic pulmonary hypertension (CTEPH)

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis as confirmed by right heart catheterizations

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, a cardiologist or pulmonologist.

### **COVERAGE DURATION**

Lifetime

### **OTHER CRITERIA**

Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2): 1. Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c): a. Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest b. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg c. Pulmonary vascular resistance (PVR) greater than 3 Wood units AND 2. Individual has WHO functional class II-IV symptoms. CTEPH: Patient meets the following (1 and 2): 1. Patient has diagnosis of CTEPH that is inoperable or persistent/recurrent after surgical treatment (i.e., pulmonary endarterectomy) AND 2. CTEPH is symptomatic.

### **PART B PREREQUISITE**



N/A

## **BOSULIF**

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### **MEDICATION(S)**

BOSULIF

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **BRAFTOVI**

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### **MEDICATION(S)**

BRAFTOVI 75 MG CAPSULE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **BRUKINSA**

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### **MEDICATION(S)**

BRUKINSA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **CABOMETYX**

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### **MEDICATION(S)**

CABOMETYX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **CALQUENCE**

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### **MEDICATION(S)**

CALQUENCE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **CAPRELSA**

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### **MEDICATION(S)**

CAPRELSA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **CARGLUMIC ACID**

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### **MEDICATION(S)**

CARGLUMIC ACID

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, genetic test

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

NAGS – pt meets criteria no genetic test – 3 mo. Pt has genetic test – 12 months. All other: 7 days

### **OTHER CRITERIA**

NAGS deficiency with hyperammonemia: Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency.

PA or MMA with hyperammonemia, acute treatment: Approve if the patient's plasma ammonia level is greater than or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies.

### **PART B PREREQUISITE**

N/A



## **CAYSTON**

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### **MEDICATION(S)**

CAYSTON

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of cystic fibrosis.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Member has *Pseudomonas aeruginosa* colonization in the lungs and has recurrence despite prior use of tobramycin inhalation solution or tobramycin resistance.

### **PART B PREREQUISITE**

N/A

## **CHENODAL**

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### **MEDICATION(S)**

CHENODAL

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patient with calcified (radiopaque) stones

### **REQUIRED MEDICAL INFORMATION**

Patient has diagnosis of radiolucent gallstones in well-opacifying gallbladder as visualized by oral cholecystography.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial and continuation: 1 year

### **OTHER CRITERIA**

For initial therapy, patient must meet both of the following (1 and 2):

1. Patient has tried and failed or has a contraindication or intolerance to ursodiol.
2. Patient is not a candidate for cholecystectomy

For continuation of therapy: Provider confirms patient's condition requires continued treatment as demonstrated by oral cholecystograms or ultrasonograms.

### **PART B PREREQUISITE**

N/A

# **CIALIS**

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## **MEDICATION(S)**

TADALAFIL 2.5 MG TABLET, TADALAFIL 5 MG TABLET

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Erectile Dysfunction. Concomitant use of nitrates.

## **REQUIRED MEDICAL INFORMATION**

The member must have a diagnosis of benign prostatic hyperplasia.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial duration 3 months. If BPH symptoms improve (AUA-SI score decrease), approve for 1 year.

## **OTHER CRITERIA**

The daily dose is prescribed as 2.5 mg or 5 mg once daily. The member must have symptoms of at least moderate severity that are bothersome, as defined by the American Urological Association Symptom Index (AUA-SI) greater than or equal to 8. Must have tried and failed or be intolerant of or contraindicated to two other drugs, one each from any two of the following different therapeutic classes: Alpha-1 adrenergic blockers (terazosin, doxazosin, tamsulosin, alfuzosin, silodosin) tried for a minimum of one month at the maximum tolerated dose, 5-alpha reductase inhibitors (finasteride, dutasteride) tried for a minimum of four months at the maximum tolerated dose, combination alpha-1 adrenergic blocker/5-alpha reductase inhibitors (dutasteride/tamsulosin) tried for a minimum of four months at the maximum tolerated dose.

## **PART B PREREQUISITE**

N/A

## **CIBINQO**

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### **MEDICATION(S)**

CIBINQO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with a biologic, targeted synthetic disease-modifying antirheumatic drug (DMARD), Anti-Interleukin monoclonal antibody, Xolair, potent immunosuppressants (e.g. azathioprine, cyclosporine) or other Janus Kinase inhibitors.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, pre-requisite treatments, BSA and/or SCORAD index value

### **AGE RESTRICTION**

12 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an allergist, immunologist, or dermatologist

### **COVERAGE DURATION**

Initial – 6 months, Continuation - 1 year

### **OTHER CRITERIA**

Refractory, moderate-to-severe atopic dermatitis:

1.Initial Therapy. Approve if patient meets both of the following (i and ii):

i.Patient has moderate to severe atopic dermatitis involvement and meets one of the following (1 or 2):

1.Involvement of at least 10 percent body surface area (BSA)

2.SCORing Atopic Dermatitis (SCORAD) index value of at least 25

ii.Patients meets both of the following (1 and 2):

1.History of failure, contraindication, or intolerance to one of the following therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication (a or b)

a.Medium to very-high potency topical corticosteroid for 2 weeks

b.Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] for 6 weeks

2.One of the following (a or b):

a.Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state OR

b.Trial and failure of one systemic treatment [e.g., oral cyclosporine, oral azathioprine, or oral mycophenolate mofetil] following a 12-week trial

2.Continuation therapy: Approve if patient meets all of the following (i, ii and iii):

i.If patient is new to plan, meets initial criteria at time they had started the medication

ii.Documented dose and frequency are within the FDA approved Dosing and Frequency

iii.Documentation of a positive clinical response to therapy as evidenced by at least one of the following (1 or 2):

1.Reduction in body surface area involvement from baseline

2.Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline

## **PART B PREREQUISITE**

N/A

## **CIMZIA**

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### **MEDICATION(S)**

CIMZIA 2X200 MG/ML(X3)START KT, CIMZIA (2 PACK)

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

### **REQUIRED MEDICAL INFORMATION**

For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication, Documented dose and frequency are within the FDA approved Dosing and Frequency. RA: diagnosis and disease severity per ACR criteria, score from objective measure/tool at baseline and continuation (e.g. CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI. AS: Diagnosis (confirmed by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc.) and an expert opinion based on clinical features, acute phase reactants and imaging modalities), pre-requisite medication trials, reauth: positive clinical response to therapy as evidenced by at least one objective measure (e.g. ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI, DFI, HAQ-S, and/or serum markers (e.g. CRP, ESR). PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. CD: Diagnosis, pre-requisite medication trials (if applicable), Reauth: positive clinical response. PP: Diagnosis of moderate to severe plaque psoriasis and has a Psoriasis Area and Severity Index (PASI) score of 10 or more. PASI score, reauth: positive response. Nr-asXpA: Diagnosis, pre-requisite medication trials, objective signs of inflammation, reauth: positive clinical response, patient has objective signs of inflammation, defined as at least one of the following (1 and 2): 1) C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory, 2) Sacroiliitis reported on magnetic resonance imaging. pJIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation.

### **AGE RESTRICTION**

pJIA - 2 years and older. All others - 18 years and older

### **PRESCRIBER RESTRICTION**

RA/AS/pJIA-prescribed by or in consultation with a rheumatologist. CD-prescribed by or in consultation with a gastroenterologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. PP-prescribed by or in consultation with a dermatologist. nr-axSpA-prescribed by or in consultation with a rheumatologist.

## **COVERAGE DURATION**

Initial 6 months, continuation 1 year

## **OTHER CRITERIA**

RA-Init-approve if pt tried 2 of following: Enbrel, pref adalimumab, Orencia, Rinvoq or Xeljanz/XR. Cont-approve if pt is responding pos to tx based on improv in objective measure/tool as compared to baseline. AS:Init-approve if pt has TF 2 of following: Enbrel, pref adalimumab, Cosentyx, Rinvoq or Xeljanz/Xeljanz XR. Cont-See required medical info. PsA:Init-approve if a and b:a.Pt is currently experiencing 1 of following (i, ii, iii, iv or v): i.Actively inflamed joints, ii.Dactylitis, iii.Enthesitis, iv.Axial dz, v. Active skin and/or nail involvement, b.Active PsA and tried 2 of following: Enbrel, pref adalimumab product, pref ustekinumab SC, Otezla, Orencia, Xeljanz/XR, Cosentyx, Rinvoq or Skyrizi.Cont-approve if documentation of pos clinical response to tx as evidenced by improv in any of following from baseline (a, b, c, d, or e): a.Number of swollen joints, b.Number of tender joints,c.Dactylitis, d.Enthesitis, e.Axial dz. CD-Init:Approve if meets all: i. Documented dx of mod/severe CD, ii. Pt currently experiencing 1 of following:a.Freq diarrhea and abdominal pain, b.At least 10% weight loss, c.Complication such as obstruction, fever, abdominal mass, d.Abn labs (e.g. CRP), e.CDAI greater than 20, iii.Pt has tried 2 of the following pref products: a pref adalimumab, Skyrizi SQ, pref ustekinumab SQ or Rinvoq. Cont:Approve if i and ii: i.Pt has been established on the med for at least 5 mo, ii. Pt has documentation of pos clinical response to tx as evidenced by 1 or 2: 1.Improv in intestinal inflammation (e.g. mucosal healing, improv of labs [PLT counts, ESR, CRP]) from baseline, 2.Reversal of high fecal output state. PP:Init:Approve if pt tried 2 of the following: Enbrel, a pref adalimumab, Skyrizi, pref ustekinumab (SC), Otezla, or Cosentyx. Cont:Approve if pt has evidence of a pos response based on a or b: a.Achieved/maintained clear/minimal dz, b.A decr in PASI score compared to baseline. nr-axSpA:Init-approve if the pt has TF both of the following: Cosentyx and Rinvoq. Cont:Approve if pt experienced a pos clinical response to tx based on at least 1 of the following:1.Dz activity (e.g. pain, fatigue, inflammation, stiffness),2.Lab values (CRP),3.Axial status (e.g. lumbar spine motion, chest expansion),4.Total active (swollen and tender) joint count. pJIA:Init-approve if pt meets all of following: a. Dx of pJIA as evidenced by 5 or more joints with active arthritis, b. Documented baseline cJADAS-10, c. Pt has T/F TWO of following: Enbrel, Orencia, pref adalimumab or Xeljanz/XR. Cont-approve if pt experienced improv in dz response based on 1 of following: i. Number of tender and swollen joint counts, ii. Reduction of CRP, iii. Improv of PGA, iv. Improv cJADAS-10 score. Note: pref adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Pref ustekinumabs include Stelara and Yesintek.



**PART B PREREQUISITE**

N/A

## **COBENFY**

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### **MEDICATION(S)**

COBENFY, COBENFY STARTER PACK

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Urinary retention. Mild, moderate or severe hepatic impairment. Gastric retention. Untreated narrow-angle glaucoma. History of hypersensitivity to Cobenfy or trospium. Moderate or severe renal impairment (eGFR less than 60 ml/min).

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, eGFR, medication history with preferred formulary alternatives

### **AGE RESTRICTION**

18 years or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

Patient meets all of the following (1 and 2):

1.Has documented diagnosis of schizophrenia

2.Meets one of the following (a or b):

a.Patient has tried and had an inadequate response to two of the following: Lybalvi, Vraylar and/or Caplyta for the same indication

b.Patient has an intolerance, hypersensitivity and/or FDA labeled contraindication to Lybalvi and Vraylar

### **PART B PREREQUISITE**

N/A

## **COLUMVI**

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### **MEDICATION(S)**

COLUMVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **COMETRIQ**

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### **MEDICATION(S)**

COMETRIQ

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **COPAXONE**

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### **MEDICATION(S)**

COPAXONE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Previous therapies.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Indefinite

### **OTHER CRITERIA**

For Copaxone (brand name) coverage, the member must meet one of the following criteria (A), (B), (C), OR (D): (A) The member has demonstrated a failure of or intolerance to the preferred product, glatiramer (generic), for the given diagnosis, (B) The member has a documented contraindication to the glatiramer (generic), (C) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to glatiramer (generic), OR (D) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to glatiramer (generic) for the requested indication.

### **PART B PREREQUISITE**

N/A

## **COPIKTRA**

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### **MEDICATION(S)**

COPIKTRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **COSENTYX**

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### **MEDICATION(S)**

COSENTYX (2 SYRINGES), COSENTYX SENSOREADY (2 PENS), COSENTYX SENSOREADY PEN, COSENTYX SYRINGE, COSENTYX UNOREADY PEN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

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

### **REQUIRED MEDICAL INFORMATION**

PP: Diagnosis, PASI score, reauth: positive response. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. AS: Diagnosis, pre-requisite medication trials, objective measure at initiation and continuation (examples outlined in other criteria). Nr-axSpA: Diagnosis, pre-requisite medication trials, objective signs of inflammation, reauth: positive clinical response. HS: Diagnosis, pre-requisite medication trials, objective measure at continuation (examples outlined in other criteria). Enthesitis-related arthritis: Diagnosis, pre-requisite medication trials, reauth: improvement in signs and symptoms. For all diagnoses: Documented Dose and Frequency are within the FDA approved Dosing and Frequency. If patient is new to plan, meets initial criteria at time they had started the medication.

### **AGE RESTRICTION**

PP: 6 years and older. PsA: 2 years and older. Enthesitis-related arthritis: 4 years and older. AS, nr-axSpa, HS: 18 and older.

### **PRESCRIBER RESTRICTION**

PP, HS: prescribed by or in consultation with a dermatologist. AS, non-radiographic axial spondyloarthritis or enthesitis related arthritis-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist.

### **COVERAGE DURATION**

Initial 6 months, continuation 3 years



## OTHER CRITERIA

PP-Initial-Approve if pt meets a and b: a. Pt has dx of mod/severe PP and 1 of the following (i, ii or iii): i. PASI score of 10 or more, ii. At least 3% BSA affected, iii. PP affects hands, feet, scalp, face or genital area, b. Pt has TF/C/I to 2 or more: i. Phototherapy (PUVA, UVB), ii. Topical therapy, iii. Systemic non-biologic DMARDs 2. Cont-Approve if pt has pos response based on a or b: a. Achieved/maintained clear or minimal dz, b. A decr in PASI score compared to baseline. PsA: Initial-approve if pt meets a and b: a. Pt is experiencing i, ii, iii, iv or v: i. Actively inflamed joints, ii. Dactylitis, iii. Enthesitis, iv. Axial disease, v. Active skin and/or nail involvement, b. Pt has active PsA and for pts 18 yrs or older, meets i, ii or iii: i. Pt has TF to MTX, leflunomide or another conventional synthetic drug (e.g. sulfasalazine), ii. Pt has intolerance/CI to MTX, leflunomide and another conventional synthetic drug (e.g. sulfasalazine), iii. Pt has predom axial disease. Cont-approve if pt has pos clinical response to tx based on improvement in a, b, c, d or e: a. Number of swollen joints, b. Number of tender joints, c. Dactylitis, d. Enthesitis, e. Axial dz. AS: Init-approve if pt meets a and b: a. The pt must have a confirmed dx of AS as defined by presence of active dz for at least 4 wks defined by any dz specific functional scoring tool (i.e. a BASDAI Index of at least 4, HAQ, MHAQ, etc.) and expert opinion based on clinical features, acute phase reactants or imaging modalities. b. Pt has TF/C/I to 2 different NSAIDs at max tolerated doses. 2. Cont-approve if pt has pos clinical response to tx based on at least 1 objective measure compared to baseline. Examples include ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI, DFI, HAQ-S, and/or serum markers (e.g. CRP, ESR). nr-axSpa: 1. Initial-approve if pt meets a and b: a. Pt has objective signs of inflammation, defined by i or ii: i. CRP elevated beyond ULN for the reporting lab, ii. Sacroiliitis reported on MRI b. Pt has TF/C/I to 2 diff NSAIDs at max tolerated doses 2. Cont-approve if pt has experienced a pos clinical response to tx compared to baseline for at least 1 of the following: Dz activity, CRP, axial status (e.g. lumbar spine motion, chest expansion), total active (swollen and tender) joint count. HS: Init-Approve if pt has tried at least 1 other therapy (Ex: intralesional or oral CS, systemic abx, and isotretinoin). Cont: Approve if pt had pos response from baseline using at least 1 objective measure (e.g. Hurley staging, Sartorius score, PGA, HASI. Enthesitis-related arthritis: Init-approve if pt meets a and b: a. Pt has active dz w/ at least 3 active joints involved and at least 1 site of active enthesitis at baseline or documented by history b. Pt has TF/C/I to NSAID, sulfasalazine or MTX. Cont-approve if pt has improvement in 1 of the following from baseline: Number of flares or joints with active arthritits or joints with limited movement, dactylitis, or enthesitis.

## PART B PREREQUISITE

N/A

## **COTELLIC**

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### **MEDICATION(S)**

COTELLIC

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **CRINONE GEL**

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### **MEDICATION(S)**

CRINONE

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Support of an established pregnancy.

### **EXCLUSION CRITERIA**

Use in patients to supplement or replace progesterone in the management of infertility.

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Secondary amenorrhea, 12 months. Support of an established pregnancy, 9 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **DANZITEN**

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### **MEDICATION(S)**

DANZITEN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **DATROWAY**

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### **MEDICATION(S)**

DATROWAY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **DAURISMO**

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### **MEDICATION(S)**

DAURISMO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **DEFERASIROX**

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### **MEDICATION(S)**

DEFERASIROX

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, ferritin levels

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist or oncologist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

1. For Chronic iron overload due to blood transfusions: Ferritin level consistently greater than 1000 mcg/L
2. For chronic overload in non-transfusion dependent thalassemia syndromes (member meets both a and b): a. Patient has liver iron concentration levels consistently greater than or equal to 5 mg Fe per gram of dry weight prior to initiation of deferasirox AND b. Patient has serum ferritin levels consistently greater than 300 mcg/L prior to initiation of treatment

### **PART B PREREQUISITE**

N/A

## **DEFERIPRONE**

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### **MEDICATION(S)**

DEFERIPRONE, DEFERIPRONE (3 TIMES A DAY)

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, ANC

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist or oncologist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Member meets all of the following (1, 2 and 3): 1. Diagnosis of transfusional iron overload due to one of the following a. Thalassemia syndromes, b. Sickle cell disease, c. Transfusional-dependent anemia AND 2. Absolute neutrophil count (ANC) is greater than  $1.5 \times 10^9/L$  AND 3. Has tried and failed, has intolerance or contraindication to one chelation therapy (e.g. generic deferasirox).

### **PART B PREREQUISITE**

N/A



## DIABETIC SUPPLIES

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### MEDICATION(S)

BD INSULIN SYRINGE, CURITY GAUZE PADS, DROPLET INSULIN SYRINGE, DROPLET MICRON PEN NEEDLE, DROPLET PEN NEEDLE, DROPSAFE PEN NEEDLE, EASY COMFORT 0.5 ML 30GX1/2", EASY COMFORT SYR 1 ML 30GX1/2", EASY TOUCH INSULIN SYR 1 ML, EASY TOUCH SYR 0.5ML 27G12.7MM, EASY TOUCH SYR 0.5ML 28G12.7MM, EASY TOUCH SYR 0.5ML 29G12.7MM, EASY TOUCH SYR 1 ML 27G 12.7MM, EASY TOUCH SYR 1 ML 28G 12.7MM, EASY TOUCH SYR 1 ML 29G 12.7MM, EASY TOUCH PEN NEEDLE 32GX1/4", EASY TOUCH PEN NEEDLE 32GX3/16, EASY-TOUCH INSULIN SYRINGE, CVS COTTON GAUZE 2"X2", STERILE GAUZE PADS 2"X 2", CVS GAUZE PADS 2"X2", GAUZE PAD, STERILE 2"X2", CVS GAUZE PAD 2"X2" STERILE, CVS GAUZE PADS 2" X 2", EQL GAUZE PADS 2"X2", GAUZE PADS 2" X 2 " STERILE, GAUZE PADS NON-STERILE 2X2, GAUZE PADS STERILE 2X2, GAUZE PADS & DRESSINGS - PADS 2 X 2, HM INSULIN SYRINGE, INCONTROL PEN NEEDLE 4MM 32G, INCONTROL PEN NEEDLE 6MM 31G, INCONTROL PEN NEEDLE 8MM 31G, COMFORT POINT PEN NDL 31GX1/4", INSULIN PEN NEEDLE, AIMSCO INS SYR 0.3 ML 29GX1/2", AIMSCO INS SYR 0.3 ML 30GX5/16, AIMSCO INS SYR 0.5 ML 29GX1/2", AIMSCO INS SYR 1 ML 29GX1/2", AIMSCO INS SYR 1 ML 30GX5/16", AIMSCO INSULIN 0.3 ML SYRINGE, AIMSCO INSULIN 0.3 ML SYRNGE, AIMSCO INSULIN 0.5 ML SYRINGE, AIMSCO INSULIN 0.5 ML SYRNGE, AIMSCO INSULIN 1 ML SYRINGE, AIMSCO SYRING 0.3 ML 31GX5/16", AIMSCO SYRING 0.5 ML 30GX5/16", AIMSCO SYRING 0.5 ML 31GX5/16", B-D INSULIN U100-1 ML SYRNG, B-D INSULIN U100-1 ML SYRNGE, B-D INSULIN U40-1 ML SYRINGE, BD INS SYR 0.3 ML 8MMX31G(1/2), BD INS SYR UF 0.3ML 12.7MMX30G, BD INS SYR UF 0.5ML 12.7MMX30G, BD INS SYRN UF 1 ML 12.7MMX30G, BD INS SYRN UF 1 ML 30G 12.7MM, BD INS SYRNG UF 0.3 ML 8MMX31G, BD INS SYRNG UF 0.5 ML 8MMX31G, BD INSULIN SYR 0.3 ML 31GX5/16, BD INSULIN SYR 0.5 ML 28GX1/2", BD INSULIN SYR 0.5 ML 30GX1/2", BD INSULIN SYR 0.5ML 31GX5/16", BD INSULIN SYR 1 ML 27GX5/8", BD INSULIN SYR 1 ML 28GX1/2", BD INSULIN SYR 1 ML 30GX1/2", BD INSULIN SYR 1 ML 31GX5/16", BD INSULIN SYR UF 1 ML 8MMX31G, BD INSULIN U100-1 ML SYRNGE, BL INSULIN 0.3 ML SYRINGE, BL INSULIN 0.5 ML SYRINGE, BL INSULIN 1 ML SYRINGE, BL INSULIN SYRINGE 0.3 ML, BL INSULIN SYRINGE 0.5 ML, BL INSULIN SYRINGE 1 ML, BROOKS INSULIN 0.3 ML SYRN, BROOKS INSULIN 1/2 ML SYRN, BROOKS INSULIN SYRINGE 1 ML, CA INS SYR 0.3 ML 30GX5/16", CA INS SYR 0.3 ML 31GX5/16", CA INS SYR 0.5 ML 30GX5/16", CA INS SYR 0.5 ML 31GX5/16", CA INSULIN SYR 0.3 ML 29GX1/2", CA INSULIN SYR 0.5 ML 29GX1/2", CA INSULIN SYR 1 ML 29GX1/2", CA INSULIN SYR 1 ML 30GX5/16", CA INSULIN SYR 1 ML 31GX5/16", CAREONE INS SYR 1 ML 30GX5/16", CAREONE SYR 0.3 ML 30GX1/2", CAREONE SYR 0.3 ML 31GX5/16", CAREONE SYR 0.5 ML 30GX1/2", CAREONE SYR 0.5 ML 31GX5/16", CAREONE SYR 1 ML 30GX1/2", CAREONE SYR 1 ML 31GX5/16", CVS INSULIN SYR 1 ML 29GX1/2", CVS SYRINGE

1/2 ML, CVS SYRINGE 3/10 ML, D&K INSULIN SYRINGE 0.3 ML, D&K INSULIN SYRINGE 0.5 ML, D&K INSULIN SYRINGE 1 ML, DG INSULIN SYR 29G-3/10 ML, DG INSULIN SYRINGE 28G-0.5 ML, DG INSULIN SYRINGE 28G-1 ML, DG INSULIN SYRINGE 29G-0.5 ML, ECK INSULIN 1 ML SYRINGE, ECK INSULIN 1/2 ML SYRINGE, ECK INSULIN 3/10 ML SYRINGE, ECK INSULIN 3/10 ML SYRINGE, EQL INS SYR 0.3 ML 29GX1/2", EQL INS SYR 0.3 ML 30GX5/16", EQL INS SYR 0.5 ML 29GX1/2", EQL INS SYR 0.5 ML 30GX5/16", EQL INSUL SYR 0.3 ML 31GX5/16", EQL INSUL SYR 0.5 ML 31GX5/16", EQL INSULIN SYR 1 ML 29GX1/2", EQL INSULIN SYR 1 ML 30GX5/16", EQL INSULIN SYR 1 ML 31GX5/16", EXEL INS SYR U100 1 ML 28GX1/2, EXEL INSUL SYR 0.5 ML 28GX1/2", FIFTY50 INS 0.3 ML 31GX5/16", FIFTY50 INS 0.5 ML 31GX5/16", FIFTY50 INS SYR 1 ML 31GX5/16", FIRST CHOICE SYRINGE 0.3 ML, FIRST CHOICE SYRINGE 0.5 ML, FIRST CHOICE SYRINGE 1 ML, FP INSULIN 0.3 ML SYRINGE, FP INSULIN 0.5 ML SYRINGE, FP INSULIN 1 ML SYRINGE, FP INSULIN SYRINGE 0.3 ML, FP INSULIN SYRINGE 0.5 ML, FP INSULIN SYRINGE 1 ML, GNP INS SYRINGE 1 ML 28G 1/2", GNP INSUL SYR 0.5 ML 31GX5/16", HCA INSULIN SYRINGE 0.3 ML, HCA INSULIN SYRINGE 0.5 ML, HCA INSULIN SYRINGE 1 ML, HM INSULIN SYRINGE 0.3 ML, HM INSULIN SYRINGE 0.5 ML, HM INSULIN SYRINGE 1 ML, INS SYR U100 0.5 ML 29GX1/2", INSULIN 1 ML SYRINGE, INSULIN 1/2 ML SYRINGE, INSULIN 3/10 ML SYRINGE, INSULIN SYR 0.3ML 31GX1/4(1/2), INSULIN SYR 1 ML HARD PACK, INSULIN SYRIN 0.3 ML 29GX1/2", INSULIN SYRIN 0.3 ML 30GX1/2", INSULIN SYRIN 0.3 ML 30GX5/16", INSULIN SYRIN 0.3 ML 31GX5/16", INSULIN SYRIN 0.5 ML 28GX1/2", INSULIN SYRIN 0.5 ML 29GX1/2", INSULIN SYRIN 0.5 ML 30G 5/16", INSULIN SYRIN 0.5 ML 30GX5/16", INSULIN SYRIN 0.5 ML 31G 5/16", INSULIN SYRIN 0.5 ML 31GX5/16", INSULIN SYRING 0.5 ML 28G 1/2", INSULIN SYRING 0.5 ML 29G 1/2", INSULIN SYRING 0.5 ML 29GX1/2", INSULIN SYRINGE 0.3 ML, INSULIN SYRINGE 0.3 ML 31GX1/4, INSULIN SYRINGE 0.5 ML, INSULIN SYRINGE 0.5 ML 31GX1/4, INSULIN SYRINGE 1 ML, INSULIN SYRINGE 1 ML 27G 1/2", INSULIN SYRINGE 1 ML 27G 16MM, INSULIN SYRINGE 1 ML 27GX1/2", INSULIN SYRINGE 1 ML 28G 1/2", INSULIN SYRINGE 1 ML 28GX1/2", INSULIN SYRINGE 1 ML 29G 1/2", INSULIN SYRINGE 1 ML 29GX1/2", INSULIN SYRINGE 1 ML 30G 1/2", INSULIN SYRINGE 1 ML 30GX1/2", INSULIN SYRINGE 1 ML 30GX5/16", INSULIN SYRINGE 1 ML 31G 5/16", INSULIN SYRINGE 1 ML 31GX1/4", INSULIN SYRINGE 1 ML 31GX5/16", INSULIN SYRINGE 1/2 ML, INSULIN SYRINGE 28GX0.5 ML, INSULIN SYRINGE 28GX1 ML, INSULIN SYRINGE 29G-0.3 ML, INSULIN SYRINGE 29G-0.5 ML, INSULIN SYRINGE 3/10 ML, INSULIN SYRINGE U-100, INSULIN SYRINGE U100 0.5 ML, INSULIN SYRINGE U100 1 ML, INSULIN SYRINGE U100 1/2 ML, KMART VALU PLUS SYR 3/10 ML, KMART VALU PLUS SYRINGE 1 ML, KRO INS SYRIN 0.3 ML 30GX5/16", KRO INS SYRIN 0.3 ML 31GX5/16", KRO INS SYRIN 0.5 ML 30GX5/16", KRO INS SYRIN 0.5 ML 31GX5/16", KRO INS SYRING 0.5 ML 29GX1/2", KRO INS SYRINGE 1 ML 29GX1/2", KRO INS SYRINGE 1 ML 30GX5/16", KRO INS SYRINGE 1 ML 31GX5/16", KROGER 0.5 ML INSULIN SYRINGE, KROGER 1 ML INSULIN SYRINGE, KROGER INS SYR 1 ML 29GX1/2", KROGER INS SYRINGE 0.5 ML, KROGER INS SYRINGE 3/10 ML, KROGER

INSULIN SYRINGE 0.3 ML, KROGER INSULIN SYRINGE 0.3ML, LEADER INS SYR 0.3 ML 29GX1/2", LEADER INS SYR 0.5 ML, LEADER INS SYR 0.5 ML 28GX1/2", LEADER INS SYR 0.5 ML 29GX1/2", LEADER INS SYR 0.5 ML 30GX1/2", LEADER INS SYR 1 ML, LEADER INS SYR 1 ML 28GX1/2", LEADER INS SYR 1 ML 29GX1/2", LEADER INS SYR 1 ML 30GX1/2", LEADER INS SYR 1 ML 31GX5/16", LEADER INS SYR 3/10 ML, LEADER INSULIN SYRINGE 0.3 ML, LEADER INSULIN SYRINGE 0.5 ML, LEADER INSULIN SYRINGE 1 ML, LEADER SYRING 0.3 ML 31GX5/16", LEADER SYRING 0.5 ML 31GX5/16", LONGS INS SYR 0.5 ML 29GX1/2", LONGS INS SYR 1 ML 29GX1/2", LONGS INSULIN SYRINGE 0.3 ML, LONGS INSULIN SYRINGE 0.5 ML, LONGS INSULIN SYRINGE 1 ML, MAJOR INSULIN SYRINGE 0.3 ML, MAJOR INSULIN SYRINGE 0.5 ML, MAJOR INSULIN SYRINGE 1 ML, MEDIC DRUG INSULIN SYR 0.3 ML, MS INS SYR 0.5 ML 29GX1/2", MS INS SYR 1 ML 29GX1/2", MS INS SYRINGE 1 ML 30GX1/2", MS INSUL SYR 0.3 ML 31GX5/16", MS INSUL SYR 0.5 ML 30GX1/2", MS INSUL SYR 0.5 ML 31GX5/16", MS INSULIN SYR 0.3 ML 29GX1/2", MS INSULIN SYR 1 ML 31GX5/16", MS INSULIN SYRINGE 0.3 ML, MS INSULIN SYRINGE 0.5 ML, MS INSULIN SYRINGE 1 ML, MS INSULIN SYRINGE 3/10 ML, PV INS SYRIN 1 ML 29GX1/2", PV INSUL SYR 0.3 ML 31GX5/16", PV INSUL SYR 0.5 ML 31GX5/16", PV INSULIN SYR 1 ML 31GX5/16", PV INSULIN SYRINGE 0.5 ML, QC INSUL SYR 0.5 ML 31GX5/16", QC INSULIN SYR 1 ML 31GX5/16", QC INSULIN SYRINGE 0.3 ML, QC INSULIN SYRINGE 0.5 ML, QC INSULIN SYRINGE 1 ML, RELI-ON INSULIN 0.3 ML SYR, RELI-ON INSULIN 0.5 ML SYR, RELI-ON INSULIN 1 ML SYR, RELION INSULIN SYR 0.3 ML, RELION INSULIN SYR 0.5 ML, RELION INSULIN SYRINGE 1 ML, SB INS SYR 0.5 ML 29GX1/2", SB INS SYR 0.5 ML 30GX5/16", SB INS SYR 1 ML 29GX1/2", SB INS SYRINGE 1 ML 30GX5/16", SB INSULIN SYR 1 ML 31GX5/16", SB INSULIN SYRINGE 0.3 ML, SB INSULIN SYRINGE 0.5 ML, SB INSULIN SYRINGE 1 ML, SB INSULN SYR 0.5 ML 30GX5/16", SCHNUCKS SYR 0.5 ML 29GX1/2", SCHNUCKS SYR 0.5 ML 30GX5/16", SM INS SYR 0.5 ML 29GX1/2", SM INS SYR 0.5 ML 30GX5/16", SM INS SYR 1 ML 29GX1/2", SM INS SYRING 0.3 ML 30GX5/16", SM INS SYRINGE 1 ML 28GX1/2", SM INS SYRINGE 1 ML 30GX5/16", SM INSUL SYR 0.3 ML 31GX5/16", SM INSUL SYR 0.5 ML 31GX5/16", SM INSULIN SYR 0.3 ML 29GX1/2", SM INSULIN SYR 0.5 ML 28GX1/2", SM INSULIN SYR 1 ML 31GX5/16", SUNMARK INSULIN SYRINGE 0.3 ML, SUNMARK INSULIN SYRINGE 0.5 ML, SUNMARK INSULIN SYRINGE 1 ML, VALUEPLUS SYR 0.3 ML 29GX1/2", VH INS SYR 0.5 ML 29GX1/2", VH INS SYR 1 ML 29GX1/2", WD MEDIC INSULIN SYR 0.3 ML, WD MEDIC INSULIN SYR 0.5 ML, WD MEDIC INSULIN SYRNGE 1 ML, WD MEDIC SYR 0.3 ML 30GX5/16", WD MEDIC SYR 0.5 ML 29GX1/2", WD MEDIC SYR 0.5 ML 30GX5/16", WD MEDIC SYR 1 ML 29GX1/2", WDMEDIC INS SYR 1 ML 30GX5/16", WDMEDIC SYRING 0.3 ML 29GX1/2", INSULIN SYRINGE (DISP) U-100 0.3 ML, INSULIN SYRINGE (DISP) U-100 1 ML, INSULIN SYRINGE (DISP) U-100 1/2 ML, BD INS SYR U-500 1/2ML 6MMX31G, INSUPEN 31G ULTRAFIN NEEDLE, INSUPEN 32G 6MM PEN NEEDLE, INSUPEN 32G 8MM PEN NEEDLE, INSUPEN PEN NEEDLE 31GX5/16", INSUPEN PEN NEEDLE 31GX8MM, ISOPROPYL ALCOHOL 0.7 ML/ML MEDICATED PAD, LITETOUCH INS 0.3 ML 29GX1/2", LITETOUCH INS 0.3 ML

30GX5/16", LITETOUCH INS 0.3 ML 31GX5/16", LITETOUCH INS 0.5 ML 31GX5/16", MINI PEN  
 NEEDLE 32G 4MM, BL MONOJECT SYRINGE 0.5 ML, BL MONOJECT SYRINGE 1 ML, BL  
 MONOJECT SYRINGE 3/10 ML, GNP MONOJECT SYRINGE 0.5 ML, GNP MONOJECT SYRINGE 1  
 ML, GNP MONOJECT SYRINGE 3/10 ML, KIN-RAY MONOJECT SYRINGE, KP MONOJECT  
 SYRINGE 0.5 ML, KP MONOJECT SYRINGE 1 ML, KP MONOJECT SYRINGE 3/10 ML, LEADER  
 MONOJECT SYR 0.5 ML, LEADER MONOJECT SYR 1 ML, LEADER MONOJECT SYR 3/10 ML,  
 LEGEND MONOJECT SYRINGE 1 ML, LEGEND MONOJECT SYRNGE 0.3 ML, LEGEND  
 MONOJECT SYRNGE 0.5 ML, MED SHOPPE MONOJECT SYR 3/10, MED SHOPPE MONOJECT  
 SYR 0.5, MED SHOPPE MONOJECT SYR 1 ML, MED-FAST MONOJECT SYRINGE, MONOJECT  
 0.3 ML INSULIN SYR, MONOJECT 0.3 ML SYRN 29GX1/2", MONOJECT 1 ML SYRN 25X5/8",  
 MONOJECT INSUL SYR U100, MONOJECT INSUL SYR U100 0.5 ML, MONOJECT INSUL SYR  
 U100 1 ML, PHARM MONOJECT SYRINGE 0.5 ML, QC MONOJECT SYRINGE 0.5 ML, QC  
 MONOJECT SYRINGE 1 ML, QC MONOJECT SYRINGE 3/10 ML, RUGBY MONOJECT SYRINGE  
 0.5 ML, RUGBY MONOJECT SYRINGE 1 ML, VALUE HEALTH MONOJECT SYRN, BD NANO 2  
 GEN PEN NDL 32G 4MM, NEEDLES, INSULIN DISP., SAFETY, NOVOFINE PLUS, FIFTY50 PEN  
 31G X 3/16" NEEDLE, FIFTY50 PEN 31G X 5/16" NEEDLE, FIFTY50 PEN NEEDLE 32G X 5/32", GS  
 PEN NEEDLE 31G X 1/4", GS PEN NEEDLE 31G X 5/16", GS PEN NEEDLE 31G X 5MM, GS PEN  
 NEEDLE 31G X 6MM, GS PEN NEEDLE 31G X 8MM, GS PEN NEEDLE 32G X 4MM, KRO PEN  
 NEEDLE 4MM X 32G, KRO PEN NEEDLE 5MM X 31G, KRO PEN NEEDLE 6MM X 31G, KRO PEN  
 NEEDLE 8MM X 31G, PEN NEEDLE 30G 8MM, PEN NEEDLE 31G 5MM, PEN NEEDLE 31G 6MM,  
 PEN NEEDLE 31G 8MM, PEN NEEDLE 31G X 1/4", PEN NEEDLE 31G X 3/16", PEN NEEDLE 31G X  
 5/16", PEN NEEDLE 32G 4MM, PEN NEEDLE 32G X 5/32", PEN NEEDLE 4MM 32G, PEN NEEDLE  
 5MM 31G, PV PEN NEEDLES 6MM 31G, QC UNIFINE PENTIP 6MM 31G, RELION PEN NEEDLE  
 31G 6MM, RELION PEN NEEDLE 31GX1/4", RELION PEN NEEDLE 31GX5/16", RELION PEN  
 NEEDLE 32GX5/32", LEADER PEN NEEDLES 31G, PEN NEEDLES 6MM 31G, PV PEN NEEDLES  
 8MM 31G, QC UNIFINE PENTIP 8MM 31G, PENTIPS, PENTIPS PEN NEEDLE, PRODIGY INS SYR  
 1ML 28GX1/2", PRODIGY SYRNG 0.5 ML 31GX5/16", RELION ULTRA COMFORT, FP STERILE  
 PAD 2" X 2", BL STERILE PADS 2"X2", ECK STERILE PADS 2"X2", GNP STERILE PADS 2"X2", PV  
 STERILE PADS 2" X 2", QC STERILE PADS 2"X2", RA STERILE PADS, SM STERILE PADS 2" X 2",  
 STERILE PADS 2" X 2", STERILE PADS 2"X2", SURE COMFORT PEN NDL 32G 4MM, TECHLITE  
 0.3 ML 31GX6MM (1/2), TECHLITE 0.3 ML 31GX8MM (1/2), TECHLITE 0.5 ML 30GX12MM (1/2),  
 TECHLITE 0.5 ML 31GX6MM (1/2), TECHLITE 0.5 ML 31GX8MM (1/2), TECHLITE INS SYR 1 ML  
 30GX12MM, TECHLITE INS SYR 1 ML 31GX6MM, TECHLITE INS SYR 1 ML 31GX8MM, TECHLITE  
 26G LANCETS, TECHLITE 28G LANCETS, TECHLITE 30G LANCETS, TECHLITE PEN NEEDLE  
 29GX1/2", TECHLITE PEN NEEDLE 31GX3/16", TECHLITE PEN NEEDLE 31GX5/16", TECHLITE  
 PEN NEEDLE 32GX1/4", TECHLITE PEN NEEDLE 32GX5/32", TECHLITE PLUS PEN NEEDLE,  
 TRUEPLUS PEN NEEDLE, GNP ULTICARE PEN NDL 31G 8MM, GNP ULTICARE PEN NDL 32G

4MM, GNP ULTICARE PEN NDL 32G 6MM, HM ULTICARE PEN NEEDLE 4MM 32G, HM ULTICARE PEN NEEDLE 8MM 31G, ULTICARE PEN NEEDLE 4MM 32G, ULTICARE PEN NEEDLE 8 MM 31G, ULTICARE PEN NEEDLE 8MM 31G, ULTICARE PEN NEEDLES 4MM 32G, ULTICARE PEN NEEDLES 6MM 32G, ULTICARE PEN NEEDLES 8MM 31G, YOURX ULTICARE PEN NDL 4MM 32G, YOURX ULTICARE PEN NDL 8MM 31G, ULTIGUARD SAFEPACK 32G 4MM, ULTRA COMFORT, CAREONE UNIFINE PENTIP 4MM 32G, CAREONE UNIFINE PENTIP 5MM 31G, CAREONE UNIFINE PENTIP 6MM 31G, CAREONE UNIFINE PENTIP 8MM 31G, CAREONE UNIFINE PNTIP 12MM 29G, DR UNIFINE PENTIPS 12MM NDL, DR UNIFINE PENTIPS 6MM NDL, DR UNIFINE PENTIPS 8MM NDL, PC UNIFINE PENTIPS 12MM NEEDLE, PC UNIFINE PENTIPS 31GX3/16", PC UNIFINE PENTIPS 6MM NEEDLE, PC UNIFINE PENTIPS 8MM NEEDLE, PV UNIFINE PENTIPS 31GX3/16", PV UNIFINE PENTIPS 32GX5/32", QC UNIFINE PENTIPS 32GX5/32", QC UNIFINE PENTIPS 4MM 32G, SHOPKO UNIFINE PENTIPS 4MM 32G, SHOPKO UNIFINE PENTIPS 5MM 31G, SHOPKO UNIFINE PENTIPS 8MM 31G, SHOPKO UNIFINE PNTIPS 12MM 29G, UNIFINE PENTIP 0.5CC NEEDLE, UNIFINE PENTIPS 12MM 29G, UNIFINE PENTIPS 12MM NEEDLE, UNIFINE PENTIPS 31G 5MM, UNIFINE PENTIPS 31G 6MM, UNIFINE PENTIPS 31G 8MM, UNIFINE PENTIPS 31GX3/16", UNIFINE PENTIPS 32G 4MM, UNIFINE PENTIPS 32G 6MM, UNIFINE PENTIPS 32GX1/4", UNIFINE PENTIPS 32GX5/32", UNIFINE PENTIPS 33GX5/32", UNIFINE PENTIPS 6MM 31G, UNIFINE PENTIPS 6MM NEEDLE, UNIFINE PENTIPS 8MM 31G, UNIFINE PENTIPS 8MM NEEDLE, UNIFINE PENTIPS 8MM NEEDLES, UNIFINE PENTIPS MAXFLOW, UNIFINE PENTIPS PLUS, UNIFINE PENTIPS PLUS MAXFLOW, UNIFINE SAFECONTROL PEN NEEDLE, UNIFINE ULTRA PEN NEEDLE, VANISHPOINT 29GX1/2" 1 ML SR, VEO INSULIN SYRINGE, VERIFINE PEN NEEDLE 31G X 8MM, VERIFINE PEN NEEDLE 32G X 4MM

#### **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**

3 years

**OTHER CRITERIA**

Approve if the prescriber confirms that the medical supply is being requested for a use that is directly associated with delivering insulin to the body.

**PART B PREREQUISITE**

N/A

## **DICHLORPHENAMIDE**

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### **MEDICATION(S)**

DICHLORPHENAMIDE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, prior medication trials, potassium levels

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 2 months, Continuation: 3 years

### **OTHER CRITERIA**

Hypokalemic periodic paralysis (HypoPP) and related variants initial therapy: Members must meet all of the following (1, 2, 3, and 4): 1. HypoPP has been confirmed by one of the following (a, b or c): a. Serum potassium concentration of less than 3.5 mEq/L during a paralytic attack OR b. Family history of the condition OR c. Genetically confirmed skeletal muscle calcium or sodium channel mutation, 2. Member had improvements in paralysis attack symptoms with potassium intake, 3. Member has tried and failed oral acetazolamide therapy, 4. The prescribing physician has excluded other reasons for acquired hypokalemia (e.g. renal, adrenal, thyroid dysfunction, renal tubular acidosis, diuretic and laxative abuse). Hyperkalemia periodic paralysis (HyperPP) and related variants initial therapy: Members must meet all of the following (1, 2, and 3): 1. HyperPP has been confirmed by one of the following (a, b, c or d) a. An increase from baseline in serum potassium concentration of greater than or equal to 1.5 mEq/L during a paralytic attack OR b. Serum potassium concentration during a paralytic

attack greater than 5.0 mEq/L OR c. A family history of the condition OR d. Genetically confirmed skeletal muscle sodium channel mutation 2. Prescribing physician has excluded other reasons for acquired hyperkalemia (e.g. drug abuse, renal and adrenal dysfunction) 3. Member has tried and failed oral acetazolamide therapy. HypoPP, HyperPP and related variants continuation of therapy: Patient has responded to dichlorphenamide (e.g. decrease in the frequency or severity of paralytic attacks) as determined by the prescribing physician.

## **PART B PREREQUISITE**

N/A



## **DICLOFENAC**

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### **MEDICATION(S)**

DICLOFENAC SODIUM 3% GEL

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **DIFICID**

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### **MEDICATION(S)**

DIFICID

### **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**

Ten days.

### **OTHER CRITERIA**

Must first try and fail or have recurrence of disease after two courses of vancomycin in the past 90 days. If members are allergic to vancomycin, Dificid will be approved. If members are continuing therapy started during a hospitalization, Dificid will be approved.

### **PART B PREREQUISITE**

N/A

## **DOPTELET**

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### **MEDICATION(S)**

DOPTELET

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, platelet count

### **AGE RESTRICTION**

18 years and older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Thrombo w/chronic liver disease-7 days. Chronic ITP-Initial - 3months, Cont - 3 years

### **OTHER CRITERIA**

Thrombocytopenia with chronic liver disease-Approve if the patient has a current platelet count less than  $50 \times 10^9/L$  AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting therapy. Chronic ITP-approve if the patient has a platelet count less than 30,000 microliters or less than 50,000 microliters and is at an increase risk of bleeding AND has tried one other therapy (for example, corticosteroids, immunoglobulins, azathioprine, cyclophosphamide and/or rituximab) or has undergone splenectomy. Continuation: Approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.

### **PART B PREREQUISITE**

N/A

## **DOXEPIN TOPICAL**

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### **MEDICATION(S)**

DOXEPIN 5% CREAM

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of moderate pruritus. Patient has atopic dermatitis or lichen simplex chronicus.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 month

### **OTHER CRITERIA**

The patient had an inadequate response, contraindication, or intolerance to at least one medium potency topical corticosteroid, or is not a candidate for topical corticosteroids (e.g., treatment is on face, axilla, or groin).

### **PART B PREREQUISITE**

N/A

## **DPP-4 THERAPY**

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### **MEDICATION(S)**

ALOGLIPTIN, ALOGLIPTIN-METFORMIN, ALOGLIPTIN-PIOGLIT 12.5-30 MG, ALOGLIPTIN-PIOGLIT 25-15 MG TB, ALOGLIPTIN-PIOGLIT 25-30 MG TB, ALOGLIPTIN-PIOGLIT 25-45 MG TB, SAXAGLIPTIN HCL, SAXAGLIPTIN-METFORMIN ER

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Janumet, Januvia, Jentadueto, Jentadueto XR and Tradjenta are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis, OR the member has a documented contraindication to one preferred formulary

alternative, or the member had an adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternative, OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

**PART B PREREQUISITE**

N/A

## **DPP-4/SGLT2**

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### **MEDICATION(S)**

QTERN, STEGLUJAN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Glyxambi and Trijardy XR are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis, OR the member has a documented contraindication to one preferred formulary alternative, or the member had an adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternative, OR the member has a clinical condition for which there is no listed preferred

formulary alternative to treat the condition based on published guidelines or clinical literature.

**PART B PREREQUISITE**

N/A



## **DROXIDOPA**

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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**

Diagnosis, Medication history, Reauth: positive clinical response to therapy

### **AGE RESTRICTION**

18 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, a cardiologist or neurologist

### **COVERAGE DURATION**

Initial: 2 months, Continuation: 1 year

### **OTHER CRITERIA**

Neurogenic orthostatic hypotension (nOH): 1. Initial - approve if the patient meets the following criteria (a and b): a. Patient has been diagnosed with symptomatic nOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy AND, b. Patient has tried/failed, has contraindication or intolerance to midodrine and fludrocortisone acetate, 2. Continuation – approve if the patient meets the following criteria: a. If patient is new to plan, meets initial criteria at time they had started the medication, b. Documented dose and frequency are within the FDA approved Dosing and Frequency, c. Patient has experienced a positive clinical response to therapy

### **PART B PREREQUISITE**

N/A

## **DUPIXENT**

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### **MEDICATION(S)**

DUPIXENT PEN, DUPIXENT 200 MG/1.14 ML SYRING, DUPIXENT 300 MG/2 ML SYRINGE

### **PENDING CMS APPROVAL**

## **EGRIFTA**

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### **MEDICATION(S)**

EGRIFTA SV

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis is HIV-associated lipodystrophy. Egrifta is prescribed for the reduction of excess abdominal fat. Patient is HIV-infected.

### **AGE RESTRICTION**

Adults, 18 years of age and older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of HIV (eg, infectious disease, oncology).

### **COVERAGE DURATION**

Authorization will be for 12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ELAHERE**

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### **MEDICATION(S)**

ELAHERE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ELIGARD**

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### **MEDICATION(S)**

ELIGARD, LEUPROLIDE DEPOT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ELREXFIO**

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### **MEDICATION(S)**

ELREXFIO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ELZONRIS**

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### **MEDICATION(S)**

ELZONRIS

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **EMGALITY**

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### **MEDICATION(S)**

EMGALITY PEN, EMGALITY SYRINGE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Chronic or episodic migraine: 12 months. Episodic cluster (Emgality): 6 months.

### **OTHER CRITERIA**

For chronic or episodic migraine initiation of therapy: The member must have a diagnosis of migraine.

For episodic cluster headache: approve.

### **PART B PREREQUISITE**

N/A

## **ENBREL**

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### **MEDICATION(S)**

ENBREL 25 MG/0.5 ML SYRINGE, ENBREL 25 MG/0.5 ML VIAL, ENBREL 50 MG/ML SYRINGE, ENBREL MINI, ENBREL SURECLICK

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Graft versus host disease, Behcet's disease

### **EXCLUSION CRITERIA**

Concurrent use with biologic therapy or targeted synthetic DMARD.

### **REQUIRED MEDICAL INFORMATION**

RA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. Member has documented moderate to severe active disease. pJIA: Diagnosis of pJIA as evidenced by 5 or more joints with active arthritis. Documented baseline 10-joint clinical juvenile arthritis disease activity score (cJADAS-10). PsA: Diagnosis, reauth: positive clinical response. AS: Diagnosis, pre-requisite medication trials, objective measure at initiation and continuation (examples outlined in other criteria). The member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc.) and an expert opinion based on one of the following: clinical features, acute phase reactants or imaging modalities. PP: Diagnosis, PASI score, reauth: positive response. GVHD: diagnosis, reauth: positive response. Behcet's: Diagnosis, pre-requisite medication trial, reauth: positive response (Ex dependent upon organ involvement but may include best-corrected visual acuity, serum markers (e.g., CRP), ulcer depth, number and/or lesion size. For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved or medically accepted Dosing and Frequency.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

RA/AS/pJIA prescribed by or in consultation with a rheumatologist. PsA, prescribed by or in consultation with a rheumatologist or a dermatologist. PP, prescribed by or in consultation with a

dermatologist. GVHD, prescribed by or in consultation with an oncologist, hematologist, or a transplant center physician. Behcet's disease, prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.

## **COVERAGE DURATION**

GVHD: 1 month, continuation 3 months. All others: Initial 6 months, continuation 3 years

## **OTHER CRITERIA**

RA-Initial—approve if the pt has TF 1 conventional synthetic DMARD for at least 3 mo (e.g. MTX, leflunomide, hydroxychloroquine, sulfasalazine). Cont—approve if pt is responding pos to tx based on improvement in pt-reported dz sx or obj measurement/tool (e.g. CDAI, PAS, PAS-II, RAPID3, SDAI) as compared to baseline. pJIA-Initial—approve if pt has TF 1 of the following conventional tx at max tolerated doses for a min 6-wk trial (a, b or c): a. MTX, b. Leflunomide, c. Sulfasalazine. Cont—approve if pt has improvement in dz response based on a, b, c or d: a. Number of tender and swollen joint counts, b. Reduction of CRP c. Improvement of PGA, d. Improvement in cJADAS-10. PsA:Initial—approve if pt meets a and b: a. Pt is currently experiencing i, ii, iii, iv or v: i. Actively inflamed joints, ii. Dactylitis, iii. Enthesitis, iv. Axial disease, v. Active skin and/or nail involvement, b. Has active PsA. Cont—approve if pos clinical response to tx based on improvement in any of the following from baseline (a, b, c, d or e): a. Number of swollen joints, b. Number of tender joints, c. Dactylitis, d. Enthesitis, e. Axial dz. AS:Initial—approve if the pt has TF/I/CI to 2 diff NSAIDs at max tolerated doses. Cont—approve if experienced a pos clinical response to tx based on at least 1 obj measure compared to baseline. Ex include ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI, DFI, HAQ-S, and/or serum markers (e.g., CRP, ESR). PP:Initial:Approve if pt meets a and b: a. Has dx of mod/severe PP and 1 of the following (i, ii or iii): i. PASI score of 10 or more, ii. At least 3% BSA affected, 3. PP affects hands, feet, scalp, face or genital area, b. Has TF/C/I to 2 or more of the following: i. Phototherapy (PUVA, UVB), ii. Topical tx (CS, calcipotriene, retinoid), iii. Systemic non-biologic DMARDs (e.g. MTX, cyclosporine, acitretin). Cont: Approve if pos response based on meeting a or b: a. Achieved/maintained clear/minimal dz, b. Decr in PASI score compared to baseline. GVHD: Init: Approve if pt has tried at least 1 conventional systemic tx for GVHD (Ex systemic CS, antithymocyte globulin, cyclosporine, tacrolimus). Cont: approve if pt meets a or b: a. When assessed by at least 1 obj measure, pt experienced a pos clinical response from baseline. Ex include normalization of LFTs, RBC count, or PLT count, or resolution of fever or rash. b. Compared with baseline, pt has pos response in at least 1 sx such as improvement in skin, oral mucosal, ocular, or GI sx (e.g., N/V, anorexia). Behcet's: Initial: Approve if pt has tried at least 1 conventional tx (e.g. CS, immunosuppressants, interferon alfa). Cont: Pt has pos clinical response from baseline.

## **PART B PREREQUISITE**

N/A



## **ENDARI**

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### **MEDICATION(S)**

ENDARI, L-GLUTAMINE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Glutamine will be used to reduce the acute complications of sickle cell disease.

### **AGE RESTRICTION**

The patient is greater than or equal to 5 years of age.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist or oncologist.

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

The patient is currently taking Hydroxyurea or has an intolerance or contraindication to Hydroxyurea therapy.

### **PART B PREREQUISITE**

N/A

## **ENSPRYNG**

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### **MEDICATION(S)**

ENSPRYNG

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant use with Soliris (eculizumab), rituximab or Uplizna (inebilizumab-cdon)

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, Previous therapies tried

### **AGE RESTRICTION**

18 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist or ophthalmologist

### **COVERAGE DURATION**

Initial or continuation: 1 year

### **OTHER CRITERIA**

For initial therapy, patient must meet following criteria (i, ii, AND iii): i. Neuromyelitis optica spectrum disorder diagnosis was confirmed by blood serum test positive for anti-aquaporin-4 antibody AND ii. Patient is currently receiving or has previously tried two of the following systemic therapies used in the maintenance setting (a, b, c, or d): a. Azathioprine OR b. Corticosteroid OR c. Mycophenolate mofetil OR d. Rituximab AND (Note: An exception to the requirement for a trial of a systemic therapy can be made if the patient has already tried Soliris (eculizumab injection) or Uplizna (inebilizumab-cdon injection) for neuromyelitis optica spectrum disorder. Patients who have already tried Soliris or Uplizna for neuromyelitis optica spectrum disorder are not required to try another systemic agent. iii. Patient has a history of at least one relapse (acute attack from neuromyelitis spectrum disorder) in the last 12 months. If patient is currently receiving Enspryng, approve if the patient meets the following (i AND ii): i. Neuromyelitis optica spectrum disorder diagnosis was confirmed by blood serum test positive for anti-

aquaporin-4 antibody ii. According to the prescriber, patient has had clinical benefit from the use of Enspryng (Note: Examples of clinical benefit include reduction in relapse rate, reduction in symptoms (e.g., pain, fatigue, motor function), and a slowing progression in symptoms.)

**PART B PREREQUISITE**

N/A

## ENTYVIO SC

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### MEDICATION(S)

ENTYVIO PEN

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD

### REQUIRED MEDICAL INFORMATION

UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score. CD: Diagnosis, pre-requisite medication trials (if applicable), Reauth: positive clinical response.

### AGE RESTRICTION

18 years and older

### PRESCRIBER RESTRICTION

Prescribed by or in consultation with a gastroenterologist

### COVERAGE DURATION

Initial: 6 months, Continuation: 1 year

### OTHER CRITERIA

1. Moderately to severely active Ulcerative Colitis-Initial therapy: Approve if the patient has tried TWO of the following preferred products: a preferred adalimumab product, Skyrizi, a preferred ustekinumab (SC), Rinvoq, Xeljanz/XR tablets and Zeposia. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Preferred ustekinumab products include Stelara and Yesintek. A previous trial with a non-preferred adalimumab or ustekinumab would also count. Continuation therapy: Approve if the patient meets ALL of the following (i, ii, iii and iv): i. If pt is new to plan, meets initial criteria at time they had started the med, ii. Pt has been established on the requested medication for at least 5 months



iii. Pt has experienced a pos clinical response compared to baseline as evidenced by improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria) iv. Documented dose and frequency are within the FDA approved Dosing and Frequency. 2. Moderately to severely active CD-Initial therapy: Approve if the patient meets ALL of the following (i, ii, iii and iv): i. Documented diagnosis of moderate to severe Crohn's disease, ii. Patient is currently experiencing one of the following (a, b, c, d or e): a. Frequent diarrhea and abdominal pain, b. At least 10% weight loss c. Complication such as obstruction, fever, abdominal mass, d. Abnormal lab values (e.g. CRP), e. CD Activity Index (CDAI) greater than 20, iii. According to the prescriber, the patient is currently receiving Entyvio intravenous or will receive induction dosing with Entyvio intravenous within 2 months prior to initiating therapy with Entyvio subcutaneous, iv. Patient has tried TWO of the following preferred products: a preferred adalimumab product, Skyrizi SQ, a preferred ustekinumab (SC) or Rinvoq. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Preferred ustekinumabs include Stelara and Yesintek. Continuation therapy: Approve if the patient meets ALL of the following (i, ii, iii and iv): i. If patient is new to plan, meets initial criteria at time they had started the medication, ii. Patient has been established on the requested medication for at least 5 months. iii. Patient has documentation of positive clinical response to therapy as evidenced by at least one of the following (a or b): a. Improvement in intestinal inflammation (e.g. mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline b. Reversal of high fecal output state iv. Documented dose and frequency are within the FDA approved Dosing and Frequency

## **PART B PREREQUISITE**

N/A

## **EPCLUSA**

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### **MEDICATION(S)**

EPCLUSA, SOFOSBUVIR-VELPATASVIR

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Indications consistent with current AASLD/IDSA guidance

### **EXCLUSION CRITERIA**

Combination use with other direct acting antivirals, excluding ribavirin

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

3 years or older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.

### **COVERAGE DURATION**

Will be consistent with AASLD/IDSA guidance

### **OTHER CRITERIA**

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

### **PART B PREREQUISITE**

N/A

## **EPIDIOLEX**

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### **MEDICATION(S)**

EPIDIOLEX

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

The member is 1 year of age or older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

Lifetime.

### **OTHER CRITERIA**

For seizures associated with Lennox-Gastaut Syndrome, the patient must have a previous trial of ONE of the following: lamotrigine, topiramate, rufinamide, clobazam, valproate, felbamate or clonazepam. For seizures associated with Dravet Syndrome, the patient must have a previous trial of ONE of the following: valproate, clobazam, topiramate, Diacomit or Fintepla. For tuberous sclerosis complex approve if the patient has tried at least one other antiepileptic drug.

### **PART B PREREQUISITE**

N/A

## **EPKINLY**

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### **MEDICATION(S)**

EPKINLY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ERIBULIN**

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### **MEDICATION(S)**

ERIBULIN MESYLATE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ERIVEDGE**

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### **MEDICATION(S)**

ERIVEDGE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ERLEADA**

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### **MEDICATION(S)**

ERLEADA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **EVEKEO**

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### **MEDICATION(S)**

AMPHETAMINE SULFATE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Weight loss.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## EVEROLIMUS

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### MEDICATION(S)

EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2 MG TAB FOR SUSP, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 3 MG TAB FOR SUSP, EVEROLIMUS 5 MG TAB FOR SUSP, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, TORPENZ

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

N/A

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

1 year

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

## **EVICORE ONCOLOGY DRUGS**

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### **MEDICATION(S)**

AVMAPKI-FAKZYNJA, EMRELIS, IBTROZI, IVRA, ROMVIMZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **EVRYSDI**

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### **MEDICATION(S)**

EVRYSDI

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Pregnant patients, female patients not utilizing effective contraception during treatment and for 1 month after the last dose of Evrysdi

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a physician who specializes in the management of patients with spinal muscular atrophy and/or neuromuscular disorders (initial and continuation)

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Spinal Muscular Atrophy, Initial Treatment - Approve if the patient meets all of the following (a, b and c): a. Patient has baseline motor ability assessment that suggests spinal muscular atrophy (based on age, motor ability, and development) is provided from one of the following exams: (i, ii, iii, iv, v, vi, or vii) i. Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [Item 22], ii. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), iii. Hammersmith Functional Motor Scale Expanded (HFMSE), iv. Hammersmith Infant Neurological Exam Part 2 (HINE-2), v. Motor Function Measure-32 Items (MFM-32), vi. Revised Upper Limb Module (RULM) test, OR vii. World Health Organization motor milestone scale AND b. Has had a genetic test confirming the diagnosis of spinal muscular atrophy with bi-allelic mutations in the survival motor neuron 1 (SMN1)

gene reported as at least one of the following: homozygous deletion, homozygous mutation, or compound heterozygous mutation [documentation required] AND c. The patient meets all of the following criteria (i, ii and iii): i. Has two to four survival motor neuron 2 (SMN2) gene copies [documentation required], ii. The patient has objective signs consistent with spinal muscular atrophy Types 1, 2, or 3 [documentation required], and iii. For patients who have received prior treatment with a survival motor neuron 2 (SMN2)-directed antisense oligonucleotide, the prescriber attests that further therapy with this product will be discontinued. Patients currently receiving Evrysdi approve if the patient meets all of the following (a, b and c): a. Patient meets all of the requirements for initial therapy, b. Patient has responded to Evrysdi, c. Patient continues to have benefit from ongoing Evrysdi therapy by the most recent (within the past 4 months) physician monitoring/assessment tool OR patient must have had a positive clinical response from pretreatment baseline (i.e., within the past 4 months) from one of the following exams: (i, ii, iii, iv, v, vi or vii): i. Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) [Item 22], ii. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), iii. Hammersmith Functional Motor Scale Expanded (HFMSE), iv. Hammersmith Infant Neurological Exam Part 2 (HINE-2), v. Motor Function Measure-32 Items (MFM-32), vi. Revised Upper Limb Module (RULM) test or vii. World Health Organization motor milestone scale.

## **PART B PREREQUISITE**

N/A

## **EXKIVITY**

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### **MEDICATION(S)**

EXKIVITY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **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**

Member will not be using in combination with Xolair or another Anti-Interleukin monoclonal antibody

### **REQUIRED MEDICAL INFORMATION**

Diagnosis. Previous therapy. Peripheral blood eosinophil count.

### **AGE RESTRICTION**

Asthma – 6 years and older. EGPA – 18 years and older

### **PRESCRIBER RESTRICTION**

Asthma: prescribed by or in consultation with an allergist, immunologist or pulmonologist. EGPA: prescribed by or in consultation with an allergist, immunologist, pulmonologist, hematologist or rheumatologist.

### **COVERAGE DURATION**

Initial 6 months. Continuation, indefinitely.

### **OTHER CRITERIA**

Asthma: Pt has dx of severe asthma w/ an eosinophilic phenotype. Must have peripheral blood eosinophil count greater than or equal to 150 cells per microliter w/in the previous 6 weeks (prior to tx with any anti-interleukin [IL-5] therapy). Must have received at least 3 months of combo therapy with an ICS AND one of the following: inhaled LABA, inhaled LAMA, LTRA, theophylline. Asthma continues to be uncontrolled as defined by one of the following: One or more asthma exacerbations requiring tx w/ systemic CS in the previous year, One or more asthma exacerbations requiring hospitalization or tx in an ED in the previous year, Has FEV1 less than 80 pct predicted for adults OR FEV1 less than 90 pct for patients ages 12 to 18 years old, has FEV1/FVC less than 0.80, or asthma worsens upon tapering of oral CS therapy. NOTE: An exception to the requirement for a trial of one additional asthma

controller/maintenance med can be made if the pt has already received anti-IL-5 therapy (e.g., Cinqair, Nucala) used in combo with an ICS for at least 3 months. Cont-Pt has responded to tx as determined by the prescribing physician (e.g., decr asthma exacerbations, decr asthma symptoms, decr hospitalizations/ED/urgent care/physician visits due to the asthma, decr requirement for oral CS therapy), AND pt continues to receive tx with an ICS. EGPA: a.Initial: Approve if the patient meets all of the following (i, ii, iii, iv): i. Diagnosis of EGPA has been confirmed based on history of presence of asthma and eosinophilia and at least 2 of the following: 1. Biopsy with eosinophilic vasculitis or perivascular/granulomatous inflammation, 2. Mono- or polyneuropathy, 3. Non-fixed pulmonary infiltrates, 4. Sino-nasal abnormality, 5. Cardiomyopathy, 6. Glomerulonephritis, 7. Alveolar hemorrhage, 8. Palpable purpura, 9. ANCA positive (myeloperoxidase or proteinase 3), ii. Patient has a history of relapsing (at least 1 confirmed EGPA relapse within the past 2 years and more than 12 weeks prior to starting the requested medication) or refractory disease (failure to attain remission at an oral corticosteroid dose less than or equal to 7.5 mg/day of prednisolone or equivalent for at least 3 months and within 6 months prior to starting the requested medication or recurrence of symptoms upon oral corticosteroid tapering at any dose greater than or equal to 7.5 mg/day prednisolone or equivalent), iii. Patient is currently on a systemic corticosteroid for at least 4 weeks, iv. Blood eosinophil count is greater than or equal to 150 cells/microL within the previous 4 weeks or prior to treatment with any monoclonal antibody that may alter eosinophil levels (for example, Nucala, Cinqair), b. Continuation: Approve if the patient meets the following: i. Patient has responded to therapy (e.g. reduced rate of relapse, corticosteroid dose reduction, reduced eosinophil levels) .

## **PART B PREREQUISITE**

N/A

## **FILGRASTIM**

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### **MEDICATION(S)**

ZARXIO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Severe chronic neutropenia: 6 mo. AIDS: 4 mo. Aplastic or agranulocytosis: 1 mo. All others: 1 year.

### **OTHER CRITERIA**

1. Severe Chronic Neutropenia - Member must have a diagnosis of congenital, cyclic or idiopathic neutropenia
2. Neutropenia associated with acquired immunodeficiency syndrome - Member has diagnosis of AIDS with neutropenia
3. Aplastic anemia – approve
4. Agranulocytosis - Member must have diagnosis of congenital or drug-induced agranulocytosis

### **PART B PREREQUISITE**

N/A



## **FINTEPLA**

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### **MEDICATION(S)**

FINTEPLA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

2 years and older (initial therapy)

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

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

### **PART B PREREQUISITE**

N/A

## **FIRAZYR**

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### **MEDICATION(S)**

ICATIBANT, SAJAZIR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Evidence of autoantibodies against the C1-INH protein, underlying lymphoproliferative, malignant, or autoimmune disorder that causes angioedema attacks, use for prophylaxis of HAE attacks, Use in combination with other agents approved for acute treatment of HAE attack (e.g. Berinert, Kalbitor, Ruconest)

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, lab results (C1-INH inhibitor, C1-INH functional level, C4 levels, C1q levels), genetic testing (if applicable)

### **AGE RESTRICTION**

18 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by an immunologist, allergist, otolaryngologist or rheumatologist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Hereditary Angioedema - Treatment of acute attacks – initial therapy – patient meets all of the following (1 and 2): 1. The patient has HAE as confirmed by one the following diagnostic criteria: i. Hereditary angioedema due to a deficiency of C1INH - patient has documentation of measurements for each of the following tests (a, b and c): a. Low serum complement factor 4 (C4) level at baseline, as defined by the laboratory reference values AND b. Low C1 inhibitor (C1-INH) level OR low C1-INH functional level (i.e. functional C1-INH less than 50% or below lower limit of normal laboratory reference range) at baseline, as defined by the laboratory reference values AND b. C1q levels are within normal limits at

baseline, as defined by the laboratory reference values or ii. Hereditary angioedema with normal C1INH - patient has documentation of all of the following (a, b and c): a. A history of recurrent angioedema in the absence of concomitant urticaria and no concomitant use of medication known to cause angioedema, b. Documentation of normal or near normal C4, C1-INH antigen and C1-INH function, c. One of the following (1 or 2): 1. Demonstration of a mutation associated with the disease or 2. A positive family history of recurrent angioedema and documented lack of efficacy of high-dose antihistamine therapy (for example, cetirizine at 40 mg/d or the equivalent) for at least 1 month or an interval expected to be associated with 3 or more attacks of angioedema, whichever is longer AND 2. The patient is experiencing at least one symptom of moderate to severe HAE attacks (e.g. airway swelling, severe abdominal pain, facial swelling, painful facial distortion, extremity swelling causing disability). Treatment of acute attacks – continuation therapy – patient meets all of the following (1 and 2): 1. If patient is new to plan, they met initial criteria at time of starting the medication, 2. Patients has had a favorable clinical response (e.g. decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment

#### **PART B PREREQUISITE**

N/A

## **FIRMAGON**

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### **MEDICATION(S)**

FIRMAGON

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **FOTIVDA**

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### **MEDICATION(S)**

FOTIVDA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **FRINDOVYX**

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### **MEDICATION(S)**

FRINDOVYX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **FRUZAQLA**

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### **MEDICATION(S)**

FRUZAQLA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **FULVESTRANT**

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### **MEDICATION(S)**

FULVESTRANT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **FYARRO**

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### **MEDICATION(S)**

FYARRO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **GATTEX**

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### **MEDICATION(S)**

GATTEX

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Members with active gastrointestinal malignancy.

### **REQUIRED MEDICAL INFORMATION**

Parenteral nutrition (PN) and/or intravenous (IV) fluid dependency.

### **AGE RESTRICTION**

Member is 1 year of age or older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a gastroenterologist

### **COVERAGE DURATION**

6 months initial, 12 months continuation.

### **OTHER CRITERIA**

For initial authorization, chart notes supporting the use of parenteral nutrition/IV fluids for 12 months and current volume of parenteral support in liters per week. For continuation, the provider must provide medical records documenting tolerance and effectiveness of therapy. Effectiveness of therapy is defined as a decrease in parenteral nutrition/IV volume from baseline weekly requirement at start of Gattex treatment.

### **PART B PREREQUISITE**

N/A

## **GAVRETO**

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### **MEDICATION(S)**

GAVRETO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **GAZYVA**

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### **MEDICATION(S)**

GAZYVA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **GILOTRIF**

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### **MEDICATION(S)**

GILOTRIF

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **GIP/GLP-1 AGONIST**

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### **MEDICATION(S)**

MOUNJARO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant use with other GLP-1 or GIP/GLP-1 agonists (e.g. Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza)

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Lifetime

### **OTHER CRITERIA**

For Type 2 diabetes mellitus (T2DM), member must have diagnosis of T2DM

### **PART B PREREQUISITE**

N/A

## **GLEOSTINE**

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### **MEDICATION(S)**

GLEOSTINE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **GLP-1 AGONIST**

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### **MEDICATION(S)**

BYDUREON BCISE, BYETTA, OZEMPIC 0.25-0.5 MG/DOSE PEN, OZEMPIC 1 MG/DOSE (4 MG/3 ML), OZEMPIC 2 MG/DOSE (8 MG/3 ML), RYBELSUS, TRULICITY, VICTOZA 2-PAK, VICTOZA 3-PAK

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant use with other GLP-1 or GIP/GLP-1 agonists (e.g. Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza, Mounjaro)

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Lifetime

### **OTHER CRITERIA**

For Type 2 diabetes mellitus (T2DM), member must have diagnosis of T2DM

### **PART B PREREQUISITE**

N/A



## **GOMEKLI**

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### **MEDICATION(S)**

GOMEKLI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **GRANIX**

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### **MEDICATION(S)**

GRANIX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **GROWTH HORMONE**

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### **MEDICATION(S)**

GENOTROPIN

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Short-bowel syndrome

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Growth Hormone in Children and Adolescents Initial Treatment. Must meet ONE of the following: 1.

Patient had hypophysectomy, OR

2. Had congenital hypopituitarism AND had one growth hormone stimulation test less than 10 ng/ml OR deficiency in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk OR 3. Patient with multiple pituitary deficiencies and patient has 3 or more pituitary hormone deficiencies or has had one growth hormone test less than 10 ng/ml, 4. Patient had a brain radiation or tumor resection and had one growth hormone stimulation test less than 10 ng/ml or has deficiency in at least 1 other pituitary hormone (e.g., ACTH, TSH, gonadotropin deficiency [LH and/or FSH are counted as one deficiency], or prolactin, 5. Patient had 2 growth hormone stimulation tests with the following: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are less than 10 ng/ml OR had at least 1 GH test less than 10 ng/ml and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). For continuing treatment: Prescriber confirms response to therapy.

### **AGE RESTRICTION**

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

### **PRESCRIBER RESTRICTION**

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

## **COVERAGE DURATION**

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

## **OTHER CRITERIA**

GH Def in Adults/Adol, Init: 1.Endo must certify tx is not being prescribed for anti-aging or to enhance athletic performance, 2.Pt has either childhood onset or adult onset GHD resulting from GH def alone, multiple hormone def from pituitary dz, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor tx, TBI or subarachnoid hemorrhage AND 3. Meets 1 of the following: a.Known perinatal insults or congenital or genetic defects or structural hypothalamic pituitary defects, OR b.3 or more pituitary hormone def (ACTH, TSH, LH/FSH or prolactin, age/gender adjusted IGF-1 below lower limits of the normal reference range) AND other causes of low serum IGF-1 have been excluded, OR c.Neg response to 1 pref GH stim test (note: for transitional adol: must be off tx for at least 1 mo b/f retesting): i.Insulin peak response less than or equal to 5 mcg/L, ii.Glucagon peak less than or equal to 3 mcg/L (BMI is less than or equal to 25), iii. Glucagon peak less than or equal to 3 mcg/L and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH def, iv.Less than or equal to 1 mcg/L and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH def, v. Less than or equal to 1 mcg/L (BMI is greater than 30), vi. If insulin and glucagon are CI, then arginine test with peak of less than or equal to 0.4 mcg/L, vii. Macrilen peak less than 2.8 ng/ml and BMI is less than or equal to 40, e.For cont tx: endo must certify tx is not being prescribed for anti-aging or to enhance athletic performance. ISS, Init: 1.Baseline height is less than 1.2 percentile or SDS less than -2.25 for age/gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR): a. Less than 4 cm/year for pts greater than or equal to 5 or, b. Growth velocity is less than 10th percentile for age/gender. ISS: Cont Tx: Prescriber confirms response to tx. CKD: Init Tx: CKD must be defined by abnormal CrCl. Noonan Syndrome, Init: Baseline height must be less than the 5th percentile. Prader-Willi, Continuing treatment in adults or adolescents who don't meet child requirements: MD must certify tx is not being prescribed for anti-aging or to enhance athletic performance. SHOX, Init: 1.SHOX must be defined by chromosomal analysis, 2.Open epiphyses, 3.Height less than the 3rd percentile for age and gender. SGA-Init: 1.Baseline height must be less than the 5th percentile for age/gender, 2.Born SGA age (birth weight/length that is more than 2 SD below the mean for gestational age/gender) AND did not have sufficient catch up growth by 2-4 y/o. SGA, Cont: Prescriber confirms response to tx. CKD, Noonan Syndrome, Prader-Willi in children/adolescents, SHOX, Turner Syndrome, Cont: Prescriber confirms response to therapy. SBS Init: Pt must be receiving specialized nutritional support. SBS Cont: A 2nd course of tx is allowed if responded to initial tx w/decr need for specialized nutritional support

## **PART B PREREQUISITE**

N/A

## **HAEGARDA**

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### **MEDICATION(S)**

HAEGARDA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant Use with Other HAE Prophylactic Therapies (e.g., Orladeyo, Takhzyro), use for acute treatment of HAE attacks, evidence of autoantibodies against the C1-INH protein, underlying lymphoproliferative, malignant, or autoimmune disorder that causes angioedema attacks

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, lab results (C1-INH inhibitor, C1-INH functional level, C4 levels, C1q level), number and severity of HAE attacks

### **AGE RESTRICTION**

6 years or older

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

Initial: 6 months, Continuation: 1 year

### **OTHER CRITERIA**

Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] – Prophylaxis. Initial Therapy: Approve if the patient meets all of the below (1 and 2): 1. The patient has HAE type I or type II as confirmed by the following diagnostic criteria:

- Documentation of TWO separate measurements for each test (i, ii and iii): i.Low serum complement factor 4 (C4) level at baseline, as defined by the laboratory reference values AND ii. Low C1 inhibitor (C1-INH) level OR low C1-INH functional level (i.e. functional C1-INH less than 50% or below lower limit of normal laboratory reference range) at baseline, as defined by the laboratory reference values

AND iii. C1q levels are within normal limits at baseline, as defined by the laboratory reference values, 2. Patient has a history of TWO or more severe HAE attacks (i.e. airway swelling, facial swelling, painful facial distortion, extremity swelling causing disability) per month. Continuation of therapy: Patient meets both of the following (1, 2 and 3): 1. If patient is new to plan, must meet initial criteria at time treatment had been started, 2. Medical chart documentation of the number and severity of HAE attacks occurring in the previous 6 months, 3. Patient has experienced a reduction in the number and/or severity of HAE attacks from baseline

#### **PART B PREREQUISITE**

N/A

## **HARVONI**

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### **MEDICATION(S)**

HARVONI 33.75-150 MG PELLET PK, HARVONI 45-200 MG PELLET PACKET, HARVONI 45-200 MG TABLET, LEDIPASVIR-SOFOSBUVIR

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Indications consistent with current AASLD/IDSA guidance

### **EXCLUSION CRITERIA**

Combination use with other direct acting antivirals, excluding ribavirin.

### **REQUIRED MEDICAL INFORMATION**

Hep C genotype, cirrhosis status.

### **AGE RESTRICTION**

3 years or older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with GI, hepatologist, ID, or liver transplant MD.

### **COVERAGE DURATION**

12 weeks or 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.

### **OTHER CRITERIA**

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

### **PART B PREREQUISITE**

N/A

# HETLIOZ

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## MEDICATION(S)

HETLIOZ LQ, TASIMELTEON

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Diagnosis. Non-24 hour sleep-wake disorder: physiologic circadian phase marker or actigraphy and sleep logs. Symptoms of disease.

## AGE RESTRICTION

Non-24: 18 years or older. SMS - 3 years and older.

## PRESCRIBER RESTRICTION

Prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders

## COVERAGE DURATION

6 months initial, 12 months cont.

## OTHER CRITERIA

Non-24 hour sleep-wake cycle disorder:

Initial: Approve if patient meets all of the following (1, 2 and 3):

1. Patient is totally blind with no perception of light,
2. Diagnosis is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month,
3. Symptoms of insomnia are causing function impairment (i.e. excessive daytime drowsiness, reduced



daytime activity, etc.).

Continuation - Approve if patient meets all of the following (1,2 and 3):

- 1.If patient is new to plan, meets initial criteria at the time they had started the medication,
- 2.Documented dose and frequency are within the FDA approved dosing and frequency,
- 3.Patient received at least 4 months of therapy and there is documentation of a positive clinical response to therapy (i.e. improvement in nighttime total sleep time compared to baseline, improvement in nighttime sleep quality).

Smith Magenis Syndrome (SMS):

Initial – Approve if patient is experiencing nighttime sleep disturbances (i.e. difficulty falling asleep, frequent nighttime waking, early waking, etc.).

Continuation - Approve if patient meets all of the following (1, 2 and 3):

- 1.If patient is new to plan, meets initial criteria at the time they had started the medication,
- 2.Documented dose and frequency are within the FDA approved dosing and frequency,
- 3.Patient received at least 4 months of therapy and there is documentation of a positive clinical response to therapy (i.e. improvement in nighttime total sleep time compared to baseline, improvement in nighttime sleep quality).

## **PART B PREREQUISITE**

N/A

## **HIGH RISK MEDICATION - FIRST GENERATION ANTIHISTAMINES**

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### **MEDICATION(S)**

PROMETHAZINE 12.5 MG TABLET, PROMETHAZINE 12.5 MG/10 ML CUP, PROMETHAZINE 25 MG TABLET, PROMETHAZINE 50 MG TABLET, PROMETHAZINE 6.25 MG/5 ML CUP, PROMETHAZINE 6.25 MG/5 ML SOLN, PROMETHAZINE 6.25 MG/5 ML SYRP

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Nausea and vomiting associated with chemotherapy.

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

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

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Authorization will be for 12 months.

### **OTHER CRITERIA**

Unless specifically referenced, all other FDA approved indications not excluded from Part D will be covered as first line therapy without other previous drug trial criteria requirements. For anti-emetic use, approve promethazine hydrochloride tablets or syrup if the patient has either tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant) for the current condition OR approve if the member requires promethazine use secondary to cancer/chemotherapy related emesis. Prior to approval of any drug, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that the physician would still like to initiate/continue therapy.

**PART B PREREQUISITE**

N/A

## **HUMIRA**

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### **MEDICATION(S)**

HUMIRA 40 MG/0.8 ML SYRINGE (ONLY NDCS STARTING WITH 00074), HUMIRA PEN 40 MG/0.8 ML (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) 10 MG/0.1 ML SYRINGE (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) 20 MG/0.2 ML SYRINGE (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) 40 MG/0.4 ML SYR (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN 40 MG/0.4 ML (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN 80 MG/0.8 ML (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN CRHN-UC-HS 80 MG (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN PEDI UC 80 MG (ONLY NDCS STARTING WITH 00074), HUMIRA(CF) PEN PS-UV-AHS 80-40 (ONLY NDCS STARTING WITH 00074), SIMLANDI(CF), SIMLANDI(CF) AUTOINJECTOR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with another biologic DMARD or targeted synthetic DMARD.

### **REQUIRED MEDICAL INFORMATION**

For all dx: If new to plan, meets init criteria at time they started the med. Documented dose/freq are w/in FDA approved Dosing/Freq. RA:Mod/severe active dz and dx of RA. MD assessed dz severity utilizing an obj measure. Cont:pos response in pt-reported dz sx or obj measure compared to baseline (BL). Ex include CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI, score from obj measure at BL and cont. pJIA:Dx of pJIA as evidenced by 5 or more joints with active arthritis, Documented BL cJADAS-10, score from obj measure/tool at BL and cont. PsA:Dx cont: pos clinical response. AS:Dx, pre-req med trials, confirmed dx of AS as defined by presence of active dz for at least 4 wks defined by any dz specific functional scoring tool (i.e.BASDAI Index of at least 4, HAQ, MHAQ, etc.) and expert opinion based on 1 of the following: clinical features, acute phase reactants or imaging. Cont:Pos clinical response to tx based on at least 1 obj measure compared to BL. Ex of obj measures include ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI, DFI, HAQ-S, and/or serum markers (e.g., CRP, ESR). PP: Dx, PASI score, cont: Approve if evidence of a pos response based on a or b: a.Achieved or maintained clear/minimal dz, b.Decr in PASI score compared to BL. CD:Dx, cont: Approve if meets a and b: a.Estab on med for at least 5 mo, b.Pos

clinical response to tx based on i or ii: i.Improvement in intestinal inflammation (e.g. mucosal healing, labs [PLT counts, ESR, CRP]) from BL, ii.Reversal of high fecal output state. UC:Dx of mod/severely active UC confirmed by endoscopy and/or an obj score (e.g. MMS, Truelove and Witts criteria). Cont:Improvement on endoscopy or obj score. HS:Dx, pre-req med trials, obj measure at cont (ex Hurley Staging, PGA, HSSI). Uveitis: Dx (non-infectious intermediate, posterior or panuveitis that is chronic, recurrent, tx-refractory or vision-threatening). Pre-req trials, cont:pos response.

## **AGE RESTRICTION**

CD-6 years or older UC-5 years or older. pJIA, uveitis: 2 years and older. HS: 12 years and older. All others: 18 years and older.

## **PRESCRIBER RESTRICTION**

RA/pJIA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. PP, HS-prescribed by or in consultation with a dermatologist. UC/CD-prescribed by or in consultation with a gastroenterologist. UV-prescribed by or in consultation with an ophthalmologist or rheumatologist.

## **COVERAGE DURATION**

Initial: 6 months, Continuation: 3 years

## **OTHER CRITERIA**

RA:Init-approve if pt TF 1 conventional synthetic DMARD for at least 3 mo (e.g. MTX, leflunomide, hydroxychloroquine and sulfasalazine). pJIA:Init-approve if pt TF 1 of the following at max tolerated doses for min 6-w trial (a, b, or c): a.MTX, b.Leflunomide, c.Sulfasalazine. Cont-approve if pt has pos response based on a, b, c or d: a.Number of tender and swollen joint counts, b.Decr of CRP, c.Improved PGA, d.Improved cJADAS-10 score. PsA:Init-approve if pt meets a and b: a.Pt is currently experiencing i, ii, iii, iv or v: i.Actively inflamed joints, ii.Dactylitis, iii.Enthesitis, iv.Axial dz, v.Active skin and/or nail involvement, b.Has active PsA, Cont-approve if pos response to tx based on improvement in a, b, c, d or e: a.Number of swollen joints, b.Number of tender joints, c.Dactylitis, d.Enthesitis, e.Axial dz. AS:Init-approve if pt has TF/CI/I to 2 diff NSAIDs at max tolerated doses. PP:Init:Approve if pt has dx of mod/severe PP and meets 1 of the following (i, ii or iii): i. PASI score of 10 or more, ii. At least 3% BSA affected, iii. PP affects hands, feet, scalp, face or genital areas, b.Has TF/CI/I to 2 or more of the following: i.Phototherapy (PUVA, UVB), ii.Topical therapy (CS, calcipotriene, retinoid), iii.Systemic non-biologic DMARDs (e.g. MTX, cyclosporine, acitretin). Mod/severely active CD:Init:Approve if pt meets both of the following (a and b): a.Dx of mod/severe CD, b.Pt is currently experiencing i, ii, iii, iv or v: i.Freq diarrhea and abdominal pain, ii.At least 10 percent weight loss, iii.Complication such as obstruction, fever, abdominal mass, iv.Abn labs (e.g. CRP), v.CDAI greater than 20. Mod/severely active UC:Init:Approve HS:Init-Approve if tried at least 1 other tx. Note:Ex include intralesional or oral

CS, systemic antibiotics (e.g., clindamycin, dicloxacillin, erythromycin), and isotretinoin. Uveitis: Init-  
Approve if TF of systemic CS for 2 wks and TF non-biologic immunosuppressive tx (e.g. MTX,  
mycophenolate mofetil, cyclosporine, cyclophosphamide).

**PART B PREREQUISITE**

N/A

## **HYFTOR**

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### **MEDICATION(S)**

HYFTOR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

6 years of age and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a dermatologist or a physician who specializes in the management of patients with tuberous sclerosis complex

### **COVERAGE DURATION**

Initial-3 months. Continuation-1 year

### **OTHER CRITERIA**

Facial angiofibroma associated with tuberous sclerosis, initial- approve if the patient meets the following criteria (i. and ii.): i.Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (a or b): a)There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, OR b)According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features, AND Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque, angiomyolipomas (two or more), cardiac rhabdomyoma, hypomelanotic macules (three or more, at least 5 mm in diameter), lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell astrocytoma, subependymal

nodule (two or more), or ungula fibromas (two or more). Minor feature criteria involve confetti skin lesions, dental enamel pits (three or more), intraoral fibromas (two or more), multiple renal cysts, nonrenal hamartomas, retinal achromic patch, and sclerotic bone lesions. ii. Patient has three or more facial angiofibromas that are at least 2 mm in diameter with redness in each. Continuation-approve if the patient meets the following criteria (i. and ii.): i. Patient has a definitive diagnosis of tuberous sclerosis complex by meeting one of the following (a or b): a) There is identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, OR b) According to the prescriber, clinical diagnostic criteria suggest a definitive diagnosis of tuberous sclerosis complex by meeting either two major features or one major feature with two minor features, AND Note: Major feature criteria involve angiofibroma (three or more) or fibrous cephalic plaque, angiomyolipomas (two or more), cardiac rhabdomyoma, hypomelanotic macules (three or more, at least 5 mm in diameter), lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell astrocytoma, subependymal nodule (two or more), or ungula fibromas (two or more). Minor feature criteria involve confetti skin lesions, dental enamel pits (three or more), intraoral fibromas (two or more), multiple renal cysts, nonrenal hamartomas, retinal achromic patch, and sclerotic bone lesions. ii. Patient has responded to Hyftor as evidenced by a reduction in the size and/or redness of the facial angiofibromas

## **PART B PREREQUISITE**

N/A



## **IBRANCE**

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### **MEDICATION(S)**

IBRANCE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ICLUSIG**

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### **MEDICATION(S)**

ICLUSIG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **IDHIFA**

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### **MEDICATION(S)**

IDHIFA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **IDIOPATHIC PULMONARY FIBROSIS**

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### **MEDICATION(S)**

OFEV, PIRFENIDONE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

18 years of age and older

### **PRESCRIBER RESTRICTION**

IPF/Chronic fibrosing ILD-Prescribed by or in consultation with a pulmonologist. ILD associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.

### **COVERAGE DURATION**

Lifetime.

### **OTHER CRITERIA**

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

**PART B PREREQUISITE**

N/A

# ILUMYA

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## MEDICATION(S)

ILUMYA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Concurrent use with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

## REQUIRED MEDICAL INFORMATION

Diagnosis, PASI score, reauth: positive response

## AGE RESTRICTION

18 years and older

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a dermatologist

## COVERAGE DURATION

Initial 6 months, continuation 1 year

## OTHER CRITERIA

Plaque Psoriasis

1.Initial: Approve if the patient meets all of the following (a and b):

a.Patient has a diagnosis of moderate to severe plaque psoriasis and has a Psoriasis Area and Severity Index (PASI) score of 10 or more

b.Patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product (SC), Otezla, or Cosentyx. Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab or ustekinumab product will also count. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Preferred ustekinumabs include Stelara and Yesintek.

2.Continuation: Approve if the patient meets both of the following (a and b):

- a.If patient is new to plan, meets initial criteria at time they had started the medication
- b.Patient has had evidence of a positive response based on one of the following (i, ii):
  - i.Achieved or maintained clear or minimal disease
  - ii.A decrease in PASI score compared to baseline
- c.Documented dose and frequency are within the FDA approved Dosing and Frequency

**PART B PREREQUISITE**

N/A

## IMATINIB

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### MEDICATION(S)

IMATINIB MESYLATE 100 MG TAB, IMATINIB MESYLATE 400 MG TAB, IMKELDI

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

N/A

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

1 year

### OTHER CRITERIA

For chronic graft versus host disease – approve if the patient has tried at least one conventional systemic treatment (e.g. corticosteroids, Imbruvica).

### PART B PREREQUISITE

N/A



## **IMBRUVICA**

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### **MEDICATION(S)**

IMBRUVICA 140 MG CAPSULE, IMBRUVICA 280 MG TABLET, IMBRUVICA 420 MG TABLET, IMBRUVICA 70 MG CAPSULE, IMBRUVICA 70 MG/ML SUSPENSION

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Central Nervous System Lymphoma (primary), Hairy Cell Leukemia, B-Cell lymphoma (e.g. gastric mucosa associated lymphoid tissue (MALT) lymphoma, nongastric MALT lymphoma, AIDS related, post-transplant lymphoproliferative disorder), marginal zone lymphoma, Mantle cell lymphoma

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, previous therapies tried

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

1. Graft versus host disease (GVHD) – approve if the patient has tried one conventional systemic treatment for GVHD (e.g. corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, imatinib),
2. B-cell Lymphoma – approve if the patient is using Imbruvica as second-line or subsequent therapy according to the prescribing physician,
3. Central Nervous System Lymphoma (primary) – approve if relapsed or refractory,
4. Hairy Cell Leukemia – approve if relapsed or refractory,
5. Mantle Cell Lymphoma, Marginal Zone Lymphomas, Chronic Lymphocytic Leukemia or Small

Lymphocytic Lymphoma – Approve.

**PART B PREREQUISITE**

N/A

## **IMDELLTRA**

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### **MEDICATION(S)**

IMDELLTRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **IMJUDO**

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### **MEDICATION(S)**

IMJUDO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **IMLYGIC**

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### **MEDICATION(S)**

IMLYGIC

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **IMPAVIDO**

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### **MEDICATION(S)**

IMPAVIDO

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Amoeba related infections.

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an infectious disease specialist

### **COVERAGE DURATION**

1 month

### **OTHER CRITERIA**

For Amoeba related infections: Approve if the patient is being treated for an infection due to one of the following: Acanthamoeba, Balamuthia mandrillaris, or Naegleria fowleri. Note: Examples of amoeba related infections are Acanthamoeba keratitis, granulomatous amoebic encephalitis (GAE), and primary amoebic meningoencephalitis (PAM).

### **PART B PREREQUISITE**

N/A

## **INHALED LAMA**

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### **MEDICATION(S)**

TUDORZA PRESSAIR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Previous therapies

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

For Tudorza approval, the member must meet one of the following criteria (A), (B), (C), OR (D): (A) The member has demonstrated a failure of or intolerance to both of the preferred products, Spiriva and Incruse, for the given diagnosis, (B) The member has a documented contraindication to both of the preferred products, Spiriva and Incruse, (C) The member had an adverse reaction or would be reasonably expected to have an adverse reaction to both of the preferred products, Spiriva and Incruse, OR (D) The member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

### **PART B PREREQUISITE**

N/A

## **INLYTA**

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### **MEDICATION(S)**

INLYTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **INQOVI**

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### **MEDICATION(S)**

INQOVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **INREBIC**

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### **MEDICATION(S)**

INREBIC

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## INSULIN THERAPY

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### MEDICATION(S)

ADMELOG, ADMELOG SOLOSTAR, APIDRA, APIDRA SOLOSTAR, HUMALOG, HUMALOG JUNIOR KWIKPEN, HUMALOG KWIKPEN U-100, HUMALOG KWIKPEN U-200, HUMALOG MIX 50-50 KWIKPEN, HUMALOG MIX 75-25, HUMALOG MIX 75-25 KWIKPEN, HUMALOG TEMPO PEN U-100, HUMULIN 70-30, HUMULIN 70/30 KWIKPEN, HUMULIN N, HUMULIN N KWIKPEN, HUMULIN R, HUMULIN R U-500, HUMULIN R U-500 KWIKPEN, INSULIN LISPRO, INSULIN LISPRO JUNIOR KWIKPEN, INSULIN LISPRO KWIKPEN U-100, INSULIN LISPRO PROTAMINE MIX, LYUMJEV, LYUMJEV KWIKPEN U-100, LYUMJEV KWIKPEN U-200, LYUMJEV TEMPO PEN U-100

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Lifetime.

### OTHER CRITERIA

NovoNordisk products are considered preferred. The drug must be prescribed within the manufacturers

published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternative for the given diagnosis, OR the member has a documented contraindication to the preferred formulary alternative, or the member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary alternative, OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature. Part B versus D determination per CMS guidance to establish if drug used in an insulin pump.

**PART B PREREQUISITE**

N/A

## **INTRAROSA/OSPHENA**

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### **MEDICATION(S)**

INTRAROSA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **IRESSA**

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### **MEDICATION(S)**

GEFITINIB

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ISTURISA**

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### **MEDICATION(S)**

ISTURISA 1 MG TABLET, ISTURISA 5 MG TABLET

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, prior treatments, Reauth: clinical response

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist

### **COVERAGE DURATION**

Initial: 6 months, Continuation: 1 year

### **OTHER CRITERIA**

Endogenous hypercortisolemia in adults with Cushing's syndrome – Initial – patient is not able to undergo pituitary surgery or surgery has not been curative for condition AND patient has trialed/failed, has intolerance or contraindication to both ketoconazole and cabergoline.. Continuation: Meets initial criteria and has documentation of positive clinical response to therapy (e.g. clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs/symptoms of disease).

### **PART B PREREQUISITE**

N/A

## **ITOVEBI**

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### **MEDICATION(S)**

ITOVEBI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **ITRACONAZOLE**

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### **MEDICATION(S)**

ITRACONAZOLE 10 MG/ML SOLUTION, ITRACONAZOLE 100 MG CAPSULE, ITRACONAZOLE 100 MG/10 ML CUP

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Superficial tinea, vaginal candidiasis.

### **EXCLUSION CRITERIA**

Vaginal candidiasis hypersensitivity syndrome.

### **REQUIRED MEDICAL INFORMATION**

Onychomycosis must be due to dermatophytes, and treatment must not be solely for cosmetic purposes as cosmetic use is excluded under Medicare Part D.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Twelve weeks.

### **OTHER CRITERIA**

Tinea or Pityriasis Versicolor requires one trial and failure of ketoconazole or a topical antifungal agent first. Tinea Capitis and Barbae require failure of one trial of griseofulvin or ketoconazole first. Tinea Cruris, Faciei, Manuum, Imbricata and Pedis (non moccasin or chronic type) require failure of one topical antifungal agent. Tinea Corporis requires failure of one topical antifungal agent first, except when condition is considered extensive. Vaginal Candidiasis requires failure of both one topical antifungal regimen and one trial of oral fluconazole (patients of age less than 16 years are excluded from a trial of a topical vaginal antifungal preparation). For oral and esophageal candidiasis, must try and fail ketoconazole or fluconazole first. Itraconazole will be covered for other systemic infection if used for continuation of itraconazole therapy that has already been started and stabilized. Itraconazole

is covered first line when the prescriber is a Pulmonologist or an Infectious Disease physician.

**PART B PREREQUISITE**

N/A

## **IVERMECTIN**

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### **MEDICATION(S)**

IVERMECTIN 3 MG TABLET

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

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

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

30 days

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **IVIG**

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### **MEDICATION(S)**

ALYGLO, FLEBOGAMMA DIF 5% VIAL, GAMMAGARD LIQUID, GAMMAGARD S-D, GAMUNEX-C, PRIVIGEN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For all indications: Diagnosis, Reauth: positive clinical response. PI initial (Pt meets 1, 2 or 3): 1) Dx of congenital agammaglobulinemia, X-linked agammaglobulinemia, other agammaglobulinemia d/t absence of B-cells, Wiskott-Aldrich syndrome, ataxia telangiectasia, DiGeorge syndrome, SCID, Hyper-Immunoglobulin M (IgM) syndromes, an IgG level lower than 250 mg/dL, or a PID confirmed by genetic or molecular testing OR 2) Dx of CVID, unspecified hypogammaglobulinemia, or other immunodeficiencies with significant hypogammaglobulinemia and meets the following (a and b) a) pre-tx IgG below normal range (age-adjusted and according to normal reference range for reporting laboratory AND b) Impaired antibody (Ab) response (i.e. failure to produce Abs to specific antigens) OR patient has recurrent infx OR 3) IgG subclass deficiency, selective Ab deficiency (SAD), or other confirmed PID and meets the following (a and b): a) Impaired Ab response AND b) Recurrent infx. CIDP initial: Has at least three of the following electrodiagnostic criteria for CIDP dx (1, 2, 3 and/or 4): 1) Partial conduction block of 1 or more motor nerve, 2) Reduced conduction velocity of 2 or more motor nerves, 3) Prolonged distal latency of 2 or more motor nerves, 4) Prolonged F-wave latencies of 2 or more nerves or absence of F waves. MMN Initial: dx confirmed by all of the following (i, ii, and iii): i) Weakness with slowly progressive or stepwise progressive course lasting at least 1 month, 2) Asymmetric involvement of 2 or more nerves AND 3) Absence of motor neuron and bulbar signs.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

CIDP, MMN, LEMS, MG, GBS: prescribed by or in consultation with a neurologist.

## **COVERAGE DURATION**

Init:PI/MG maint. 1 yr, CIDP 6 mo, MMN 6 mo, GBS/LEMS/MG acute 1 mo. Cont-GBS 1 mo, Others 1 yr.

## **OTHER CRITERIA**

All requests will be subject to a Part B vs Part D review. If patient is new to plan, must meet initial criteria at time they had started the medication. Documented dose and frequency must be within the FDA approved dosing and frequency or consistent with compendial sources (e.g. Micromedex, current clinical guidelines, etc.). PI Cont: Pt dx with PI and, according to the prescriber, the patient is continuing to receive benefit from the product (e.g. increased IgG levels or prevention and/or controlling of infections.) CIDP initial: Pt meets following criteria: has had progressive sx present for at least 2 months AND Has had symptomatic polyradiculoneuropathy with progressive or relapsing motor or sensory impairment in more than 1 limb. CIDP and MMN Cont.: Pt has had clinically significant improvement to tx as measured by an objective scale (e.g. Rankin, Modified Rankin, Medical Research Council [MRC] scale). GBS initial: Pt has dx of severe GBS requiring aid to walk AND onset occurred within the last 4 weeks. GBS cont: Approve a second course of tx if requested within 3 weeks after the first course. LEMS initial: Pt is having refractory weakness after symptomatic treatment of LEMS with an amifampridine, guanidine or pyridostigmine AND Pt meets one of the following (1 or 2): 1) Has paraneoplastic LEMS or 2) Has non-paraneoplastic LEMS and has TF/CI to corticosteroids and/or another immunosuppressive agent (e.g. azathioprine). LEMS cont: Pt has had response or continued effectiveness from therapy (e.g. improved muscle strength or other clinical response). MG initial acute exacerbations: Approve if pt is experiencing any of the following sx in the past month: Difficulty swallowing, Acute respiratory failure or Major functional disability leading to inability to continue physical activity. MG initial for maintenance therapy: Approve if pt meets all of the following (i, ii and iii): i\_Patient has refractory MG, ii) Pt has TF/CI to pyridostigmine AND iii) Pt has tried and failed immunosuppressive therapy with at least 1 of the following agents: azathioprine, cyclosporine, cyclophosphamide, mycophenolate mofetil, methotrexate, tacrolimus AND has had an inadequate response. MG cont. therapy for maintenance: Approve if pt has responded to tx according to the prescriber.

## **PART B PREREQUISITE**

N/A

## **IWILFIN**

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### **MEDICATION(S)**

IWILFIN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# JAKAFI

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## **MEDICATION(S)**

JAKAFI

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## JAYPIRCA

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### MEDICATION(S)

JAYPIRCA

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Diagnosis

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

1 year

### OTHER CRITERIA

Mantle Cell Lymphoma, Chronic lymphocytic lymphoma, small lymphocytic lymphoma – Approve if patient meets one of the following (1, 2, 3 or 4):

- 1.The patient has demonstrated a failure of or intolerance to one of the preferred products, Calquence and Brukinsa
- 2.The patient has a documented contraindication to one of the preferred products, Calquence and Brukinsa
- 3.The patient had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Calquence and Brukinsa
- 4.The patient has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.



**PART B PREREQUISITE**

N/A

## **JEMPERLI**

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### **MEDICATION(S)**

JEMPERLI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **JYLAMVO**

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### **MEDICATION(S)**

JYLAMVO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, Reason unable to take oral methotrexate (tablets)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

All requests will be subject to a Part B vs Part D review. Patient must meet one of the following (1, 2, 3 or 4): 1.Patient has demonstrated a failure of or intolerance to oral methotrexate (tablets) for the given diagnosis 2.Patient has a documented contraindication to oral methotrexate (tablets) 3.Patient has had an adverse reaction or would be reasonably expected to have an adverse reaction to oral methotrexate (tablets) 4.Patient has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

### **PART B PREREQUISITE**

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**

Use in patients homozygous for the F508del mutation. Combination use with Orkambi, Trikafta or Symdeko.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, evidence of abnormal CFTR function, relevant mutation

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

1. Diagnosis is cystic fibrosis AND 2. Patient must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF AND 3. Evidence of abnormal CFTR function as demonstrated by a, b or c: a. Elevated sweat chloride test, b. Two CFTR mutations, c. Abnormal nasal potential difference AND 4. The patient has one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic

### **PART B PREREQUISITE**

N/A



## KERENDIA

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### MEDICATION(S)

KERENDIA 10 MG TABLET, KERENDIA 20 MG TABLET

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

Concomitant use with spironolactone or eplerenone

### REQUIRED MEDICAL INFORMATION

Diagnosis, lab values (eGFR, UACR, potassium), medication trials

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

1 year

### OTHER CRITERIA

Diabetic kidney disease, approve if the patient meets the following criteria (i, ii, iii, and iv):

- i. Patient has a diagnosis of type 2 diabetes AND
- ii. Patient meets one of the following (a or b):
  - a. Patient is currently receiving a maximally tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR
  - b. According to the prescriber, patient has a contraindication to ACE inhibitor or ARB therapy, AND
- iii. Patient has tried/failed, has a contraindication or intolerance to one sodium-glucose cotransporter 2 (SGLT2) inhibitor (e.g. Jardiance, Farxiga)
- iv. Patient meets all of the following (a, b, and c) despite use (if not intolerant or contraindicated) of ACEI/ARB and SGLT2:
  - a. Estimated glomerular filtration rate greater than or equal to 25 mL/min/1.73 m<sup>2</sup> AND

- b. Urine albumin-to-creatinine ratio greater than or equal to 30 mg/g AND
- c. Serum potassium level less than or equal to 5.0 mEq/L.

**PART B PREREQUISITE**

N/A

## **KEVZARA**

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### **MEDICATION(S)**

KEVZARA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

### **REQUIRED MEDICAL INFORMATION**

RA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation.

PMR: Diagnosis, pre-requisite medication trials, reauth: positive response. pJIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation.

### **AGE RESTRICTION**

RA, PMR: 18 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a rheumatologist

### **COVERAGE DURATION**

Initial 6 months, continuation 1 year

### **OTHER CRITERIA**

RA: Init-approve if the patient meets all of the following: i. Provider has assessed disease severity utilizing an objective measure/tool. Examples include [CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI], ii. Pt has documented moderate to severe active dz and dx of RA per ACR criteria. iii. Approve if the patient has tried two of the following: Enbrel, a preferred adalimumab product, Orencia, Rinvoq or Xeljanz/XR. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Cont-approve if the pt meets all of the following: i. If pt is new to plan, meets initial criteria at time they had started the medication, ii. Pt is responding positively to therapy based on improvement in objective measurement/tool as compared to baseline, iii. Documented dose and frequency is within the FDA approved Dosing and Frequency. PMR:



Init-Approve if the pt meets all of the following (a and b): a. Pt has a dx of PMR according to ACR/EULAR classification criteria. b. Patient meets one of the following (i or ii): i. Pt has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR for a minimum of 8 weeks. ii. Pt is currently being treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg. Cont-Approve if the pt meets all of the following (a, b and c): a. If pt is new to plan, meets initial criteria at time they had started the medication, b. Pt has achieved or maintained a positive clinical response to therapy as evidenced by one of the following (i or ii): i. When assessed by at least one objective measure, pt experienced a beneficial clinical response from baseline (prior to initiating Kevzara) (e.g. CRP, ESR), ii. Compared with baseline, pt experienced an improvement in at least one symptom, such as decreased shoulder, neck, upper arm, hip, or thigh pain or stiffness or improved range of motion, c. Documented Dose and Frequency are within the FDA approved Dosing and Frequency. PJIA: Initial– approve if the pt meets all of the following (a, b, c and d): a. Dx of pJIA as evidenced by 5 or more joints with active arthritis, b. Documented baseline cJADAS-10, c. Pt has T/F TWO of the following: Enbrel, Orencia, a preferred adalimumab product, Rinvoq or Xeljanz/XR. Please note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. d. Patient weighs 63kg or greater. Cont–approve if the patient has experienced improvement in disease response based on one of the following (a, b, c or d): a. Number of tender and swollen joint counts, b. Reduction of C-reactive protein, c. Improvement of patient global assessment, d. Improvement in cJADAS-10 score.

## **PART B PREREQUISITE**

N/A

## **KIMMTRAK**

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### **MEDICATION(S)**

KIMMTRAK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **KINERET**

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### **MEDICATION(S)**

KINERET

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Still's disease (SD). Systemic Juvenile Idiopathic Arthritis (SJIA).

### **EXCLUSION CRITERIA**

Concurrent use with another biologic DMARD or targeted synthetic DMARD.

### **REQUIRED MEDICAL INFORMATION**

For RA/SJIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. For Cryopyrin Associated Periodic Syndrome: diagnosis reauth: positive response. DIRA: Diagnosis, genetic testing, reauth: positive response. For all diagnoses: Documented Dose and Frequency are within the FDA approved Dosing and Frequency. If patient is new to plan, meets initial criteria at time they had started the medication.

### **AGE RESTRICTION**

RA: 18 years and older

### **PRESCRIBER RESTRICTION**

RA, SIJA and Still's disease-prescribed by or in consultation with a rheumatologist. CAPS-prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, pediatrician. DIRA-prescribed by or in consultation with a rheumatologist, geneticist, dermatologist or physician specializing in tx of autoinflammatory disorders.

### **COVERAGE DURATION**

Initial 6 months, continuation 1 year

### **OTHER CRITERIA**

RA:Init-approve if the pt meets a, b and c: a.MD assessed dz severity utilizing an obj measure/tool. Ex include CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI. b.Pt has mod/severe active dz and dx of RA per ACR criteria c. Approve if pt tried 2 of: Enbrel, a pref adalimumab product, Orencia SC, Olumiant, Rinvoq or Xeljanz/XR. Pref adalimumabs include:

Humira (NDCs starting with -00074) and Simlandi. Cont-approve if the pt has positive response to tx based on improvement in obj measure/tool as compared to baseline. sJIA: Init-approve if pt meets a, b and c: a.MD assessed baseline dz severity utilizing obj measure/tool such as sJADAS or ACR pedi 30 criteria, b.Dx of SJIA, c.T/F 1 of the following conventional tx at max tolerated doses (i, ii, or iii): i.Min 1-mo trial of NSAID, ii.Min 2-wk trial of systemic glucocorticoid, iii.One of the following biologic tx: Ilaris or TNFi. Cont-approve if improvement in dz response based on a, b, c or d: a. Number of tender/swollen joint counts, b. Decr CRP, c. Improvement of PGA d. Improvement on a dz activity scoring tool (e.g. composite scoring index like sJADAS or ACR-Pedi 30). Still's dz:Init: Approve if pt meets a, b or c: a.Pt meets both i and ii: i.Tried 1 CS, ii.TF an NSAID, b.Has at least mod/severe active systemic features. Ex include fever/rash/lymphadenopathy/hepatomegaly/splenomegaly/serositis, c.Has active systemic features with concerns of progression to macrophage activation syndrome. Cont:Based on at least 1 obj measure, pt had a beneficial clinical response from baseline. Ex include resolution of fever, improvement in rash/skin manifestations, clinically sign improvement or normalization of serum markers (e.g., CRP, ESR), and/or reduced dosage of CS. CAPS-Init-Approve if the dx has been confirmed by a or b: a.NLRP3 gene mutation. b.Pt has i and ii: i.Two of the following clinical sx:Urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal sx, chronic aseptic meningitis, skeletal abnormalities, ii.Incr acute phase reactants (e.g. ESR, CRP, SAA). Cont-Pt meets a or b: a.Based on at least 1 obj measure, pt had beneficial clinical response from baseline. Ex include resolution of fever, improvement in at least 1 sx, such as fewer cold-induced attacks, less joint pain/tenderness, stiffness or swelling, decr fatigue, improved fx or activities of daily living. DIRA:Init:Pt has IL1RN gene mutation. Cont:Approve if pt meets a or b: a.Based on at least 1 obj measure, pt had a beneficial clinical response from baseline. Ex of obj measures include improvement in rash/skin manifestations, clinically sign improvement or normalization of serum markers (e.g. CRP, ESR), red proteinuria, stabilization of serum Cr, b.Improvement in at least 1 sx (skin/bone sx, les joint pain/tenderness, stiffness, swelling).

## **PART B PREREQUISITE**

N/A

## **KISQALI**

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### **MEDICATION(S)**

KISQALI, KISQALI FEMARA CO-PACK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **KORLYM**

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### **MEDICATION(S)**

MIFEPRISTONE 300 MG TABLET

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Pregnancy.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, reauth: positive response

### **AGE RESTRICTION**

Aged 18 years or older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist or specialist in treating Cushing's syndrome

### **COVERAGE DURATION**

Initial – 6 months, Continuation: 1 year

### **OTHER CRITERIA**

The member must have failed surgery, or is not a candidate for surgery. Members must utilize adequate measures such as non-hormonal contraceptive methods to prevent pregnancy.

### **PART B PREREQUISITE**

N/A

## **KOSELUGO**

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### **MEDICATION(S)**

KOSELUGO

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Astrocytoma.

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

2 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist, oncologist, or a medical geneticist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

For neurofibromatosis type 1, must have symptomatic, inoperable plexiform neurofibromas (PN).

### **PART B PREREQUISITE**

N/A

## **KRAZATI**

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### **MEDICATION(S)**

KRAZATI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## KUVAN

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### MEDICATION(S)

SAPROPTERIN DIHYDROCHLORIDE

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

Concurrent use with Palynziq (continuation only)

### REQUIRED MEDICAL INFORMATION

N/A

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Initial 3 months, if positive response, then 1 year. In pregnancy, through term.

### OTHER CRITERIA

For continuation of therapy, allow for continuation of therapy if the patient has experienced improvement after the initial three months of therapy, as determined by the prescriber.

### PART B PREREQUISITE

N/A

## **LAZCLUZE**

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### **MEDICATION(S)**

LAZCLUZE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **LENALIDOMIDE**

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### **MEDICATION(S)**

LENALIDOMIDE, REVLIMID

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **LENVIMA**

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### **MEDICATION(S)**

LENVIMA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **LITFULO**

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### **MEDICATION(S)**

LITFULO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with an oral or topical Janus Kinase Inhibitor (JAKi), a biologic immunomodulator or other potent immunosuppressants (e.g., cyclosporine, azathioprine, methotrexate)

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of severe alopecia areata

### **AGE RESTRICTION**

12 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a dermatologist

### **COVERAGE DURATION**

Initial: 6 months, Continuation: 1 year

### **OTHER CRITERIA**

Alopecia areata, initial therapy: approve if the patient: 1. Has a current episode of alopecia areata lasting for greater than or equal to 6 months without spontaneous re-growth 2. Has greater than or equal to 50 percent scalp hair loss 3. Does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss or other causes of hair loss other than alopecia areata. Alopecia areata, continuation of therapy: approve if the patient meets the following: 1. Has been established on Litfulo for at least 6 months (less than 6 months or a restart, review under initial therapy) 2. Experienced a beneficial clinical response defined as improvement from baseline (prior to initiating Litfulo) in extent and density of scalp hair loss 3. The prescriber states the patient continues to require systemic therapy for treatment of alopecia areata.

**PART B PREREQUISITE**

N/A

## **LIVTENCITY**

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### **MEDICATION(S)**

LIVTENCITY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant use with ganciclovir or valganciclovir

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

12 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist, infectious disease specialist, oncologist, or a physician affiliated with a transplant center.

### **COVERAGE DURATION**

2 months

### **OTHER CRITERIA**

Cytomegalovirus Infection, Treatment-approve if the patient meets the following criteria (A, B, and C):  
A) Patient weighs greater than or equal to 35 kg, AND B) Patient is post-transplant (Note: This includes patients who are post hematopoietic stem cell transplant or solid organ transplant.) AND C) Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir

### **PART B PREREQUISITE**

N/A

## **LONSURF**

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### **MEDICATION(S)**

LONSURF

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **LOQTORZI**

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### **MEDICATION(S)**

LOQTORZI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **LORBRENA**

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### **MEDICATION(S)**

LORBRENA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **LUMAKRAS**

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## **MEDICATION(S)**

LUMAKRAS

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **LUNSUMIO**

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### **MEDICATION(S)**

LUNSUMIO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **LUPRON DEPOT**

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### **MEDICATION(S)**

LUPRON DEPOT, LUPRON DEPOT (LUPANETA)

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, Reauth: lifetime duration with which member has been on therapy

### **AGE RESTRICTION**

Premenstrual disorders – 18 years and older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Endometriosis: 1 year, Uterine leiomyomata: 6 months All others: 1 year

### **OTHER CRITERIA**

1. Endometriosis: a. For initial therapy – member meet all of the following (i, ii, and iii):
  - i. Has had surgical ablation to prevent recurrence OR trial/failure, contraindication or intolerance to one NSAID and one oral contraceptive,
  - ii. Medication will be used in combination with add-back therapy in combination with norethindrone 5 mg,
  - iii. Total lifetime duration of use does not exceed 12 months.
2. Uterine leiomyomata (fibroids): - member meets all of the following (i, ii and iii):
  - i. Will be used prior to surgery to reduce size of fibroids OR treatment of anemia,
  - ii. Will be used in combination with iron therapy,
  - iii. Total lifetime duration of use does not exceed 6 months.
3. Gender dysphoric/gender-incongruent persons, Persons undergoing gender reassignment (female-to-male or male-to-female) – approve.
4. Premenstrual disorders (including premenstrual syndrome and premenstrual dysphoric disorder) –

Approve if patient meets both of the following (a and b):

a. Patient has severe refractory premenstrual symptoms,

b. Patient has tried a selective serotonin reuptake inhibitor (SSRI) AND a combined oral contraceptive for treatment of premenstrual disorder.

**PART B PREREQUISITE**

N/A

## **LYNPARZA**

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### **MEDICATION(S)**

LYNPARZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **LYTGOBI**

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### **MEDICATION(S)**

LYTGOBI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **MARGENZA**

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### **MEDICATION(S)**

MARGENZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **MAVYRET**

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### **MEDICATION(S)**

MAVYRET

**PENDING CMS APPROVAL**

## **MEKINIST**

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### **MEDICATION(S)**

MEKINIST

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **MEKTOVI**

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### **MEDICATION(S)**

MEKTOVI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **MEMANTINE**

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### **MEDICATION(S)**

MEMANTINE 5-10 MG TITRATION PK, MEMANTINE HCL 10 MG/5 ML CUP, MEMANTINE HCL 2 MG/ML SOLUTION, MEMANTINE HCL ER

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Memantine titration pack or solution-Mild to moderate vascular dementia.

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Lifetime

### **OTHER CRITERIA**

For members requesting memantine ER, titration pack or solution: must have trialed and failed memantine 5 mg or 10 mg tablets.

### **PART B PREREQUISITE**

N/A

## **MOTTEGRITY**

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### **MEDICATION(S)**

MOTTEGRITY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

For chronic idiopathic constipation – the member must meet one of the following criteria (1, 2, 3 or 4):

- 1.The member has demonstrated a failure of or intolerance to the preferred product, Linzess
- 2.The member has a documented contraindication to the preferred products, Linzess
- 3.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred products, Linzess OR
- 4.The patient has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.

### **PART B PREREQUISITE**

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**

Partial lipodystrophy, HIV-related lipodystrophy, Liver disease, including nonalcoholic steatohepatitis, Metabolic disease including diabetes mellitus and hypertriglyceridemia (without concurrent evidence of generalized lipodystrophy)

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, Reauth: positive clinical response

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist or a geneticist

### **COVERAGE DURATION**

Authorization will be for 3 years.

### **OTHER CRITERIA**

Initial criteria – Approve if patient meets both of the following (1 and 2):

1. Patient has diagnosis of congenital or acquired generalized lipodystrophy,
2. Patient has experienced one or more signs of leptin deficiency (e.g. hyperinsulinemia, type 2 diabetes mellitus, and hypertriglyceridemia).

Continuation Criteria – Approve if patient meets all of the following (1, 2 and 3):

1. If patient is new to plan, meets initial criteria at time they had started the medication,
2. Documented dose and frequency are within the FDA approved Dosing and Frequency,
3. Patient has experienced a positive clinical response to treatment (e.g. sustained improvement in triglyceride levels, hemoglobin A1c from baseline)

**PART B PREREQUISITE**

N/A



## **MYLOTARG**

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### **MEDICATION(S)**

MYLOTARG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **NASAL CORTICOSTEROIDS**

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### **MEDICATION(S)**

AZELASTINE-FLUTICASONE, MOMETASONE FUROATE 50 MCG SPRY, RYALTRIS

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

Requests for mometasone will be authorized if using for treatment of nasal polyps - member will not need to try preferred products. Flunisolide and fluticasone propionate are the preferred products. The drug must be prescribed within the manufacturer's published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to one preferred formulary alternative OR the member has had an adverse reaction or would be reasonably

expected to have an adverse reaction to one preferred formulary alternatives OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

**PART B PREREQUISITE**

N/A

## **NERLYNX**

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### **MEDICATION(S)**

NERLYNX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **NEXAVAR**

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### **MEDICATION(S)**

SORAFENIB

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **NEXLETOL**

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### **MEDICATION(S)**

NEXLETOL, NEXLIZET

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

LDL-C and response to other agents, prior therapies tried

### **AGE RESTRICTION**

18 years and older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

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

equal to 20 mg daily) AND ezetimibe concomitantly for greater than or equal to 8 weeks and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Atherosclerotic Cardiovascular Disease (ASCVD) -approve if pt meets all of the following: Pt has one of the following conditions: prior MI, history of ACS, diagnosis of angina (stable or unstable), history of stroke or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND Pt tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily) AND ezetimibe concomitantly for greater than or equal to 8 weeks and LDL-C remains greater than or equal to 70 mg/dL unless the patient is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. Primary HLPD (not associated with HeFH or ASCVD): Approve if pt meets all of the following (a, b and c): a. The member has tried one high-intensity statin therapy (i.e. atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily), unless member has been determined to be statin intolerant (as defined above) AND b. The member has tried ezetimibe for 8 weeks AND c.LDL remains 100 mg/dL or higher unless statin intolerant.

## **PART B PREREQUISITE**

N/A

## **NINLARO**

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### **MEDICATION(S)**

NINLARO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **NITISINONE**

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### **MEDICATION(S)**

NITISINONE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

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

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Hereditary Tyrosinemia, Type 1 – approve if diagnosis was confirmed by genetic testing confirming a mutation of the FAH gene OR elevated serum levels of alpha-fetoprotein (AFP) and succinylacetone.

### **PART B PREREQUISITE**

N/A

## **NSAIDS**

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### **MEDICATION(S)**

INDOMETHACIN 25 MG CAPSULE, INDOMETHACIN 50 MG CAPSULE, INDOMETHACIN ER

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

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

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Authorization will be for 12 months.

### **OTHER CRITERIA**

For gout, approve indomethacin as first line therapy without other previous drug trial criteria requirements. For other indications for indomethacin, the patient must try and fail at least two other FDA-approved products for the indication being treated. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that the physician would still like to initiate/continue therapy.

### **PART B PREREQUISITE**

N/A

## **NUBEQA**

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### **MEDICATION(S)**

NUBEQA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# NUCALA

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## MEDICATION(S)

NUCALA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Concurrent use with Xolair or another Anti-Interleukin (IL) monoclonal antibody.

## REQUIRED MEDICAL INFORMATION

COPD: Reason for contraindication to inhaled corticosteroid (ICS), if applicable, eosinophil count (blood eosinophil count is at greater than or equal to 150 cells/microL within previous 6 weeks or prior to treatment with Nucala or another monoclonal antibody), diagnosis (moderate to very severe COPD as indicated by a post-bronchodilator FEV1/forced vital capacity (FVC) ratio less than 0.7 AND post-bronchodilator FEV1 percent predicted greater than 20 percent but equal or less than 80 percent). For COPD Reauth: documented improved response from therapy (for example, reduced exacerbations, hospitalizations/ED/urgent care visits or improved lung function).

## AGE RESTRICTION

Asthma - 6 years of age. EGPA, polyps, COPD - 18 years of age and older. HES - 12 years and older.

## PRESCRIBER RESTRICTION

Asthma/EGPA - prescribed by or in consultation with an allergist, immunologist, rheumatologist, or pulmonologist. HES-prescribed by or in consultation with an allergist, immunologist, hematologist, pulmonologist or rheumatologist. Polyps - prescribed by or in consultation with an allergist, immunologist, or otolaryngologist. COPD- prescribed by or in consultation with allergist, immunologist or pulmonologist.

## COVERAGE DURATION

Asthma/EGPA/Polyps/COPD: Init 6 mo. HES: Initial 8 months. Continuation all diagnoses - lifetime.

## OTHER CRITERIA

Init asthma: have blood eos count greater than or equal to 150 cells/mcL w/in previous 6 wks (prior to

tx with any IL-5 therapy) AND has received at least 3 mo of combo tx with an ICS AND 1 of following A. LABA, B. LAMA, C. LTRA, or D. Theophylline. Asthma continues to be uncontrolled as defined by 1 of following: pt experienced 2 or more asthma exacer requiring tx with systemic CS in the previous yr, pt experienced 1 or more asthma exacer requiring hospitalization or an ED visit in previous yr, pt has a FEV1 less than 80PP for adult or 90PP for ped, Pt has an FEV1/FVC less than 0.8 for adult or 0.9 for ped, or asthma worsens upon tapering oral CS. NOTE: An exception to the requirement for a trial of 1 additnl asthma controller/maintenance med can be made if the pt already received anti-IL-5 tx. For cont asthma: pt responded to tx as determined by prescriber (e.g., decr asthma exacer, decr asthma sx, decr hospitalizations, ED/urgent care, or MD visits due to asthma, decr requirement for oral CS) AND continues to receive tx with an ICS. For init tx EGPA-pt has/had eos level of greater than or equal to 150 cells/mcL w/in previous 6 wks or w/in 6 wks prior to tx with any IL-5 tx AND has active, non-severe dz. Cont of tx for EGPA-pt has responded to tx as determined by the prescriber (e.g., reduced rate of relapse, CS dose reduction, reduced eos level). HES initial- has HES for greater than or equal to 6 mo AND has FIP1L1-PDGFRalpha-negative dz AND the pt does NOT have an identifiable non-hematologic secondary cause of HES AND prior to initiating tx with any anti-IL-5 therapy, has/had a blood eos level of greater than or equal to 1,000 cells/mcL. Cont HES-approve if the pt has received at least 8 mo of tx with Nucala and pt has responded to Nucala therapy. Init nasal polyps-Pt has CRSwNP as evidenced by direct examination, endoscopy or sinus CT scan AND Pt has experienced 2 or more of the following sx for at least 6 mo nasal congestion/obstruction/discharge and/or reduction/loss of smell AND Pt has received at least 8 wks of tx with intranasal CS AND Pt will continue to receive tx with intranasal CS concomitantly with Nucala AND pt meets 1 of the following (a, b or c): a)has received at least 1 course of tx with a systemic CS for 5 days or more w/in previous 2 yrs OR b)has CI to systemic CS tx OR c) Had prior surgery for nasal polyps. Cont polyps-approve if the pt has received at least 6 mo of tx, continues to receive tx with an intranasal CS and has responded to tx. COPD init: Pt had at least 3 mo of LAMA/LABA/ICS, unless ICS is CI AND meets a or b: a.2 or more COPD exac in past 12 mo requiring systemic CS or abx and at least 1 one required systemic CS and at least 1 occurred while on LAMA/LABA/ICS therapy, unless ICS is CI, b.1 or more COPD exacerbations requiring hospitalization in the previous 12 mo and occurred while on LAMA/LABA/ICS therapy, unless ICS is CI. COPD cont: continues to receive tx with LAMA/LABA/ICS, unless ICS CI.

## **PART B PREREQUISITE**

N/A

## **NUEDEXTA**

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### **MEDICATION(S)**

NUEDEXTA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, CNS-LS score, Reauth: documented improvement with medication (e.g. reduction in episodes of inappropriate laughing or crying)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by a neurologist or a psychiatrist.

### **COVERAGE DURATION**

Initial: 3 months, Continuation: 1 year.

### **OTHER CRITERIA**

Pseudobulbar Affect - Diagnosis is confirmed by all of the following:

- a. Physician attestation that the patient has experienced involuntary, sudden, or frequent episodes of laughing and/or crying consistent with PBA at baseline
- b. Documentation of a Center for Neurologic Study-Lability Scale (CNS-LS) baseline score of at least 13.
- c. Patient has a brain injury or neurologic disease from one of the following: amyotrophic lateral sclerosis, multiple sclerosis, Parkinson's disease, stroke or traumatic brain injury.

### **PART B PREREQUISITE**

N/A

## **NUPLAZID**

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### **MEDICATION(S)**

NUPLAZID

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of Parkinson's disease psychosis, Reauth: documentation of response

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

Initial: 3 months. Continuation: 1 year

### **OTHER CRITERIA**

Parkinson's disease psychosis: Initial – Patient meets the following criteria:

- 1.Symptoms of psychosis developed after the PD diagnosis
- 2.Symptoms include at least one of the following: visual hallucinations, auditory hallucinations or delusions
- 3.Symptoms have been present for at least one month AND individual has experienced symptoms at least once weekly
- 4.Psychiatric symptoms cannot be attributed to disorders such as schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features, or a general medical condition including delirium.

Continuation: Individual has experienced a reduction in psychosis symptoms compared to baseline.



**PART B PREREQUISITE**

N/A

## **NURTEC ODT**

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### **MEDICATION(S)**

NURTEC ODT

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

For preventative treatment: Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Acute treatment: Approve if the patient has trialed and failed, has an intolerance or has a contraindication [documentation required] to two different triptans (must be different active ingredients).  
Preventative treatment of episodic migraine: For initial therapy: Approve if the patient has a diagnosis of episodic migraine

### **PART B PREREQUISITE**

N/A

## **ODOMZO**

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### **MEDICATION(S)**

ODOMZO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **OGSIVEO**

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### **MEDICATION(S)**

OGSIVEO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **OJEMDA**

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### **MEDICATION(S)**

OJEMDA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **OJJAARA**

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### **MEDICATION(S)**

OJJAARA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **OLUMIANT**

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### **MEDICATION(S)**

OLUMIANT

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with other biologics, DMARDs, or other potent immunosuppressants. Exclude for indication of COVID-19 treatment in hospitalized patients (ie, non-D use).

### **REQUIRED MEDICAL INFORMATION**

RA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. Alopecia areata: diagnosis, scalp involvement, length of current episode, pre-requisite medication trials, reauth: positive response.

### **AGE RESTRICTION**

18 years of age and older

### **PRESCRIBER RESTRICTION**

RA - Prescribed by or in consultation with a rheumatologist. Alopecia areata-prescribed by or in consultation with a dermatologist.

### **COVERAGE DURATION**

Initial 6 months, continuation 1 year

### **OTHER CRITERIA**

Rheumatoid arthritis:

1.Initial - approve if the patient meets all of the following:

i.Provider has assessed disease severity utilizing an objective measure/tool. Examples include [Clinical Disease Activity Index (CDAI), Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein), Patient Activity Scale (PAS or PAS-II), Routine Assessment of Patient Index Data 3 (RAPID3), Simplified Disease Activity Index (SDAI)]

ii.Patient has documented moderate to severe active disease and diagnosis of RA per American

College of Rheumatology (ACR) criteria

iii. Approve if the patient has tried two of the following: Enbrel, a preferred adalimumab product, Orencia, Rinvoq or Xeljanz/XR. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi.

2. Continuation - approve if the patient meets all of the following (i, ii, and iii):

i. If patient is new to plan, meets initial criteria at time they had started the medication

ii. Member is responding positively to therapy based on improvement in objective measurement/tool as compared to baseline

iii. Documented dose and frequency are within the FDA approved Dosing and Frequency.

Alopecia Areata:

1. Initial – approve if the patient meets all of the following (a, b, c and d):

a. Patient has a current episode of alopecia areata lasting for 6 months or more

b. Patient has 50 percent or more scalp hair loss

c. Patient has tried at least one of the following for alopecia areata (a or b):

i. Conventional systemic therapy (e.g. corticosteroids, methotrexate and cyclosporine.)

ii. Topical corticosteroids

d. Patient does not have hair loss due to androgenetic alopecia, chemotherapy-induced hair loss, or other causes of hair loss other than alopecia areata

2. Continuation - approve if the patient meets all of the following (a, b and c):

a. If patient is new to plan, meets initial criteria at time they had started the medication

b. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Olumiant) in extent and density of scalp hair loss

c. Documented dose and frequency are within the FDA approved Dosing and Frequency

## **PART B PREREQUISITE**

N/A



## OMNIPOD

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### MEDICATION(S)

OMNIPOD 5 (G6/LIBRE 2 PLUS), OMNIPOD 5 DEXG7G6 INTRO(GEN 5), OMNIPOD 5 DEXG7G6 PODS (GEN 5), OMNIPOD 5 G6-G7 INTRO KT(GEN5), OMNIPOD 5 G6-G7 PODS (GEN 5), OMNIPOD 5 INTRO(G6/LIBRE2PLUS), OMNIPOD CLASSIC PODS (GEN 3), OMNIPOD DASH INTRO KIT (GEN 4), OMNIPOD DASH PODS (GEN 4), OMNIPOD GO PODS

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Diagnosis, insulin therapy regimen

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

3 years

### OTHER CRITERIA

Patient must meet ALL of the following requirements (A, B, C, and D):

A. Diagnosis of diabetes, as indicated by 1 or more of the following (1 or 2):

(1.) Type 1 diabetes mellitus OR

(2.) Type 2 diabetes mellitus and 1 or more of the following (a. or b.): (a.) Daily insulin requirement of 0.7 to 1.8 units per kg or (b.) Total daily insulin dose is 220 units or less

B. Failure of multiple daily injection insulin administration, as indicated by 1 or more of the following:

- (1.) Abnormal early-morning increase in blood glucose (“dawn phenomenon”), unresponsive to management with long-acting insulin analogue (eg, insulin glargine, insulin detemir) regimens
- (2.) Child for whom multiple daily insulin injections are impractical or inappropriate
- (3.) Diabetes complications (eg, neuropathy, nephropathy, retinopathy), and need for more intensive management
- (4.) Extreme insulin sensitivity
- (5.) HbA1c greater than 7% (53 mmol/mol), despite intensified multiple daily injection insulin therapy
- (6.) Hypoglycemia requiring third-party assistance, including unconsciousness, seizure, glucagon administration, and emergency attendance or admission to hospital
- (7.) Patient is pregnant or planning pregnancy
- (8.) Wide swings in glycemic control

C. Patient or caregiver is motivated, adherent, knowledgeable, and able to monitor blood glucose 3 or more times per day.

D. Provider team is experienced and expert in management and support of patient with insulin pumps

**PART B PREREQUISITE**

N/A

## OMVOH

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### MEDICATION(S)

OMVOH 100 MG/ML SYRINGE, OMVOH 300 MG DOSE - 2 SYRINGES, OMVOH 100 MG/ML PEN, OMVOH 300 MG DOSE - 2 PENS

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

### REQUIRED MEDICAL INFORMATION

UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score. CD: Diagnosis, pre-requisite medication trials (if applicable), Reauth: positive clinical response.

### AGE RESTRICTION

18 years and older

### PRESCRIBER RESTRICTION

Prescribed by or in consultation with a gastroenterologist

### COVERAGE DURATION

Initial: 6 months, Continuation: 1 year

### OTHER CRITERIA

Moderately to severely active Ulcerative Colitis

1.Initial therapy: Approve if the patient has tried TWO of the following preferred products: a preferred adalimumab product, Skyrizi, a preferred ustekinumab product (SC), Rinvoq, Xeljanz/XR tablets and Zeposia. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Preferred ustekinumabs include Stelara and Yesintek. A previous trial with a non-preferred adalimumab or ustekinumab would also count.

2.Continuation therapy: Approve if the patient meets ALL of the following (i, ii, iii and iv):

- i.If patient is new to plan, meets initial criteria at time they had started the medication
  - ii.Patient has been established on the requested medication for at least 5 months
  - iii.Patient has experienced a positive clinical response compared to baseline as evidenced by improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria).
  - iv.Documented dose and frequency are within the FDA approved Dosing and Frequency
- Moderately to severely active Crohn's Disease
- 1.Initial therapy: Approve if the patient meets ALL of the following (i, ii and iii):
    - i.Documented diagnosis of moderate to severe Crohn's disease
    - ii.Patient is currently experiencing one of the following:
      - a.Frequent diarrhea and abdominal pain
      - b.At least 10% weight loss
      - c.Complication such as obstruction, fever, abdominal mass
      - d.Abnormal lab values (e.g. C-reactive protein)
      - e.CD Activity Index (CDAI) greater than 20
    - iii.Patient has tried TWO of the following preferred products: a preferred adalimumab product, Skyrizi SQ, a preferred ustekinumab product (SQ) or Rinvoq. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Preferred ustekinumabs include Stelara and Yesintek.
  - 2.Continuation therapy: Approve if the patient meets ALL of the following (i, ii, iii and iv):
    - i.If patient is new to plan, meets initial criteria at time they had started the medication
    - ii.Patient has been established on the requested medication for at least 5 months
    - iii.Patient has documentation of positive clinical response to therapy as evidenced by at least one of the following (1 or 2):
      - 1.Improvement in intestinal inflammation (e.g. mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
      - 2.Reversal of high fecal output state
    - iv.Documented dose and frequency are within the FDA approved Dosing and Frequency.

## **PART B PREREQUISITE**

N/A

## **ONUREG**

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### **MEDICATION(S)**

ONUREG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **OPDIVO**

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### **MEDICATION(S)**

OPDIVO, OPDIVO QVANTIG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **OPDUALAG**

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### **MEDICATION(S)**

OPDUALAG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **OPHTHALMIC BETA BLOCKER**

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### **MEDICATION(S)**

BETOPTIC S, TIMOLOL MALEATE PF EYE DROPS 0.25%, TIMOLOL MALEATE PF EYE DROPS 0.5%

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

Betaxalol, carteolol, dorzolamide/timolol, levobunolol, timolol (excluding timolol maleate preservative free dropperette) are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to one preferred formulary alternative OR the member has had an



adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternatives OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

**PART B PREREQUISITE**

N/A

## **OPHTHALMIC PROSTAGLANDIN**

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### **MEDICATION(S)**

LUMIGAN, ROCKLATAN, TAFLUPROST, TRAVOPROST, VYZULTA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

Latanoprost and bimatoprost are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis OR the member has a documented contraindication to one preferred formulary alternative OR the member has had an adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternatives OR the member has a clinical condition for which there is no listed

preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

**PART B PREREQUISITE**

N/A

## **OPSUMIT**

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### **MEDICATION(S)**

OPSUMIT

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis as confirmed by right heart catheterization

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2): 1. Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c): a. Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest b. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg c. Pulmonary vascular resistance (PVR) greater than 3 Wood units AND 2. Individual has WHO functional class II-IV symptoms.

### **PART B PREREQUISITE**

N/A

## **ORENCIA**

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### **MEDICATION(S)**

ORENCIA 125 MG/ML SYRINGE, ORENCIA 50 MG/0.4 ML SYRINGE, ORENCIA 87.5 MG/0.7 ML SYRINGE, ORENCIA CLICKJECT

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

### **REQUIRED MEDICAL INFORMATION**

RA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation.

Member has confirmed diagnosis of moderate to severe RA and the disease must be active. JIA:

diagnosis and disease severity, score from objective measure/tool at baseline and continuation. For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication.

Documented dose and frequency are within the FDA approved Dosing and Frequency.

### **AGE RESTRICTION**

RA: 18 and older. pJIA/PsA: 2 years and older.

### **PRESCRIBER RESTRICTION**

RA/JIA: Prescribed by or in consultation with a rheumatologist. Prescribed by or in consultation with a Rheumatologist, Dermatologist

### **COVERAGE DURATION**

Initial 6 months, continuation 3 years

### **OTHER CRITERIA**

Rheumatoid Arthritis: 1. Initial - approve if the patient has tried and failed one conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g. methotrexate, leflunomide, hydroxychloroquine and sulfasalazine), 2.Continuation - approve if the patient is responding positively to therapy based on improvement in patient-reported disease symptoms or objective measurement/tool (e.g. CDAI, PAS or PAS-II, RAPID3, SDAI) as compared to baseline. Polyarticular Juvenile Idiopathic

Arthritis: 1. Initial - approve if the patient meets all of the following (a, b and c):

a. Diagnosis of pJIA as evidenced by 5 or more joints with active arthritis, b. Documented baseline 10-joint clinical juvenile arthritis disease activity score (cJADAS-10), c. Patient has tried and failed one of the following conventional therapies at maximally tolerated doses for a minimum 6-week trial (i, ii or iii):

i. Methotrexate, ii. Leflunomide, iii. Sulfasalazine. 2. Continuation - approve if the patient has experienced improvement in disease response based on one of the following (i, ii, iii or iv): i. Number of tender and swollen joint counts, ii. Reduction of C-reactive protein, iii. Improvement of patient global assessment, iv. Improvement in cJADAS-10 score.

Psoriatic Arthritis: 1. Initial therapy - approve if the patient meets the following criteria (a and b): a. Patient is currently experiencing one of the following (i, ii, iii, iv or v): i. Actively inflamed joints ii. Dactylitis, iii. Enthesitis, iv. Axial disease

v. Active skin and/or nail involvement b. Patient has active psoriatic arthritis. 2. Continuation therapy - approve if the patient has documentation of positive clinical response to therapy as evidenced by improvement in any of the following from baseline (a, b, c, d or e): a. Number of swollen joints, b. Number of tender joints, c. Dactylitis, d. Enthesitis, e. Axial disease.

## **PART B PREREQUISITE**

N/A

## **ORGOVYX**

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### **MEDICATION(S)**

ORGOVYX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ORKAMBI**

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### **MEDICATION(S)**

ORKAMBI

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Combination use with Kalydeco, Trikafta or Symdeko.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, evidence of abnormal CFTR function, relevant mutation

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

1. Diagnosis is cystic fibrosis, AND 2. Patient must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF AND 3. Evidence of abnormal CFTR function as demonstrated by a, b or c:  
a. Elevated sweat chloride test, b. Two CFTR mutations, c. Abnormal nasal potential difference, 4. For Orkambi: The patient who has two mutated copies of F508del mutation in the CFTR gene.

### **PART B PREREQUISITE**

N/A



## **ORSERDU**

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### **MEDICATION(S)**

ORSERDU

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **OTEZLA**

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### **MEDICATION(S)**

OTEZLA 10-20 MG STARTER 28 DAY, OTEZLA 10-20-30MG START 28 DAY, OTEZLA 20 MG TABLET, OTEZLA 30 MG TABLET

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARD)

### **REQUIRED MEDICAL INFORMATION**

For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented Dose and Frequency are within the FDA approved Dosing and Frequency. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. PP: Diagnosis, PASI score, reauth: positive response. Behcet's: Diagnosis, pre-requisite medication trial, reauth: positive response.

### **AGE RESTRICTION**

PP: 6 years of age and older. All others: 18 years and older.

### **PRESCRIBER RESTRICTION**

PsA: Prescribed by or in consultation with a Rheumatologist, Dermatologist. PP: Prescribed by or in consultation with a dermatologist. Behcet's: prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.

### **COVERAGE DURATION**

Initial - 6 months, continuation 3 years

### **OTHER CRITERIA**

Psoriatic Arthritis: 1. Initial therapy - approve if the patient meets the following criteria (a and b): a. Patient is currently experiencing one of the following (i, ii, iii, iv or v): i. Actively inflamed joints, ii. Dactylitis, iii. Enthesitis, iv. Axial disease, v. Active skin and/or nail involvement, b. Patient has active

psoriatic arthritis and meets one of the following criteria (i, ii or iii) i. Pt had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g. sulfasalazine), ii. Pt has an intolerance or contraindication to methotrexate, leflunomide and another conventional synthetic drug (e.g. sulfasalazine) iii. Pt has predominantly axial disease

2.Continuation therapy - approve if there is documentation of positive clinical response to therapy as evidenced by improvement in any of the following from baseline (a, b, c, d or e):

a.Number of swollen joints

b.Number of tender joints

c.Dactylitis

d.Enthesitis

e.Axial disease

Plaque Psoriasis:

1.Initial: Approve if the patient meets all of the following (a and b)

a. Patient meets one of the following (i or ii): i. Patient is 18 years or older and has a diagnosis of mild to severe plaque psoriasis with 1 of the following (a or b): a. PASI score of 5 or more, or b. PP affects hands, feet, scalp, face or genital area, ii. Patient is between 6 and 17 years of age, has a diagnosis of moderate to severe plaque psoriasis and meets 1 of the following (i, ii or iii): i. PASI score of 10 or more, ii. At least 3% BSA affected, iii PP affects hands, feet, scalp, face or genital area, b. Patient has tried and failed, has a contraindication or intolerance to two or more of the following: i. Phototherapy (PUVA, UVB), ii. Topical therapy (topical corticosteroid, calcipotriene, retinoid), iii. Systemic non-biologic DMARDs (e.g. methotrexate, cyclosporine, acitretin)

2. Continuation: Approve if the patient has had evidence of a positive response based on one of the following (a or b): a. Achieved or maintained clear or minimal disease, b. A decrease in PASI score compared to baseline. Behcet's disease: 1. Initial: Approve if patient has tried at least one conventional

therapy (e.g. corticosteroids {methylprednisolone}, immunosuppressants [azathioprine, methotrexate {MTX}, tacrolimus, Leukeran {chlorambucil}, cyclophosphamide, or cyclosporine], interferon alfa), 2.

Continuation: Approve if patient has experienced a beneficial clinical response from baseline when assessed by at least one objective measure. Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), ulcer depth, number, and/or lesion size.

## **PART B PREREQUISITE**

N/A

## **PANRETIN**

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### **MEDICATION(S)**

PANRETIN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **PARATHYROID HORMONE AGENTS**

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### **MEDICATION(S)**

BONSITY, FORTEO, TERIPARATIDE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## PART D VS PART B

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### MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10% VIAL, ACETYLCYSTEINE 20% VIAL, ACYCLOVIR 1,000 MG/20 ML VIAL, ACYCLOVIR 500 MG/10 ML VIAL, ADCETRIS, ALBUTEROL 100 MG/20 ML SOLN, ALBUTEROL 15 MG/3 ML SOLUTION, ALBUTEROL 2.5 MG/0.5 ML SOL, ALBUTEROL 25 MG/5 ML SOLUTION, ALBUTEROL 5 MG/ML SOLUTION, ALBUTEROL 75 MG/15 ML SOLN, ALBUTEROL SUL 0.63 MG/3 ML SOL, ALBUTEROL SUL 1.25 MG/3 ML SOL, ALBUTEROL SUL 2.5 MG/3 ML SOLN, ALYMSYS, AMPHOTERICIN B 50 MG VIAL, AMPHOTERICIN B LIPOSOME, APREPITANT, ARFORMOTEROL TARTRATE, ARSENIC TRIOXIDE, ARZERRA, ASPARLAS, ASTAGRAF XL, AVASTIN, AZACITIDINE, AZATHIOPRINE 50 MG TABLET, BAVENCIO, BCG (TICE STRAIN), BELEODAQ, BENDAMUSTINE HCL, BESPONSA, BLEOMYCIN SULFATE, BLINCYTO 35MCG VL W-STABILIZER, BORTEZOMIB 1 MG VIAL, BORTEZOMIB 2.5 MG VIAL, BORTEZOMIB 3.5 MG IV VIAL, BORTEZOMIB 3.5 MG VIAL, BORTEZOMIB 3.5 MG/1.4 ML VIAL, BUDESONIDE 0.25 MG/2 ML SUSP, BUDESONIDE 0.5 MG/2 ML SUSP, BUDESONIDE 1 MG/2 ML INH SUSP, CARBOPLATIN, CARMUSTINE, CIDOFOVIR 375 MG/5 ML VIAL, CINACALCET HCL, CISPLATIN 100 MG/100 ML VIAL, CISPLATIN 200 MG/200 ML VIAL, CISPLATIN 50 MG VIAL, CISPLATIN 50 MG/50 ML VIAL, CLADRIBINE, CLINIMIX, CLINIMIX E, CLOFARABINE, CROMOLYN 20 MG/2 ML NEB SOLN, CYCLOPHOSPHAMIDE 1 GM VIAL, CYCLOPHOSPHAMIDE 1 GM/5 ML VL, CYCLOPHOSPHAMIDE 2 GM VIAL, CYCLOPHOSPHAMIDE 2 GM/10 ML VL, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 25 MG TABLET, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG TABLET, CYCLOPHOSPHAMIDE 500 MG VIAL, CYCLOPHOSPHAMIDE 500 MG/2.5 ML, CYCLOSPORINE 100 MG CAPSULE, CYCLOSPORINE 25 MG CAPSULE, CYCLOSPORINE MODIFIED, CYRAMZA, CYTARABINE, DACARBAZINE, DACTINOMYCIN, DANYELZA, DARZALEX, DARZALEX FASPRO, DAUNORUBICIN HCL, DECITABINE, DOCETAXEL, DOXORUBICIN HCL, DOXORUBICIN HCL LIPOSOME, DRONABINOL, EMPliciti, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, ENHERTU, ENVARSUS XR, EPIRUBICIN 200 MG/100 ML VIAL, EPIRUBICIN 50 MG/25 ML VIAL, ERBITUX, ERWINASE, ETOPOSIDE 1,000 MG/50 ML VIAL, ETOPOSIDE 100 MG/5 ML VIAL, ETOPOSIDE 500 MG/25 ML VIAL, EVEROLIMUS 0.25 MG TABLET, EVEROLIMUS 0.5 MG TABLET, EVEROLIMUS 0.75 MG TABLET, EVEROLIMUS 1 MG TABLET, FLOXURIDINE, FLUDARABINE PHOSPHATE, FLUOROURACIL 1 GRAM/20 ML VIAL, FLUOROURACIL 2.5 GRAM/50 ML VL, FLUOROURACIL 5 GRAM/100 ML VL, FLUOROURACIL 500 MG/10 ML VIAL, FORMOTEROL 20 MCG/2 ML NEB VL, FOSCARNET SODIUM, GANCICLOVIR SODIUM, GEMCITABINE HCL, GENGRAF, GRANISETRON HCL 1 MG TABLET, HEPLISAV-B, HERCEPTIN 150 MG VIAL, HERCEPTIN HYLECTA, HERCESSI, HERZUMA, IDARUBICIN HCL, IFOSFAMIDE, IMFINZI, INTRALIPID, IPRATROPIUM BR 0.02% SOLN, IPRATROPIUM-ALBUTEROL, IRINOTECAN HCL, IXEMPRA, JEVTANA, JYNNEOS,

JYNNEOS (NATIONAL STOCKPILE), KADCYLA, KANJINTI, KEYTRUDA, KYPROLIS, LEUCOVORIN CAL 100 MG/10 ML VL, LEUCOVORIN CAL 500 MG/50 ML VL, LEUCOVORIN CALCIUM 100 MG VIAL, LEUCOVORIN CALCIUM 200 MG VIAL, LEUCOVORIN CALCIUM 350 MG VIAL, LEUCOVORIN CALCIUM 50 MG VIAL, LEUCOVORIN CALCIUM 500 MG VIAL, LEVALBUTEROL CONCENTRATE, LEVALBUTEROL HCL, LEVOLEUCOVORIN CALCIUM, LIBTAYO, MELPHALAN HCL, METHOTREXATE 1 GM VIAL, METHOTREXATE 2.5 MG TABLET, METHOTREXATE 250 MG/10 ML VIAL, METHOTREXATE 50 MG/2 ML VIAL, METHOTREXATE SODIUM, MITOMYCIN 20 MG VIAL, MITOMYCIN 40 MG VIAL, MITOMYCIN 5 MG VIAL, MITOXANTRONE HCL, MONJUVI, MVASI, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, NELARABINE, NIPENT, OGIVRI, ONCASPAR, ONDANSETRON 4 MG/5 ML SOLN CUP, ONDANSETRON 4 MG/5 ML SOLUTION, ONDANSETRON HCL 4 MG TABLET, ONDANSETRON HCL 8 MG TABLET, ONDANSETRON ODT 4 MG TABLET, ONDANSETRON ODT 8 MG TABLET, ONIVYDE, ONTRUZANT, OXALIPLATIN, PACLITAXEL, PACLITAXEL PROTEIN-BOUND, PADCEV, PEMETREXED 1 GM/40 ML VIAL, PEMETREXED 100 MG VIAL, PEMETREXED 100 MG/4 ML VIAL, PEMETREXED 500 MG VIAL, PEMETREXED 500 MG/20 ML VIAL, PEMETREXED DISODIUM, PENTAMIDINE 300 MG INHAL POWDR, PERJETA, PLENAMINE, PRALATREXATE, PREHEVBRIO, PREMASOL, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 1 MG GRANULE PACKET, PROLEUKIN, PROSOL, PULMOZYME, RECOMBIVAX HB, RIABNI, RITUXAN, RITUXAN HYCELA, ROMIDEPSIN, RUXIENCE, SANDIMMUNE 100 MG/ML SOLN, SIROLIMUS 0.5 MG TABLET, SIROLIMUS 1 MG TABLET, SIROLIMUS 1 MG/ML ORAL SOLN, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TABLET, SYLVANT, TACROLIMUS 0.5 MG CAPSULE, TACROLIMUS 0.5 MG CAPSULE (IR), TACROLIMUS 1 MG CAPSULE, TACROLIMUS 1 MG CAPSULE (IR), TACROLIMUS 5 MG CAPSULE, TACROLIMUS 5 MG CAPSULE (IR), TECENTRIQ, TECENTRIQ HYBREZA, TEMSIROLIMUS, THIOTEPA 100 MG VIAL, THIOTEPA 15 MG VIAL, TOBRAMYCIN 300 MG/4 ML AMPULE, TOBRAMYCIN 300 MG/5 ML AMPULE, TOPOTECAN HCL 4 MG VIAL, TOPOTECAN HCL 4 MG/4 ML VIAL, TRAVASOL, TRAZIMERA, TROPHAMINE, TRUXIMA, VALRUBICIN, VECTIBIX, VEGZELMA, VINBLASTINE SULFATE, VINCASAR PFS, VINCRISTINE SULFATE, VINORELBINE TARTRATE, VYXEOS, YERVOY, YONDELIS, ZALTRAP, ZANOSAR, ZEPZELCA, ZIRABEV

## 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.

## **PAZOPANIB**

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### **MEDICATION(S)**

PAZOPANIB HCL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **PEGFILGRASTIM**

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### **MEDICATION(S)**

NYVEPRIA, STIMUFEND

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **PEMAZYRE**

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### **MEDICATION(S)**

PEMAZYRE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **PHESGO**

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### **MEDICATION(S)**

PHESGO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **PIQRAY**

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### **MEDICATION(S)**

PIQRAY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **POLIVY**

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### **MEDICATION(S)**

POLIVY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **POMALYST**

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### **MEDICATION(S)**

POMALYST

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **PORTRAZZA**

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### **MEDICATION(S)**

PORTRAZZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **POTELIGEO**

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### **MEDICATION(S)**

POTELIGEO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **PREVYMIS**

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### **MEDICATION(S)**

PREVYMIS 120 MG PELLET PACKET, PREVYMIS 20 MG PELLET PACKET, PREVYMIS 240 MG TABLET, PREVYMIS 480 MG TABLET

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Severe hepatic impairment (Child-Pugh C). Members on dialysis or with end-stage renal disease (CrCl less than 10 ml/min) (unless receiving Prevymis for kidney transplant indication).

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, CMV lab value

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist, oncologist, infectious disease specialist, or transplant specialist (or nephrologist if for kidney transplant indication)

### **COVERAGE DURATION**

7 months

### **OTHER CRITERIA**

CMV prophylaxis in patients who have received an allogeneic hematopoietic stem cell transplant must meet all of the following (1, 2 and 3) 1.Member is CMV-seropositive, 2.Medication is started within 28 days post-transplant AND 3. Patient does not have active CMV infection (CMV PCR level over 250 IU/ml)

CMV prophylaxis in kidney transplant recipients must meet all of the following (1, 2, 3 and 4):

- 1.Member is a recipient of a kidney transplant
- 2.Member is CMV-seronegative
- 3.Donor is CMV-seropositive

4.Provider attests Prevymis will be initiated between Day 0 and 7 post-transplantation

**PART B PREREQUISITE**

N/A

## **PROMACTA**

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### **MEDICATION(S)**

ALVAIZ, ELTROMBOPAG OLAMINE, PROMACTA

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Thrombocytopenia in myelodysplastic syndrome (MDS)

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Chronic ITP is defined as greater than 6 months. For ITP, baseline platelet count must be less than 30,000/mm<sup>3</sup>, OR baseline platelet count must be 30,000-50,000/mm<sup>3</sup> AND in the presence of a clinically significant previous bleeding episode OR at high risk of experiencing a clinically significant bleeding episode (for example, upcoming surgery, if the member is at high risk of falls, etc...). For continuation of therapy, a clinically positive response is either a platelet count with a positive increase to greater than 50,000/mm<sup>3</sup> OR a clinically significant improvement in bleeding status if platelet count remains less than 50,000/mm<sup>3</sup>. If the platelet count does not increase after 4 weeks at maximum dose, then therapy will not be reauthorized. Diagnosis of Severe Aplastic Anemia, as defined based on the criteria of the International Aplastic Anemia Study Group (IAASG), requires that the member meet BOTH of the following criteria (1 and 2): (1.) Any two or three of the following peripheral blood criteria (Neutrophils less than  $0.5 \times 10^9$  to the 9th/L AND/OR Platelets less than  $20 \times 10^9$  to the 9th/L AND/OR absolute reticulocyte count less than 60,000/microL) AND (2.) Any one of the following marrow criteria (Severe hypocellularity OR Moderate hypocellularity with hematopoietic cells representing less than 30% of residual cells). For MDS - platelet counts.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

For Hepatitis C related thrombocytopenia, must be prescribed by or in consultation with a gastroenterologist, hematologist, or infectious disease physician. MDS - prescribed by or in consultation with hematologist or oncologist.

**COVERAGE DURATION**

ITP 90 day initial, w/pos clinical resp then 1 yr. Hep C & MDS thrombocytopenia and Aplastic Anemia 12mo.

**OTHER CRITERIA**

For chronic ITP must try and have insufficient response to (defined as the inability to achieve a platelet count of greater than 50,000/mm<sup>3</sup>) or be intolerant to both of the following: Corticosteroids AND one of either splenectomy, IVIG, or anti-D immunoglobulins. For Hepatitis C related thrombocytopenia, if currently on interferon based therapy, the member must have attempted and failed to improve platelet levels through interferon dose reduction. For aplastic anemia, the member will use eltrombopag in combination with standard immunosuppressive therapy or had an insufficient response to immunosuppressive therapy. For MDS - approve if patient has low- to intermediate-risk MDS AND according to the prescriber the patient has clinically-significant thrombocytopenia (e.g. low platelet counts [pretreatment], is platelet transfusion-dependent, active bleeding, and/or a history of bleeding at low platelet counts.)

**PART B PREREQUISITE**

N/A

## **PROVIGIL/NUVIGIL**

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### **MEDICATION(S)**

ARMODAFINIL, MODAFINIL 100 MG TABLET, MODAFINIL 200 MG TABLET

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Modafinil will be allowed for patients with Multiple Sclerosis-related fatigue, Excessive daytime sleepiness (EDS) associated with myotonic dystrophy, Adjunctive/augmentation for treatment of depression in adults.

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Confirmed diagnosis for a covered use. For Sleep Work Shift Disorder, other sleep disorders or contributing factors to sleep disorder have been ruled out, such as sleep apnea, restless leg syndrome/periodic limb movements, insomnia, or other causes for circadian rhythm misalignment (depression, gastrointestinal problems).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

For narcolepsy, the prescriber is a neurologist or sleep specialist

### **COVERAGE DURATION**

For Sleep Work Disorder, 12 months. All others, Lifetime.

### **OTHER CRITERIA**

For narcolepsy, therapy will be allowed if one of the following is met: The member tried and failed or has a contraindication to TWO first line products: Amphetamine/dextroamphetamine (amphetamine salt combinations), Dextroamphetamine, Methamphetamine, Methylphenidate, OR the member has a history of substance abuse. For Sleep Work Shift Disorder, the member must have a documented shift work schedule (night shifts, rotating shifts). Modafinil will be allowed for patients with Multiple Sclerosis-related fatigue. Adjunctive/augmentation for treatment of depression in adults (modafinil only) -

Approve if the patient is concurrently receiving other medication therapy for depression.

**PART B PREREQUISITE**

N/A

## **QINLOCK**

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### **MEDICATION(S)**

QINLOCK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **QULIPTA**

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### **MEDICATION(S)**

QULIPTA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Combination with a CGRP antagonist when the CGRP antagonist is being used for prophylaxis

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

18 years of age and older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 3 months, Continuation: 12 months

### **OTHER CRITERIA**

Preventative treatment of episodic migraine: For initial therapy: Approve if the patient meets (A, B and C): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication) B) Patient has tried and failed one of the following prior to approval of Qulipta: Nurtec ODT, Aimovig, Emgality, or Ajovy, C) Patient has tried and failed one of the following drug classes prior to approval of Qulipta: Beta blockers (ex. Metoprolol, Propranolol, and Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate) or Calcium Channel Blockers (ex. Verapamil). For continuation of therapy: Prescriber confirms that the member demonstrates improvement after a 3-month trial.

Preventative treatment of chronic migraine - initial therapy: Approve if the patient meets the following (A and B):

A) Patient has a diagnosis of chronic migraine as indicated by 15 or more attacks per month, for 3 or



more months in a row, that include BOTH of the following: Headache Symptoms (as indicated by 2 or more of the following: unilateral location and/or pulsating quality and/or moderate to severe pain intensity and/or aggravation by or causing avoidance of routine physical activity) AND Associated Symptoms (as indicated by 1 or more of the following: Nausea/vomiting and/or photophobia). B) Patient has tried and failed two different drug classes prior to Qulipta approval: Beta blockers (ex. Metoprolol, propranolol, and timolol), antidepressants (ex. Amitriptyline, nortriptyline, venlafaxine), anticonvulsants (ex. Valproate and topiramate) and calcium channel blockers (ex. Verapamil). For continuation of therapy: Prescriber confirms that the member demonstrates improvement after a 3-month trial.

#### **PART B PREREQUISITE**

N/A

## **RETACRIT**

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### **MEDICATION(S)**

RETACRIT

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Anemia related to Multiple Myeloma. Refractory Anemia related to Myelodysplastic Syndrome. Anemia in patients with Hepatitis C who are being treated with the combination ribavirin and interferon alfa or ribavirin and peginterferon alfa. Anemia due to myelodysplastic syndrome (MDS).

### **EXCLUSION CRITERIA**

Uncontrolled hypertension. Anemic patients willing to donate autologous blood. Anemia due to factors other than diagnoses noted (iron or folate deficiency, hemolysis, GI bleeding). Patients receiving hormonal agents, therapeutic biological products, or radiotherapy UNLESS also receiving concomitant myelosuppressive chemotherapy. For immediate anemia correction or as a substitute for emergency transfusion. Prophylactic use to prevent chemotherapy included anemia.

### **REQUIRED MEDICAL INFORMATION**

Chronic renal failure patients not on dialysis must have symptomatic anemia with a HGB of 10g/dl or less. HIV-infected Zidovudine use requires a Zidovudine dose of 4200mg/week or less and an endogenous serum EPO level less than or equal to 500mUnits/ml. Non myeloid malignancy chemotherapy induced anemia must have HGB of 10g/dl or less to start AND serum ferritin greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% or patient is receiving supplemental iron - if previously receiving Aranesp or epoetin alfa, Hgb must be 12 g/dL or less and the patient must have had a response to therapy. For MDS refractory anemia diagnosis must include excess blasts, or excess blasts in transformation to leukemia when, for medical reasons, the patient is not a candidate for active treatment of active leukemia. For MDS the patient must have endogenous EPO serum level less than 500mu/ml AND serum ferritin greater than or equal to 100 mcg/L or serum transferrin saturation greater than or equal to 20% or patient is receiving supplemental iron - if previously receiving Aranesp or epoetin alfa, Hgb must be 12 g/dL or less and the patient has had a response to therapy. Anemia patients scheduled to undergo elective surgery require hemoglobin greater than 10 but 13 or less. Anemia related to ribavirin therapy in Hepatitis C treatment requires a pretreatment hemoglobin 10g/dl or less.

### **AGE RESTRICTION**

For Hep C treatment related anemia, 18 or older.

**PRESCRIBER RESTRICTION**

For Hep C treatment related anemia, hematologist, hepatologist, gastroenterologist, or infectious disease physician who specializes in the management of Hep C.

**COVERAGE DURATION**

Chemo-induced anemia: 6 months. All other indications - 1 year.

**OTHER CRITERIA**

For non myeloid malignancy anemia related to chemotherapy, the member must have received chemotherapy in past 8 weeks and will be receiving chemo for a minimum of 2 months. In anemic patients scheduled to undergo surgery, the surgery must be elective, noncardiac and nonvascular, or in patients at high risk for perioperative transfusion with significant anticipated blood loss who are receiving anticoagulant prophylaxis. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.

**PART B PREREQUISITE**

N/A

## **RETEVMO**

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### **MEDICATION(S)**

RETEVMO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## REVATIO

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### MEDICATION(S)

ALYQ, SILDENAFIL 20 MG TABLET, TADALAFIL 20 MG TABLET

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

Erectile dysfunction. Benign Prostatic hyperplasia.

### REQUIRED MEDICAL INFORMATION

N/A

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Lifetime.

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

## **REVUFORJ**

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### **MEDICATION(S)**

REVUFORJ

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **REYVOW**

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### **MEDICATION(S)**

REYVOW

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Approve if the patient has trialed and failed or has a contraindication [documentation required] Nurtec ODT.

### **PART B PREREQUISITE**

N/A

## **REZLIDHIA**

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### **MEDICATION(S)**

REZLIDHIA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## REZUROCK

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### MEDICATION(S)

REZUROCK

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Diagnosis.

### AGE RESTRICTION

12 years and older

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

1 year

### OTHER CRITERIA

GVHD-Patient has chronic GVHD and has tried at least two prior lines of systemic therapy for GVHD.

### PART B PREREQUISITE

N/A

## **RHOPRESSA**

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### **MEDICATION(S)**

RHOPRESSA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Prior therapies

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Member must try and fail latanoprost AND one Ophthalmic Beta Blocker (ex. Timolol, betaxolol, levobunolol, metipranolol) prior to Rhopressa therapy

### **PART B PREREQUISITE**

N/A

## **RILUTEK**

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### **MEDICATION(S)**

TEGLUTIK, TIGLUTIK

### **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**

Neurologist.

### **COVERAGE DURATION**

Lifetime.

### **OTHER CRITERIA**

Requires documentation of exclusion of other diagnoses by neurologist.

### **PART B PREREQUISITE**

N/A

## **RINVOQ**

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### **MEDICATION(S)**

RINVOQ, RINVOQ LQ

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with a biologic, targeted synthetic DMARD, other potent immunosuppressants, anti-interleukin monoclonal antibodies, janus kinase inhibitors or with Xolair.

### **REQUIRED MEDICAL INFORMATION**

For all dx: If pt is new to plan, meets init criteria at time they started the med. Dose/freq are w/in the FDA approved Dosing/Freq. RA:dx and dz severity, score from obj measure/tool at baseline (BL) and cont. Pt has documented mod/severe active dz. PsA:Dx, pre-requisite med trials, reauth: pos clinical response. AD: Dx (mod/severe AD and at least 10% BSA affected or SCORAD index value of at least 25), pre-req tx, BSA and/or SCORAD index value. UC:must have confirmed dx of mod/severely active UC by endoscopy and/or an obj score (e.g. MMS, Truelove and Witts criteria). Trial of pref products. Reauth: Improvement on endoscopy or obj score. CD: Dx, pre-req med trials (if applicable), Reauth: pos clinical response. AS: Dx, pre-req med trials, reauth: pos clinical response to tx as evidenced by at least 1 obj measure compared to BL. Ex of obj measures include ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI), DFI, HAQ-S, and/or serum markers (e.g., CRP, ESR). Nr-asXpA: Dx, obj signs of inflammation (CRP beyond ULN for the reporting lab OR Sacroiliitis on MRI, pre-req med trials, obj signs of inflammation, reauth: pos clinical response (Dz activity (e.g. pain, fatigue, inflammation, stiffness), Labs (CRP), Axial status (e.g. lumbar spine motion, chest expansion) or Total active (swollen and tender) joint count). pJIA: Dx of pJIA w/5 or more joints w/active arthritis and documented BL cJADAS-10. GCA: diagnosis, pre-req med trial. Dx of large vessel arteritis verified with bx or imaging of the large vessels (MRI, PET-CT, or CT angiography). Pt has active dz and elevated CRP and ESR. Cont: Approve if achieved/maintained a pos clinical response to tx as evidenced by low dz activity or improvement in s/s of the condition when there is improvement in any of the following from BL: HA, scalp tenderness, tenderness or thickening of superficial temporal arteries, constitutional sx (weight loss/fever/fatigue/night sweats), jaw/tongue/limb claudication, sx of PMR, acute visual sx.

### **AGE RESTRICTION**

Rheumatoid arthritis (RA), Ulcerative colitis (UC), Ankylosing Spondylitis (AS), Non-radiographic Axial Spondyloarthritis (nr-axSpA), Crohn's Disease (CD), Giant cell arteritis (GCA)-18 years and older. Atopic dermatitis (AD)-12 years and older. Psoriatic arthritis, pJIA,: 2 years and older.

## **PRESCRIBER RESTRICTION**

RA/AS/nr-axSpA/pJIA/GCA, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescribed by or in consultation with an allergist, immunologist or dermatologist. UC/CD-prescribed by or in consultation with a gastroenterologist.

## **COVERAGE DURATION**

Initial - 6 months, continuation 3 years

## **OTHER CRITERIA**

RA: Init-approve if TF 1 TNFi after 3-mo trial. Cont-approve if responding pos to tx based on pt-reported dz sx or obj measure/tool (e.g. CDAI, PAS or PAS-II, RAPID3, SDAI) as compared to baseline. PsA: Init-approve if a and b: a. Experiencing 1 of the following (i, ii, iii, iv or v):i. Actively inflamed joints, ii.Dactylitis, iii.Enthesitis, iv.Axial dz, v.Active skin or nail involvement, b.Active PsA and TF 1 TNFi after 3-mo trial. Cont-approve if documentation of pos clinical response based on a, b, c, d or e: a.Number of swollen joints, b.Number of tender joints, c.Dactylitis, d.Enthesitis, e.Axial dz. Refractory Mod/Severe AD:Init-Approve if i and ii: i.Hx of TF/C/I to 1 of following topical tx (1 or 2): 1.Med to very-high potency CS for 2 wks, 2.Calcineurin inhibitor [e.g., pimecrolimus] for 6 wks, ii.One of the following (1 or 2): 1.Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low/mild dz activity OR 2.TF of 1 systemic tx [e.g., oral cyclosporine, oral azathioprine, or oral mycophenolate mofetil] following a 12-wk trial. Cont:Approve if documentation of a pos clinical response based on 1 or 2: 1.Decr in BSA involvement from baseline, 2.Decr in SCORAD index value from baseline. Mod/severely active UC: Init:Approve if pt meets a or b: a.TF 1 TNFi following a 3-mo trial. Cont:Approve if pt meets a and b: a.Pt has been on med for at least 5 mo, b.Pt has experienced a pos clinical response compared to baseline based on endoscopy or using an obj scoring system (e.g. MMS, Truelove and Witts criteria). Mod/severely active CD:Init:Approve if i, ii and iii: i.Documented dx of mod/severe CD, ii.Experiencing a, b, c, d or e: a.Freq diarrhea and abdominal pain, b. At least 10% weight loss, c.Complication such as obstruction, fever, abdominal mass, d.Abn labs (e.g. CRP), e.CDAI greater than 20, iii.TF TNFi after 3-mo trial. Cont:Approve if i and ii: i.Estab on med for at least 5 mo, ii.Documentation of pos clinical response to tx based on 1 or 2: 1.Intestinal inflammation (e.g. mucosal healing, labs [PLTs, ESR, CRP level]) from baseline, 2.Reversal of high fecal output state. AS:Init-approve if a and b: a.Dx of AS w/ active dz for at least 4 wks defined by any dz specific functional scoring tool (i.e. a BASDAI Index of at least 4, HAQ, MHAQ, etc.) and expert opinion based on clinical features, acute phase reactants or imaging. b.TF TNFi after 3-mo trial. 2.Cont-see required medical

info. nr-aXspa:Init-Approve if had 3 mo TF 1 TNFi or was unable to tolerate 3 mo trial. Cont–see required medical info. pJIA:Init-approve if TF 1 TNFi following a 3-mo trial:Cont-approve if improvement in dz response based on a, b, c or d: a.Number of tender and swollen joint counts, b.Decr CRP, c.Improved PGA, d.Improved cJADAS-10 score. GCA: Approve if the patient TF of at least a 12-week trial of a CS, unless intolerant or tx is CI. Cont: See required medical info.

## **PART B PREREQUISITE**

N/A

## **ROZLYTREK**

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### **MEDICATION(S)**

ROZLYTREK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **RUBRACA**

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### **MEDICATION(S)**

RUBRACA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **RYBREVANT**

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### **MEDICATION(S)**

RYBREVANT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **RYDAPT**

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### **MEDICATION(S)**

RYDAPT

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **RYLAZE**

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### **MEDICATION(S)**

RYLAZE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **RYTELO**

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### **MEDICATION(S)**

RYTELO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **SANDOSTATIN**

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### **MEDICATION(S)**

OCTREOTIDE ACETATE, OCTREOTIDE ACETATE ER, SANDOSTATIN LAR DEPOT

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Pheochromocytoma/paraganglioma, Meningioma, Thymoma and thymic carcinoma, Management of volume depletion from enterocutaneous fistula

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Acromegaly-prescr/consult w/endocrinologist. All neuroendocrine tumors-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro. Meningioma-prescr/consult w/oncologist, radiologist or neurosurgeon. Thymoma/Thymic carcinoma-prescr/consult w/oncologist

### **COVERAGE DURATION**

Enterocutaneous fistula: 3 months, All others: 1 year

### **OTHER CRITERIA**

Acromegaly-approve if the patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas)-approve.

**PART B PREREQUISITE**

N/A

## **SARCLISA**

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### **MEDICATION(S)**

SARCLISA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **SCEMBLIX**

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### **MEDICATION(S)**

SCEMBLIX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



**MEDICATION(S)**

CUVITRU, HIZENTRA, HYQVIA, XEMBIFY

**PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

**OFF LABEL USES**

N/A

**EXCLUSION CRITERIA**

N/A

**REQUIRED MEDICAL INFORMATION**

Diagnosis, Reauth: positive clinical response

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

CIDP: prescribed by or in consultation with a neurologist.

**COVERAGE DURATION**

PI initial and continuation: 1 year. CIDP initial: 3 months, continuation: 1 year.

**OTHER CRITERIA**

All requests will be subject to a Part B vs Part D review. If patient is new to plan, must meet initial criteria at time they had started the medication. Documented dose and frequency must be within the FDA approved dosing and frequency or consistent with compendial sources (e.g. Micromedex, current clinical guidelines, etc.). PI: Initial therapy: Approve if pt meets ONE of the following (1, 2 or 3): 1. Pt has diagnosis of congenital agammaglobulinemia, X-linked agammaglobulinemia, other agammaglobulinemia due to absence of B-cells, Wiskott-Aldrich syndrome, ataxia telangiectasia, DiGeorge syndrome, severe combined immunodeficiency, Hyper-Immunoglobulin M (IgM) syndromes, an IgG level lower than 250 mg/dL, or a primary immune deficiency which has been confirmed by genetic or molecular testing OR 2. Pt has a diagnosis of common variable immunodeficiency, unspecified hypogammaglobulinemia, or other immunodeficiencies with significant hypogammaglobulinemia and meets the following (a and b) a. Pts pretreatment IgG level is below

normal range (age-adjusted and according to normal reference range for reporting laboratory AND b. Pt has an impaired antibody response (i.e. failure to produce antibodies to specific antigens) OR pt has recurrent infections OR 3. Pt has an IgG subclass deficiency, selective antibody deficiency (SAD), or other confirmed primary immunodeficiency and meets the following (a and b): a. Pt has an impaired antibody response (i.e. failure to produce antibodies to specific antigens) AND b. Patient has recurrent infections. PI Continuation of therapy: Approve if pt has been diagnosed with PI and, according to the prescriber, the pt is continuing to receive benefit from the product (e.g. increased IgG levels or prevention and/or controlling of infections). CIDP or Polyradiculoneuropathy: Initial therapy: Approve if member meets following criteria (i, ii and iii) i. Member has had progressive symptoms present for at least 2 months ii. Has had symptomatic polyradiculoneuropathy with progressive or relapsing motor or sensory impairment in more than one limb iii. Member meets at least three of the following electrodiagnostic criteria for CIDP diagnosis (1, 2, 3 and/or 4): 1. Partial conduction block of one or more motor nerve, 2. Reduced conduction velocity of 2 or more motor nerves, 3. Prolonged distal latency of 2 or more motor nerves, 4. Prolonged F-wave latencies of 2 or more nerves or absence of F waves. CIDP Continuation therapy: Approve if pt has had clinically significant improvement to treatment as measured by an objective scale (e.g. Rankin, Modified Rankin, Medical Research Council [MRC] scale).

## **PART B PREREQUISITE**

N/A

## **SGLT-2**

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### **MEDICATION(S)**

DAPAGLIFLOZIN, DAPAGLIFLOZIN-METFORMIN ER, FARXIGA, SEGLUROMET, STEGLATRO, XIGDUO XR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

One year.

### **OTHER CRITERIA**

Invokana, Invokamet, Jardiance, Synjardy and Synjardy XR are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis, OR the member has a documented contraindication to one preferred formulary alternative, or the member had an adverse reaction or would be reasonably expected to have an

adverse reaction to one preferred formulary alternative, OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

**PART B PREREQUISITE**

N/A

## **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**

N/A

### **AGE RESTRICTION**

18 years and older (initial therapy)

### **PRESCRIBER RESTRICTION**

Cushings disease/syndrome: Prescribed by, or in consultation with, an endocrinologist or a physician that specializes in the treatment of Cushings syndrome.

### **COVERAGE DURATION**

Cushings int: 4 mo. Cont 1 yr.

### **OTHER CRITERIA**

For Cushings disease/syndrome Approve Signifor if the following criteria are met: Initial therapy: Approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Continuation therapy: Approve if the patient has already been started on Signifor and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.

### **PART B PREREQUISITE**

N/A

## **SILIQ**

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### **MEDICATION(S)**

SILIQ

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

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

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, PASI score, reauth: positive response

### **AGE RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a dermatologist.

### **COVERAGE DURATION**

Initial 6 months, continuation 1 year

### **OTHER CRITERIA**

Plaque Psoriasis:

1.Initial: Approve if the patient meets all of the following (a and b):

a.Patient has a diagnosis of moderate to severe plaque psoriasis and has a Psoriasis Area and Severity Index (PASI) score of 10 or more

b.Patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product (SC), Otezla, or Cosentyx. Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab or ustekinumab product will also count. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Preferred ustekinumabs include Stelara and Yesintek.

2.Continuation: Approve if the patient meets both of the following (a and b):

- a.If patient is new to plan, meets initial criteria at time they had started the medication
- b.Patient has had evidence of a positive response based on one of the following (i, ii):
  - i.Achieved or maintained clear or minimal disease
  - ii.A decrease in PASI score compared to baseline
- c.Documented dose and frequency are within the FDA approved Dosing and Frequency

**PART B PREREQUISITE**

N/A

## **SIMBRINZA**

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### **MEDICATION(S)**

SIMBRINZA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Preferred products include generic eye drops used to treat glaucoma. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to two preferred formulary/preferred drug list alternatives for the given diagnosis, OR the member has a documented contraindication to two preferred formulary alternatives, or the member had an adverse reaction or would be reasonably expected to have an adverse reaction to two preferred formulary alternative, OR the member has a clinical condition for which there is no



listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

**PART B PREREQUISITE**

N/A

## **SIMPONI**

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### **MEDICATION(S)**

SIMPONI

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

### **REQUIRED MEDICAL INFORMATION**

For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented Dose and Frequency are within the FDA approved Dosing and Frequency. AS: member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc.) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. Reauth: positive clinical response to therapy as evidenced by at least one objective measure compared to baseline. Examples of objective measures include ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI, DFI, HAQ-S, and/or serum markers (e.g., CRP, ESR). PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. RA: diagnosis and disease severity per ACR criteria, score from objective measure/tool at baseline and continuation (e.g. CDAI, Disease Activity Score with 28-joint counts (ESR or CRP), PAS or PAS-II, RAPID3, SDAI.) UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score.

### **AGE RESTRICTION**

18 years and older

### **PRESCRIBER RESTRICTION**

RA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. UC-prescribed by or in consultation with a gastroenterologist.

## **COVERAGE DURATION**

Initial - 6 months, Continuation - 1 year

## **OTHER CRITERIA**

Ankylosing Spondylitis:

1.Initial therapy - approve if the patient has tried and failed TWO of the following: Enbrel, a preferred adalimumab product, Cosentyx, Rinvoq or Xeljanz/Xeljanz XR. Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi.

2.Continuation therapy – see required medical information for detail.

Psoriatic Arthritis:

1.Initial therapy - approve if the patient meets the following criteria (a and b):

a.Patient is currently experiencing one of the following (i, ii, iii, iv or v):

i.Actively inflamed joints

ii.Dactylitis

iii.Enthesitis

iv.Axial disease

v.Active skin and/or nail involvement

b.Patient has active psoriatic arthritis and patient has tried TWO of the following: Enbrel, a preferred adalimumab product, a preferred ustekinumab product (SC), Otezla, Orencia, Xeljanz/XR, Cosentyx, Rinvoq or Skyrizi. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Preferred ustekinumab products include Stelara and Yesintek.

2.Continuation therapy - approve if there is documentation of positive clinical response to therapy as evidenced by improvement in any of the following from baseline (a, b, c, d, or e):

a.Number of swollen joints

b.Number of tender joints

c.Dactylitis

d.Enthesitis

e.Axial disease

Rheumatoid Arthritis:

1.Initial - approve if the patient has tried two of the following: Enbrel, a preferred adalimumab product, Orencia, Rinvoq or Xeljanz/XR. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi.

2.Continuation - approve if the patient is responding positively to therapy based on improvement in objective measurement/tool as compared to baseline.

Ulcerative Colitis:

1.Initial therapy: Approve if the patient has tried TWO of the following preferred products: a preferred adalimumab product, Skyrizi, a preferred ustekinumab product (SC), Rinvoq, Xeljanz/XR tablets and Zeposia. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and

Simlandi. Preferred ustekinumabs include Stelara and Yesintek.

2.Continuation therapy: Approve if the patient meets ALL of the following (a and b):

a.Patient has been established on the requested medication for at least 5 months

b.Patient has experienced a positive clinical response compared to baseline as evidenced by improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria).

#### **PART B PREREQUISITE**

N/A

## **SKYCLARYS**

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### **MEDICATION(S)**

SKYCLARYS

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Severe hepatic impairment (Child-Pugh C)

### **REQUIRED MEDICAL INFORMATION**

Diagnosis based on genetic test, BNP, LVEF, A1c, mFARS score

### **AGE RESTRICTION**

16 years of age and older

### **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, a neurologist or a physician who specializes in ataxias and/or neuromuscular disorders

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Friedreich's Ataxia: Initial Therapy – approve if patient meets all of the following (1, 2, 3, and 4):

1. Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia (mutation of the FXN gene),
  2. Patient has all of the following in the past year (a, b and c):
    - a. Patient has a B-type natriuretic peptide (BNP) less than or equal to 200 pg/mL, AND
    - b. Patient has a left ventricular ejection fraction greater than or equal to 40%, AND
    - c. Patient has a hemoglobin A1c (HbA1c) less than or equal to 11 percent,
  3. Patient has been assessed using the modified Friedreich's Ataxia Rating Scale (mFARS) and has a score greater than or equal to 20, but less than or equal to 80,
  4. Patient is ambulatory.
- Continuation Therapy – approve if patient meets all of the following (1, 2, 3 and 4):
1. If patient is new to plan, meets initial criteria at time

they had started the medication, 2. Documented dose and frequency are within the FDA approved Dosing and Frequency, 3. Patient has had a trinucleotide repeat expansion assay genetic test confirming the diagnosis of Friedreich's ataxia, 4. Patient continues to benefit from therapy, as demonstrated by improvement or stabilization on the modified Friedreich's Ataxia Rating Scale

**PART B PREREQUISITE**

N/A

## **SKYRIZI**

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### **MEDICATION(S)**

SKYRIZI 150 MG/ML SYRINGE, SKYRIZI ON-BODY, SKYRIZI PEN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

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

### **REQUIRED MEDICAL INFORMATION**

For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved Dosing and Frequency. PP: Diagnosis, PASI score, reauth: positive response. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. CD: Diagnosis, pre-requisite medication trials (if applicable), Reauth: positive clinical response. UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Reauth: Established on med for at least 5 mo AND experienced a pos clinical response compared to baseline as evidenced by improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria)

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

PP-Prescribed by or in consultation with a dermatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. CD, UC-prescribed by or in consultation with a gastroenterologist.

### **COVERAGE DURATION**

Initial 6 months, continuation 3 years

### **OTHER CRITERIA**

PP:Init:Approve if pt meets a and b: a.Pt has a dx of mod/severe PP and one of the following (i, ii or

iii): i. PASI score of 10 or more, ii. At least 3% BSA affect, iii. PP affects hands, feet, scalp, face or genital area b. Pt has TF/C/I to 2 or more of following: i. Phototherapy (PUVA, UVB), ii. Topical tx (topical CS, calcipotriene, retinoid), iii. Systemic non-biologic DMARDs (e.g. MTX, cyclosporine, acitretin).  
 Cont: Approve if pt has evidence of pos response based on a or b: a. Achieved/maintained clear or minimal dz, b. A decr in PASI score compared to baseline. PsA: Init-approve if pt meets a and b: a. Pt is currently experiencing 1 of the following (i, ii, iii, iv or v): i. Actively inflamed joints, ii. Dactylitis, iii. Enthesitis, iv. Axial dz, v. Active skin and/or nail involvement, b. Pt has active PsA and meets i, ii or iii: i. Pt had an inadeq response to MTX, leflunomide, or another conventional synthetic drug (e.g. sulfasalazine), ii. Pt has an intolerable CI to MTX, leflunomide and another conventional synthetic drug (e.g. sulfasalazine), iii. Pt has predominantly axial dz. Cont-approve if there is documentation of pos clinical response to tx as evidenced by improvement in a, b, c, d or e: a. Number of swollen joints, b. Number of tender joints, c. Dactylitis, d. Enthesitis, e. Axial disease. CD: Init: Approve if pt meets a, b and c: a. Documented dx of mod/severe CD, b. Pt is currently experiencing 1 of the following (i, ii, iii, iv or v): i. Freq diarrhea and abdominal pain, ii. At least 10% weight loss, iii. Complication such as obstruction, fever, abdominal mass, iv. Abn labs (e.g. CRP), v. CDAI greater than 20, c. Pt meets 1 of the following conditions (i, ii, iii or iv): i. Tried or currently taking CS or CS are CI in this pt, ii. Has tried 1 other conventional systemic tx for CD (e.g., azathioprine, 6-mercaptopurine, MTX). Note: A previous trial of a biologic other than the requested drug also counts as a trial of 1 other agent for CD. A biosimilar of the requested biologic does not count. A trial of mesalamine does not count as a systemic agent for CD. iii. Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, iv. Had ileocolonic resection (to reduce the chance of CD recurrence). Cont: Approve if pt meets a and b: a. Been on med for at least 5 mo, b. Documentation of pos clinical response to tx as evidenced by at least 1 of the following (1 or 2): i. Improvement in intestinal inflammation (e.g. mucosal healing, improvement of labs [PLT counts, ESR, CRP level]) from baseline, ii. Reversal of high fecal output state. Mod to severely active UC: Initial: Approve

## **PART B PREREQUISITE**

N/A



## **SODIUM OXYBATE PRODUCTS**

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### **MEDICATION(S)**

SODIUM OXYBATE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant use of sodium oxybate, Xywav, Wakix, or Sunosi

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, ESS or MWT score

### **AGE RESTRICTION**

7 years of age or older

### **PRESCRIBER RESTRICTION**

Prescribed by a sleep specialist physician or a Neurologist

### **COVERAGE DURATION**

Initial - 1 year, Continuation – 1 year

### **OTHER CRITERIA**

Narcolepsy with Excessive Daytime Sleepiness (EDS): Approve if the patient meets the following criteria (1, 2, 3, 4 and 5): 1. Narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT), 2. Adults only: Patient has tried and failed or is intolerant to one preferred stimulant treatment (e.g. methylphenidate, dextroamphetamine), 3. Adults only: Patient has tried and failed or is intolerance to modafinil or armodafinil, 4. Confirmation that sleepiness is significantly impacting daytime functioning, 5. Provider must submit baseline Epworth Sleepiness Scale (ESS) and/or Maintenance of Wakefulness Test (MWT). Narcolepsy with cataplexy: Approve if the patient meets the following criteria (1 and 2): 1. Diagnosis has been confirmed with polysomnography and a multiple sleep latency test (MSLT), 2. Provider must submit baseline Epworth Sleepiness Scale (ESS) and/or Maintenance of Wakefulness Test (MWT). Continuation in narcolepsy with EDS or cataplexy: Approve if the patient meets the following criteria (1, 2 and 3): 1. If member is new to plan, must meet

initial criteria at time of starting the medication, 2. Documented dose and frequency are within the FDA approved Dosing and Frequency, 3. Documented improvement in ESS or MWT score demonstrating response to current therapy

**PART B PREREQUISITE**

N/A

## **SOMATULINE**

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### **MEDICATION(S)**

LANREOTIDE 120 MG/0.5 ML SYRNG

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Pheochromocytoma/paraganglioma

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, previous treatments/therapies

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescribed by or in consultation with an endo/onc/neuro.

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Acromegaly-approve if the patient has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)-approve. Carcinoid Syndrome-approve.

**PART B PREREQUISITE**

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**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Acromegaly approve if patient meets has a pre-treatment (baseline) IGF-1 level above the upper limit of normal based on age and gender for the reporting laboratory and ONE of the following (1, 2 or 3): 1. Patient has had an inadequate response to surgery and/or radiotherapy OR 2. The patient is not an appropriate candidate for surgery and/or radiotherapy OR 3. The patient is experiencing negative effects due to tumor size (e.g. optic nerve compression)

### **PART B PREREQUISITE**

N/A

# **SOTYKTU**

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## **MEDICATION(S)**

SOTYKTU

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

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

## **REQUIRED MEDICAL INFORMATION**

Diagnosis, PASI score, reauth: positive response

## **AGE RESTRICTION**

18 years of age and older

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a dermatologist

## **COVERAGE DURATION**

Initial 6 months, continuation 1 year

## **OTHER CRITERIA**

Plaque Psoriasis 1.Initial: Approve if the patient meets all of the following (a and b):

a.Patient has a diagnosis of moderate to severe plaque psoriasis and has a Psoriasis Area and Severity Index (PASI) score of 10 or more

b.Patient has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab product (SC), Otezla, or Cosentyx. Note: If the patient does not meet this requirement, a trial of a non-preferred adalimumab or ustekinumab product will also count. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Preferred ustekinumabs include Stelara and Yesintek.

2.Continuation: Approve if the patient meets both of the following (a and b):

a.If patient is new to plan, meets initial criteria at time they had started the medication

- b. Patient has had evidence of a positive response based on one of the following (i, ii):
  - i. Achieved or maintained clear or minimal disease
  - ii. A decrease in PASI score compared to baseline
- c. Documented dose and frequency are within the FDA approved Dosing and Frequency

**PART B PREREQUISITE**

N/A

## **SOVALDI**

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### **MEDICATION(S)**

SOVALDI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

18 years or older. 3 and older in Genotype 2 and 3

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

12 wk, 16 wk, 24 wk, or 48 wk. Criteria will be applied consistent with current AASLD/IDSA guidance.

### **OTHER CRITERIA**

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

### **PART B PREREQUISITE**

N/A



## **SPRYCEL**

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### **MEDICATION(S)**

DASATINIB, SPRYCEL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **STELARA**

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### **MEDICATION(S)**

STELARA 45 MG/0.5 ML SYRINGE, STELARA 45 MG/0.5 ML VIAL, STELARA 90 MG/ML SYRINGE, YESINTEK 45 MG/0.5 ML SYRINGE, YESINTEK 45 MG/0.5 ML VIAL, YESINTEK 90 MG/ML SYRINGE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthesis DMARD.

### **REQUIRED MEDICAL INFORMATION**

PP: Diagnosis, PASI score, reauth: positive response. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Reauth: Improvement on endoscopy or objective score. CD: Diagnosis, pre-requisite medication trials (if applicable), Reauth: positive clinical response. For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved Dosing and Frequency.

### **AGE RESTRICTION**

Adults-CD. PsA and PP-6 years and older

### **PRESCRIBER RESTRICTION**

PP (Plaque Psoriasis)-prescribed by or in consultation with a dermatologist. PsA(Psoriatic Arthritis)-prescribed by or in consultation with a rheumatologist or dermatologist. CD /UC (Ulcerative Colitis)-prescribed by or in consultation with a gastroenterologist.

### **COVERAGE DURATION**

Initial 6 months, continuation 3 years

### **OTHER CRITERIA**

Please note: Preferred ustekinumab products include Stelara and Yesintek. PP:Initial: Approve if pt meets a and b: a.Dx of mod/severe PP and (i, ii or iii): i. Has PASI score 10 or more or ii. At least 3% BSA affected, iii. PP affects hands, feet, scalp, face, or genital area, b.Pt has TF/C/I to 2 or more of the following: i. Phototherapy (PUVA, UVB), ii.Topical tx (topical corticosteroid, calcipotriene, retinoid), iii. Systemic non-biologic DMARDs (e.g. MTX, cyclosporine, acitretin). Cont:Approve if pt has evidence of a pos response based on a or b: a. Achieved/maintained clear or minimal disease b.Decr in PASI score compared to baseline. PsA:Initial therapy-approve if pt meets a and b: a.Currently experiencing one of the following i, ii, iii, iv or v: i. Actively inflamed joints, ii.Dactylitis, iii. Enthesitis, iv.Axial disease, v.Active skin and/or nail involvement, b.Active PsA and for pats 18 yrs and older, meets i, ii or iii: i.Inadeq response to MTX, leflunomide, or another conventional synthetic drug (e.g. sulfasalazine), ii.I/C to MTX, leflunomide and another conventional synthetic drug (e.g. sulfasalazine) iii.Predominantly axial dz. Cont-approve if documentation of pos clinical response to tx by improvement in a, b, c, d or e: a. Number of swollen joints, b. Number of tender joints, c. Dactylitis, d. Enthesitis, e. Axial disease. CD:Init:Approve if pt meets a, b and c:a. Documented dx of mod/severe CD, b.Pt is currently experiencing i, ii, iii, iv or v: i. Frequent diarrhea and abdominal pain, ii.At least 10 percent weight loss, iii.Complication (e.g. obstruction, fever, abdominal mass) iv.Abnormal labs (e.g. CRP), v.CDAI greater than 20, c.Pt meets i, ii, iii or iv: i. Tried or is currently taking CS, or CS are CI ii. Tried 1 other conventional systemic tx for CD (e.g., azathioprine, 6-mercaptopurine, MTX). A previous trial of a biologic other than the requested drug also counts as trial of 1 other agent for CD. A biosimilar of the requested drug does not count. iii.Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, iv.Had ileocolonic resection (to reduce the chance of CD recurrence).Cont:Approve if documentation of pos clinical response to tx by meeting a or b: a.Improvement in intestinal inflammation (e.g. mucosal healing, improvement of labs [plt counts, ESR, CRP level]) from baseline b. Reversal of high fecal output state. Mod/severe active UC-Init: Approve. Cont: Approve if the pt meets i and ii:i.Estab on med for at least 5 mo, ii.Had pos clinical response compared to baseline based on objective scoring system (e.g. MMS, Trulove and Witts)

## **PART B PREREQUISITE**

N/A

## **STIVARGA**

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### **MEDICATION(S)**

STIVARGA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **STRENSIQ**

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### **MEDICATION(S)**

STRENSIQ

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, lab values, radiographic reports

### **AGE RESTRICTION**

Disease onset-less than or equal to 18

### **PRESCRIBER RESTRICTION**

Prescribed by an endocrinologist or specialist experienced in treatment of metabolic bone disorders

### **COVERAGE DURATION**

Initial – 6 months. Continuation – 12 months.

### **OTHER CRITERIA**

Initial Coverage – member meets all of the following requirements (1, 2 and 3): 1. Documented diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) AND diagnosis supported by one of the following (a or b): a. Molecular genetic testing documenting tissue non-specific alkaline phosphatase (ALPL) gene mutation OR b. Documentation of ALL of the following (i, ii and iii): i. An elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (i.e., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPI] level) ii. Findings on radiographic imaging support diagnosis of hypophosphatasia (e.g. infantile rickets, alveolar bone loss, osteoporosis, low bone mineral content for age [as detected by DXA scan])

iii. Low baseline ALP activity (age adjusted), 2. Member is 18 years or less at age of disease onset 3.

Member has clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, respiratory problems, hypercalcemia, seizures). Continuation of coverage – member meets the following (1, 2 and 3) 1. Member meets criteria for initial approval, 2. Documentation of positive clinical response to Strensiq (e.g. improvement in clinical symptoms, improvement in Radiographic Global Impression of Change), 3. Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate (i.e., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPI] level).

#### **PART B PREREQUISITE**

N/A

## **SUTENT**

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### **MEDICATION(S)**

SUNITINIB MALATE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **SYMDEKO**

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### **MEDICATION(S)**

SYMDEKO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with Orkambi, Kalydeco or Trikafta. Patients with unknown CFTR gene mutations.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, specific CFTR gene mutations

### **AGE RESTRICTION**

6 years of age or older.

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

Cystic Fibrosis: Approve if the patient meets the following criteria (1, 2, 3, 4 and 5): 1. Diagnosis of cystic fibrosis, 2. Patient meets one of the following (a or b): a. Patient has at least one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic and responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence, b. Patient is homozygous for the F508del mutation, 3. Patient has at least one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic, 4. Patient must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF, 5. Evidence of abnormal CFTR function as demonstrated by a, b or c: a. Elevated sweat chloride test, b. Two CFTR mutations, c. Abnormal nasal potential difference



**PART B PREREQUISITE**

N/A

## **TABRECTA**

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### **MEDICATION(S)**

TABRECTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TAFAMIDIS**

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### **MEDICATION(S)**

VYNDAMAX, VYNDAQEL

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant use with Onpattro or Tegsedi. Concurrent use of Vyndaqel and Vyndamax. Presence of primary (light chain) amyloidosis. Prior liver or heart transplantation or implanted cardiac mechanical assist device.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, genetic and/or diagnostic tests as outlined in other criteria, NYHA functional class. Reauth: positive response.

### **AGE RESTRICTION**

18 years and older.

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

1 year.

### **OTHER CRITERIA**

Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis

1.Initial – Approve if the patient meets all of the following criteria (A, B, C, D and E):

A.The patient has genetic testing to identify a transthyretin (TTR) mutation (e.g., Val122Ile mutation, Thr60Ala mutation) or wild-type amyloidosis AND

B.The diagnosis was confirmed by one of the following (a or b):

a.A technetium pyrophosphate scan (i.e., nuclear scintigraphy) OR

b.Amyloid deposits are identified on cardiac biopsy AND

- C. Patient must have evidence of cardiac involvement by echocardiography with an end-diastolic intraventricular septal wall thickness greater than 12 mm
- D. Patient has a diagnosis of New York Heart Association (NYHA) class I, II or III
- E. Patient has a medical history of either of the following (a or b):
  - a. At least one prior hospitalization for heart failure
  - b. Clinical evidence of heart failure as demonstrated by signs or symptoms consistent with volume overload or elevated intracardiac pressures (e.g. elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) requiring treatment with a diuretic for improvement
- 2. Continuation – Approve if the patient meets all of the following (a, b, c and d):
  - a. If patient is new to plan, meets initial criteria at time they had started the medication
  - b. Documented dose and frequency are within the FDA approved Dosing and Frequency
  - c. Patient continues to have NYHA Functional Class I, II, or III heart failure
  - d. Patient has experienced a positive clinical response to the medication (e.g. cardiac function, quality of life assessment, serum TTR levels, etc.)

## **PART B PREREQUISITE**

N/A

## **TAFINLAR**

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### **MEDICATION(S)**

TAFINLAR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TAGRISSO**

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### **MEDICATION(S)**

TAGRISSO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# TALTZ

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## MEDICATION(S)

TALTZ AUTOINJECTOR, TALTZ AUTOINJECTOR (2 PACK), TALTZ AUTOINJECTOR (3 PACK), TALTZ SYRINGE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

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

## REQUIRED MEDICAL INFORMATION

For all diagnoses: If patient is new to plan, meets initial criteria at time they had started the medication. Documented dose and frequency are within the FDA approved Dosing and Frequency. PP: Confirmed diagnosis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc.) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. PASI score, reauth: positive response. AS: Diagnosis, pre-requisite medication trials, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc.) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. Continuation: Patient has experienced a positive clinical response to therapy as evidenced by at least one objective measure compared to baseline. Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate). Nr-asXpA: Diagnosis, pre-requisite medication trials, objective signs of inflammation, reauth: positive clinical response.

## AGE RESTRICTION

Plaque psoriasis 6 years and older. All other diagnoses - 18 years of age and older.

### **PRESCRIBER RESTRICTION**

Plaque Psoriasis (PP)-prescribed by or in consultation with a dermatologist. Psoriatic Arthritis (PsA)- Prescribed by or in consultation with a rheumatologist or a dermatologist. AS/nr-asXpA -prescribed by or in consultation with a rheumatologist.

### **COVERAGE DURATION**

Initial - 6 months, Continuation - 1 year

### **OTHER CRITERIA**

PP:Initial:Approve if pt meets a and b: a. Pt has a dx of mod/severe PP and has a PASI score of 10 or more, b. Pt has tried TWO of the following: Enbrel, a preferred adalimumab product, Skyrizi, Stelara (SC), Otezla, or Cosentyx. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Cont: Approve if pt has evidence of a positive response based on i, ii or iii: i. Achieved or maintained clear or minimal disease, ii. A decr in PASI score compared to baseline. PsA: 1. Init-approve if pt meets a and b: a. Pt is currently experiencing one of the following (i, ii, iii, iv or v): i. Actively inflamed joints, ii. Dactylitis, iii. Enthesitis, iv. Axial dz, v. Active skin and/or nail involvement, b. Pt has active mod/severe PsA and pt has tried TWO of the following: Enbrel, a preferred adalimumab product, Stelara SC, Otezla, Orencia, Xeljanz/XR, Cosentyx, Rinvoq or Skyrizi. Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Cont-approve if there is documentation of positive clinical response to therapy as evidenced by improvement in any of the following from baseline (a, b, c, d or e): a. Number of swollen joints, b. Number of tender joints, c. Dactylitis, d. Enthesitis, e. Axial dz. AS:Init-approve if pt has TF 2 of the following: Enbrel, a preferred adalimumab product, Cosentyx, Rinvoq or Xeljanz/Xeljanz XR. Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Cont-see required medical information for details. nr-asXpA:Init-approve if pt has objective signs of inflammation, defined as at least one of the following (a or b): a. CRP elevated beyond the ULN for the reporting lab, b. Sacroiliitis reported on MRI. Cont-approve if pt has experienced a positive clinical response to tx as evidenced by improvement from baseline for at least one of the following (a, b, c or d): a. Dz activity (e.g. pain, fatigue, inflammation, stiffness, b. Labs (CRP), c. Axial status (e.g. lumbar spine motion, chest expansion), d. Total active (swollen and tender) joint count.

### **PART B PREREQUISITE**

N/A



## **TALVEY**

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### **MEDICATION(S)**

TALVEY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TALZENNA**

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### **MEDICATION(S)**

TALZENNA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TARCEVA**

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### **MEDICATION(S)**

ERLOTINIB HCL 100 MG TABLET, ERLOTINIB HCL 150 MG TABLET, ERLOTINIB HCL 25 MG TABLET

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TARGRETIN - ORAL**

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### **MEDICATION(S)**

BEXAROTENE 75 MG CAPSULE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TARGRETIN TOPICAL**

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### **MEDICATION(S)**

BEXAROTENE 1% GEL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TARPEYO**

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### **MEDICATION(S)**

TARPEYO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

eGFR less than 30 ml/min/1.73m<sup>2</sup>

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, medication history

### **AGE RESTRICTION**

18 years of age and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a nephrologist

### **COVERAGE DURATION**

10 months

### **OTHER CRITERIA**

For Primary IgAN: Initial therapy. Approve if patient meets the following (i, ii and iii): i.Diagnosis has been confirmed by biopsy AND ii.Patient is at high risk of disease progression, defined by meeting the following criteria (a and b): a.Patient meets ONE of the following (1 or 2): 1.Proteinuria greater than 0.5 g/day OR 2. Urine protein-to-creatinine ratio equal to or greater than 0.8 g/g AND b. Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for 90 days or greater (1 and 2): 1. Angiotensin converting enzyme inhibitor OR 2. Angiotensin receptor blocker, AND iii. Member trial and failed or has a contraindication to use of either prednisone, prednisolone or methylprednisolone, AND iv. Patient has not previously been treated with Tarpeyo. Continuation of therapy. Approve for up to 10 months (total) if the patient meets the following criteria (i and ii): i.Diagnosis has been confirmed by biopsy AND ii. Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for 90 days or greater (1 and 2): 1. Angiotensin

converting enzyme inhibitor OR 2. Angiotensin receptor blocker

**PART B PREREQUISITE**

N/A

## **TASIGNA**

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### **MEDICATION(S)**

NILOTINIB HCL, TASIGNA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **TAVNEOS**

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### **MEDICATION(S)**

TAVNEOS

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, Lab values for antibodies (as described in other criteria), Reauth: positive response

### **AGE RESTRICTION**

18 years and older (initial and continuation therapy)

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist

### **COVERAGE DURATION**

Initial 6 months, Continuation 1 year

### **OTHER CRITERIA**

Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, initial-approve if the patient meets (i, ii, iii and iv):

i. Patient has granulomatosis with polyangiitis or microscopic polyangiitis, AND

Note: Granulomatosis with polyangiitis is also known as Wegener's granulomatosis.

ii. Patient has active disease, AND

Note: This includes patients that have newly diagnosed or relapsed disease. This does not include patients already in remission.

iii. Patient is positive for proteinase 3 antibodies, anti-neutrophil cytoplasmic autoantibody (ANCA) or myeloperoxidase antibodies, AND

iv. Patient is using this medication in combination with at least one immunosuppressant

Note: Examples of immunosuppressants include cyclophosphamide, rituximab, azathioprine, or

mycophenolate mofetil.

Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, continuation-approve if the patient meets at least one of the following (a and b):

a) If patient is new to plan, meets initial criteria at time they had started the medication,

b) Patient meets one of the following (1 or 2):

(1) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Tavneos), OR

Note: Examples of objective measure include improvement in estimated glomerular filtration rate, decrease in urinary albumin creatinine ratio, or improvement in the Birmingham Vasculitis Activity Score [BVAS].

(2) Compared with baseline (prior to receiving Tavneos), patient experienced an improvement in at least one symptom, such as joint pain, ulcers, myalgia, persistent cough, abdominal pain, or improvement in function or activities of daily living.

#### **PART B PREREQUISITE**

N/A

## **TAZAROTENE**

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### **MEDICATION(S)**

TAZAROTENE 0.1% CREAM, TAZAROTENE 0.1% GEL

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Pregnancy. Fine wrinkle disorder/fine wrinkles on face.

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Lifetime.

### **OTHER CRITERIA**

Diagnosis of acne vulgaris requires failure on at least two other formulary anti-acne preparations (e.g. topical retinoid products, topical antibacterial products). Members must utilize adequate measures to prevent pregnancy.

### **PART B PREREQUISITE**

N/A

## **TAZVERIK**

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### **MEDICATION(S)**

TAZVERIK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TECVAYLI**

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### **MEDICATION(S)**

TECVAYLI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TEGSEDI**

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### **MEDICATION(S)**

TEGSEDI

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant use with Onpattro or a tafamidis product

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, genetic testing, biopsy results. FAP score.

### **AGE RESTRICTION**

18 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Initial: Approve if the patient meets all of the following (1, 2, 3 and 4):

- 1.Patient has a documented transthyretin (TTR) mutation verified by genetic testing
- 2.Patient has documentation of biopsy proven amyloid deposits
- 3.Patient has symptomatic polyneuropathy (e.g., reduced motor strength/coordination, impaired sensation [e.g., pain, temperate, vibration, touch]).
- 4.Patient has baseline familial amyloidotic polyneuropathy (FAP) stage 1 or 2

Continuation: Approve if the patient meets all of the following:

- 1.Patient has demonstrated a benefit from therapy (e.g. improved neurological impairment, slowing of disease progression, quality of life assessment)
- 2.Patient continues to have a FAP stage 1 or 2

**PART B PREREQUISITE**

N/A

## **TEPMETKO**

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### **MEDICATION(S)**

TEPMETKO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **TERIFLUNOMIDE**

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### **MEDICATION(S)**

TERIFLUNOMIDE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

MS, patient must have a relapsing form of MS (RRMS, SPMS with relapses, or PRMS), clinically-isolated syndrome, or active secondary progressive disease with evidence of new brain lesions.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

Lifetime.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# TESTOSTERONE

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## MEDICATION(S)

TESTOSTERONE 1% (25MG/2.5G) PK, TESTOSTERONE 1% (50 MG/5 G) PK, TESTOSTERONE 1.62% (2.5 G) PKT, TESTOSTERONE 1.62% GEL PUMP, TESTOSTERONE 1.62%(1.25 G) PKT, TESTOSTERONE 10 MG GEL PUMP, TESTOSTERONE 12.5 MG/1.25 GRAM, TESTOSTERONE 30 MG/1.5 ML PUMP, TESTOSTERONE 50 MG/5 GRAM GEL, TESTOSTERONE 50 MG/5 GRAM PKT

## PA INDICATION INDICATOR

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

## OFF LABEL USES

Gender dysphoria in transgender male patients.

## EXCLUSION CRITERIA

Erectile dysfunction. Decreased Libido.

## REQUIRED MEDICAL INFORMATION

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

## AGE RESTRICTION

Aged 18 years or older.

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Lifetime.

## OTHER CRITERIA

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

by the normal laboratory reference values. Hypogonadism has been confirmed by a low for age serum testosterone (total or free) level defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]

## **PART B PREREQUISITE**

N/A

## **TEVIMBRA**

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### **MEDICATION(S)**

TEVIMBRA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TEZSPIRE**

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### **MEDICATION(S)**

TEZSPIRE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with other monoclonal antibodies for asthma (e.g. Cinqair, Fasenra, Nucala, Dupixent, or Xolair)

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, medication history

### **AGE RESTRICTION**

12 years of age and older

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

Initial: 6 months, Continuation: 3 years

### **OTHER CRITERIA**

Severe Asthma: Initial Therapy: Approve if the patient meets the following criteria (i and ii): i. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b): a. The member must have received at least 3 months of combination therapy with an oral corticosteroid or inhaled corticosteroid AND one of the following b. At least one additional asthma controller or asthma maintenance medication (examples include inhaled long-acting beta-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, or theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta-agonist would fulfill the requirement for both criteria a and b). ii. The patient's asthma continues to be uncontrolled as defined by one of the following (a, b, c, d, or e): a. Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b. Patient

experienced one or more asthma exacerbation(s) requiring hospitalization or an Emergency Department visit in the previous year OR c.Patient has a forced expiratory volume in 1 second (FEV1) less than 80 percent predicted OR d.Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e.The patient has asthma that worsens upon tapering of oral corticosteroid therapy. Continuation of Therapy. Approve if the patient meets the following criteria (i, ii and iii): i.Patient has already received at least 6 months of therapy with Tezspire AND ii.The patient continues to receive therapy with an oral or inhaled corticosteroid AND iii.The patient has responded to Tezspire therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations/emergency department/urgent care/physician visits due to the asthma, decreased requirement for oral corticosteroid therapy).

#### **PART B PREREQUISITE**

N/A

## **THALOMID**

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### **MEDICATION(S)**

THALOMID

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi sarcoma, Castlemans Disease, Histiocytic neoplasms

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, previous therapies tried

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

For Erythem Nodosum Leprosum approve. For Multiple myeloma approve if Thalomid is being taken in combination with dexamethasone. For Discoid lupus erythematosus or cutaneous lupus erythematosus approve if the patient has tried at least two other therapies (e.g. corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). For Myelofibrosis approve if, according to the prescriber, the patient has anemia and has serum erythropoietin levels greater than or equal to 500 mU/ml OR the patient has serum erythropoietin levels less than 500 mU/ml and no response or loss of response to erythropoietic stimulating agents. For Prurigo nodularis approve. For Recurrent aphthous ulcers or aphthous stomatitis approve if the patient has tried at least two other therapies (e.g. topical or intralesional

corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [e.g. benzocaine lozenges], antimicrobial mouthwashes [e.g. tetracycline], acyclovir, colchicine) 7.Kaposi sarcoma approve if the patient has tried at least one regimen or therapy and has relapsed or refractory disease 8.Castlemans disease approve if patient meets ALL of the following criteria: a. Has multicentric Castlemans disease AND b. Is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). Histiocytic neoplasms – approve if the patient has Langerhans cell histiocytosis with single-system multifocal skin disease or Rosai-Dorfman cutaneous disease.

## **PART B PREREQUISITE**

N/A



## **TIBSOVO**

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### **MEDICATION(S)**

TIBSOVO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TIOPRONIN**

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### **MEDICATION(S)**

TIOPRONIN, VENXXIVA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis of severe homozygous cystinuria

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, a nephrologist or urologist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Initiation of therapy: patient has urinary cysteine concentration greater than 250 mg/L.

### **PART B PREREQUISITE**

N/A

## **TIVDAK**

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### **MEDICATION(S)**

TIVDAK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TOPICAL ALPHA-ADRENERGIC AGENTS FOR ROSACEA**

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### **MEDICATION(S)**

BRIMONIDINE 0.33% GEL PUMP

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## TOPICAL RETINOID PRODUCTS

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### MEDICATION(S)

ADAPALENE 0.1% CREAM, ADAPALENE 0.3% GEL, AKLIEF, TRETINOIN 0.01% GEL, TRETINOIN 0.025% CREAM, TRETINOIN 0.025% GEL, TRETINOIN 0.05% CREAM, TRETINOIN 0.1% CREAM, TRETINOIN MICROSPHERE

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

Coverage is not provided for cosmetic use.

### REQUIRED MEDICAL INFORMATION

N/A

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

Authorization will be for 12 months.

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

## **TRANSMUCOSAL IR FENTANYL DRUGS**

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### **MEDICATION(S)**

FENTANYL CIT OTFC 1,200 MCG, FENTANYL CIT OTFC 1,600 MCG, FENTANYL CITRATE OTFC 200 MCG, FENTANYL CITRATE OTFC 400 MCG, FENTANYL CITRATE OTFC 600 MCG, FENTANYL CITRATE OTFC 800 MCG

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Authorization will be for 12 months.

### **OTHER CRITERIA**

For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate).

### **PART B PREREQUISITE**

N/A



## **TRELSTAR**

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### **MEDICATION(S)**

TRELSTAR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **TREMFYA**

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### **MEDICATION(S)**

TREMFYA 100 MG/ML SYRINGE, TREMFYA 200 MG/2 ML SYRINGE, TREMFYA ONE-PRESS, TREMFYA PEN, TREMFYA PEN INDUCTION PK-CROHN

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

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

### **REQUIRED MEDICAL INFORMATION**

PP: Diagnosis, PASI score, reauth: positive response. PsA: Diagnosis, reauth: positive clinical response. UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score. CD: Diagnosis, pre-requisite medication trials (if applicable), Reauth: positive clinical response. For all: If patient is new to plan, meets initial criteria at time they had started the medication and documented dose and frequency are within the FDA approved Dosing and Frequency.

### **AGE RESTRICTION**

18 years of age or older.

### **PRESCRIBER RESTRICTION**

Plaque psoriasis - prescribed by or in consultation with a dermatologist. Psoriatic arthritis prescribed by or in consultation with a dermatologist or rheumatologist. UC, CD – prescribed by or in consultation with a gastroenterologist.

### **COVERAGE DURATION**

Initial 6 months, continuation 1 year

### **OTHER CRITERIA**

PP: Init: Approve if the pt meets all of the following (a and b): a. Pt has a dx of mod to severe PP and

has a PASI score of 10 or more, b. Pt has tried 2 of the following: Enbrel, a preferred adalimumab product, Skyrizi, a preferred ustekinumab (SQ), Otezla, or Cosentyx. Note: If pt does not meet this requirement, a trial of a non-preferred adalimumab or ustekinumab product will also count. 2. Cont: Approve if pt meets the following: Pt has had evidence of a positive response based on one of the following (i or ii): i. Achieved or maintained clear or minimal dz, ii. A decr in PASI score compared to baseline. PsA: Initial - approve if the pt meets the following criteria (a and b): a. Pt is currently experiencing one of the following (i, ii, iii, iv or v): i. Actively inflamed joints, ii. Dactylitis, iii. Enthesitis, iv. Axial dz, v. Active skin and/or nail involvement, b. Pt has active PsA. Cont - Documentation of positive clinical response to tx as evidenced by improvement in any of the following from baseline (i, ii, iii, iv or v): i. Number of swollen joints, ii. Number of tender joints, iii. Dactylitis, iv. Enthesitis, v. Axial disease. Moderately to severely active UC: Init: Approve if the pt has tried 2 of the following preferred products: a preferred adalimumab product, Skyrizi, a preferred ustekinumab (SQ), Rinvoq, Xeljanz/XR tablets and Zeposia. Note: If pt does not meet this requirement, a trial of a non-preferred adalimumab or ustekinumab product will also count. Cont: Approve if the pt meets both of the following: i. Patient has been established on the requested medication for at least 5 months, iii. Pt has experienced a positive clinical response compared to baseline as evidenced by improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria). CD: Init: Approve if pt meets ALL (a, b, c and d): a. Documented dx of mod to severe CD, b. Pt is currently experiencing 1 (i, ii, iii, iv or v): i. Frequent diarrhea and abdominal pain, ii. At least 10% weight loss. iii. Complication such as obstruction, fever, abdominal mass, iv. Abnormal labs (e.g. CRP), v. CDAI greater than 20, c. According to MD, pt is currently receiving Tremfya IV or will receive induction dosing with Tremfya IV w/in 4 months prior to initiating tx with Tremfya SQ. d. Pt has tried 2 of the following: a preferred adalimumab product, Skyrizi SQ, preferred ustekinumab SQ or Rinvoq. Note: preferred adalimumabs include: Humira (NDCs starting with -00074) and Simlandi. Preferred ustekinumabs include: Stelara, Yesintek. Cont tx: Approve if pt meets both (a and b): a. Has been on the Tremfya for at least 5 mo, b. Has documentation of pos clinical response to tx based on 1 of the following (i or ii): i. Improvement in intestinal inflammation (e.g. mucosal healing, improvement of labs [plt counts, ESR, CRP level]) from baseline, ii. Reversal of high fecal output state.

## **PART B PREREQUISITE**

N/A

## **TRETINOIN**

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### **MEDICATION(S)**

TRETINOIN 10 MG CAPSULE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

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**

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

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, specific CFTR gene mutations, concurrent medications.

### **AGE RESTRICTION**

2 years of age and older.

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

3 years.

### **OTHER CRITERIA**

Cystic Fibrosis - approve if the patient meets the following criteria (1, 2, 3, 4 and 5): 1. Diagnosis of cystic fibrosis, 2. Has at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive to the requested medication, 3. Patient must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF, 4. Has at least one mutation in the CFTR gene that is considered to be pathogenic or likely pathogenic, 5. Evidence of abnormal CFTR function as demonstrated by a, b or c: a. Elevated sweat chloride test, b. Two CFTR mutations, c. Abnormal nasal potential difference

### **PART B PREREQUISITE**

N/A



## TRINTELLIX

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### MEDICATION(S)

TRINTELLIX

### 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

Lifetime

### OTHER CRITERIA

For Major depressive disorder: Member must have tried and failed one generic serotonin selective reuptake inhibitor (SSRI)

### PART B PREREQUISITE

N/A

## **TRIPTAN THERAPY**

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### **MEDICATION(S)**

ZOLMITRIPTAN 2.5 MG NASAL SPRY, ZOLMITRIPTAN 2.5MG NASAL SPRAY, ZOLMITRIPTAN 5 MG NASAL SPRAY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experience with the preferred product, or the clinical condition for which an exception to the preferred product is requested.)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 years

### **OTHER CRITERIA**

Almotriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan (tablet and ODT), and eletriptan are the preferred products. . The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to the preferred formulary drug OR the member has a documented contraindication to the preferred formulary drug OR the member has had an adverse reaction or would be reasonably expected to have an

adverse reaction to the preferred formulary drug OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

**PART B PREREQUISITE**

N/A



## **TRODELVY**

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### **MEDICATION(S)**

TRODELVY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## TRUQAP

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### MEDICATION(S)

TRUQAP

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

N/A

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

1 year

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

## **TUKYSA**

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### **MEDICATION(S)**

TUKYSA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TURALIO**

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### **MEDICATION(S)**

TURALIO 125 MG CAPSULE

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TYKERB**

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### **MEDICATION(S)**

LAPATINIB

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **UBRELVY**

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### **MEDICATION(S)**

UBRELVY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

For acute treatment: Combination with a CGRP antagonist when the CGRP antagonist is being used for acute treatment.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

18 years of age and older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Approve if the patient has trialed and failed or has a contraindication [documentation required] to Nurtec ODT.

### **PART B PREREQUISITE**

N/A

## **VALCHLOR**

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### **MEDICATION(S)**

VALCHLOR

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **VANFLYTA**

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### **MEDICATION(S)**

VANFLYTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **VELSIPITY**

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### **MEDICATION(S)**

VELSIPITY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.

### **REQUIRED MEDICAL INFORMATION**

The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score

### **AGE RESTRICTION**

18 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a gastroenterologist

### **COVERAGE DURATION**

Initial: 6 months, Continuation: 1 year

### **OTHER CRITERIA**

1. Moderately to severely active Ulcerative Colitis a. Initial therapy: Approve if the patient has tried TWO of the following preferred products: a preferred adalimumab product, Skyrizi, a preferred ustekinumab product (SC), Rinvoq, Xeljanz/XR tablets and Zeposia. Please Note: preferred adalimumabs include: Humira (NDCs starting with -00074), and Simlandi. Preferred ustekinumabs include Stelara and Yesintek. b. Continuation therapy: Approve if the patient meets all of the following (1, 2, 3 and 4): 1. If patient is new to plan, meets initial criteria at time they had started the medication, 2. Patient has been established on the requested medication for at least 5 months, 3. Patient has experienced a positive clinical response compared to baseline as evidenced by improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria,

4.Documented dose and frequency are within the FDA approved Dosing and Frequency

**PART B PREREQUISITE**

N/A

## **VENCLEXTA**

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### **MEDICATION(S)**

VENCLEXTA, VENCLEXTA STARTING PACK

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **VENTAVIS**

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### **MEDICATION(S)**

VENTAVIS

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis as confirmed by right heart catheterizations

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, a cardiologist or pulmonologist.

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Pulmonary arterial hypertension (PAH) WHO Group 1: Patient meets the following (1 and 2): 1. Diagnosis of PAH confirmed on pretreatment right heart catheterization showing all of the following (a, b and c): a. Mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mm Hg at rest b. Pulmonary capillary wedge pressure (PCWP), mean pulmonary artery wedge pressure (PAWP), left atrial pressure, or left ventricular end-diastolic pressure (LVEDP) less than or equal to 15 mm Hg AND c. Pulmonary vascular resistance (PVR) greater than 3 Wood units. 2. Individual has WHO functional class III or IV symptoms. Part B vs D determination will be made based on location of administration.

### **PART B PREREQUISITE**

N/A

## **VEOZAH**

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### **MEDICATION(S)**

VEOZAH

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Use in patients with cirrhosis, severe renal impairment (eGFR less than 30 ml/min/1.73m<sup>2</sup>) or end-stage renal disease, concomitant use with CYP1A2 inhibitors (e.g. allopurinol, acyclovir, fluvoxamine, mexiletine, cimetidine)

### **REQUIRED MEDICAL INFORMATION**

Continuation of therapy: documentation of a positive clinical response to therapy (e.g. decreased frequency and severity of vasomotor symptoms from baseline)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Vasomotor symptoms due to menopause - Initial: Member meets all of the following (1, 2 and 3):  
1. History of failure (following minimum 1-month trial), contraindication or intolerance to a hormonal therapy (e.g., estradiol, Premarin, Prempro) 2. History of failure (following minimum 1-month trial), contraindication or intolerance to a non-hormonal therapy (e.g., selective serotonin reuptake inhibitors [SSRIs], serotonin and norepinephrine reuptake inhibitors [SNRIs], gabapentin, clonidine) 3. Diagnosis of moderate to severe vasomotor symptoms due to menopause

### **PART B PREREQUISITE**

N/A

## **VERZENIO**

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### **MEDICATION(S)**

VERZENIO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

For advanced or metastatic breast cancer – the member must meet one of the following criteria (1, 2, 3 or 4):

- 1.The member has demonstrated a failure of or intolerance to one of the preferred products, Ibrance and Kisqali, for the given diagnosis
- 2.The member has a documented contraindication to one of the preferred products, Ibrance and Kisqali
- 3.The member had an adverse reaction or would be reasonably expected to have an adverse reaction to one of the preferred products, Ibrance and Kisqali, OR
- 4.The patient has a clinical condition for which there is no listed preferred formulary alternatives to treat the condition based on published guidelines or clinical literature.

### **PART B PREREQUISITE**

N/A



## **VIJOICE**

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### **MEDICATION(S)**

VIJOICE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Patient has laboratory confirmation of PIK3CA mutation

### **AGE RESTRICTION**

2 years of age or older

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Patient has severe or life-threatening clinical manifestations of PROS, as assessed by the treating physician, that necessitates use of systemic treatment.

### **PART B PREREQUISITE**

N/A

## VITRAKVI

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### MEDICATION(S)

VITRAKVI

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

N/A

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

N/A

### COVERAGE DURATION

1 year

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A

## **VIZIMPRO**

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### **MEDICATION(S)**

VIZIMPRO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## VONJO

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### **MEDICATION(S)**

VONJO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **VORANIGO**

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### **MEDICATION(S)**

VORANIGO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **VOSEVI**

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### **MEDICATION(S)**

VOSEVI

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Indications consistent with current AASLD/IDSA guidance

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Previous therapy. Member has been tested for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment of Vosevi.

### **AGE RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

The medication must be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.

### **COVERAGE DURATION**

12 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.

### **OTHER CRITERIA**

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

### **PART B PREREQUISITE**

N/A

## **VOWST**

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### **MEDICATION(S)**

VOWST

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

18 years and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an infectious disease physician or gastroenterologist

### **COVERAGE DURATION**

One month

### **OTHER CRITERIA**

Prevention of C. difficile infection (CDI): Patient must meet all of the following (1, 2, 3 and 4):

1. Patient has a diagnosis of recurrent CDI as defined by all of the following (a, b and c):

a. Greater than or equal to 3 episodes of CDI in a 12 month period, b. A positive C. difficile stool sample during each episode, c. A CDI episode of diarrhea greater than or equal to 3 unformed stools per day for at least 2 consecutive days during each episode, 2. The patient has completed at least 10 days of standard of oral vancomycin or fidaxomicin for recurrent CDI at least 2 to 4 days before initiating treatment with the requested medication,

3. The patient has had an adequate clinical response to standard of care oral antibiotic regimen as defined by less than 3 unformed stools in 24 hours for 2 or more consecutive days,

4. The patient will not be using the requested agent in combination with any antibiotic regimen for any indication

**PART B PREREQUISITE**

N/A



## **VTAMA**

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### **MEDICATION(S)**

VTAMA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, a dermatologist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Plaque psoriasis: Patients meets all of the following criteria (1, 2 and 3):

1. Patient has psoriasis involvement estimated to affect less than or equal to 20 percent of the body surface area
2. Patient meets one of the following criteria (a or b): a. Patient meets all of the following criteria (i and ii):
  - i. Patient has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid, ii. Inadequate efficacy was demonstrated with this topical corticosteroid, according to the prescriber, b. Patient is treating psoriasis affecting one of the following areas: face, eyes/eyelids, skin folds, scalp, palmoplantar and/or genitalia
3. Patient meets all of the following criteria (a and b): a. Patient has tried at least one topical vitamin D analog (e.g. calcipotriene cream, ointment or foam, calcitriol ointment), b. Inadequate efficacy was

demonstrated with the topical Vitamin D analog.

Atopic dermatitis: Patient meets both of the following (1 and 2): History of failure, contraindication, or intolerance to both of the following therapeutic classes of topical therapies (document drug, date of trial, and/or contraindication to medication):

1. Medium to very-high potency topical corticosteroid for 2 weeks

2. Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] for 6 weeks

## **PART B PREREQUISITE**

N/A

## **VYLOY**

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### **MEDICATION(S)**

VYLOY

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **WEGOVY**

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### **MEDICATION(S)**

WEGOVY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patients with personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2, patients with type 1 or type 2 diabetes mellitus, A1c 6.5 percent or greater, Patients with NYHA Class IV heart failure, ESRD, intermittent dialysis or peritoneal dialysis, history of chronic pancreatitis, concomitant use with a DPP-4 inhibitor. Prescribed by or in consultation with a bariatric provider.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, Body Mass Index (BMI), History of established cardiovascular disease (CVD), A1c

### **AGE RESTRICTION**

18 years of age and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a cardiologist or endocrinologist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Patient must meet all of the following criteria (1 and 2): 1. Current BMI of 27 kg/m<sup>2</sup> or greater 2. History of established cardiovascular disease as defined by one or more of the following (a, b or c): a. Prior myocardial infarction b. Prior stroke (ischemic or hemorrhagic) c. Symptomatic peripheral arterial disease as defined by one or more of the following: i. Intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), ii. Peripheral arterial revascularization procedure, iii. Amputation due to atherosclerotic disease

**PART B PREREQUISITE**

N/A

## **WELIREG**

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### **MEDICATION(S)**

WELIREG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **XALKORI**

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### **MEDICATION(S)**

XALKORI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **XDEMVY**

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### **MEDICATION(S)**

XDEMVY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an ophthalmologist or optometrist

### **COVERAGE DURATION**

2 months

### **OTHER CRITERIA**

Demodex blepharitis: Approve if the patient meets all of the following (1 and 2): 1. Patient's diagnosis of Demodex blepharitis has been verified by the presence of collarettes on more than 10 lashes on the upper lid and presence of at least mild erythema on the upper eyelid margin, 2. Patient has moderate to severe blepharitis symptoms that interfere with daily life (e.g. ocular irritation, itching, dryness, visual disturbances)

### **PART B PREREQUISITE**

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**

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

### **REQUIRED MEDICAL INFORMATION**

RA, JIA: diagnosis and disease severity, score from objective measure/tool at baseline and continuation. PsA: Diagnosis, pre-requisite medication trials, reauth: positive clinical response. UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score. AS: Diagnosis, pre-requisite medication trials, objective measure at initiation and continuation (examples outlined in other criteria). For continuation: If patient is new to plan, must meet initial criteria at time they had started the medication.

### **AGE RESTRICTION**

JIA: 2 and older. All others – 18 and older.

### **PRESCRIBER RESTRICTION**

RA, JIA, AS: prescribed by or in consultation with a rheumatologist. PsA: prescribed by or in consultation with a rheumatologist or dermatologist. UC: prescribed by or in consultation with a gastroenterologist.

### **COVERAGE DURATION**

Initial 6 months, Continuation 3 years

## OTHER CRITERIA

RA—approve tabs if following are met: 1. Init—approve if pt meets a and b: a. Mod to severe active dz and dx of RA, b. Had a 3 mo trial of at least 1 TNFi or unable to tolerate 3 mo trial. 1. Cont—approve if pt is responding positively to tx based on improvement in objective measurement/tool as compared to baseline (e.g. CDAI, Disease Activity Score with 28-joint counts [ESR, CRP], PAS or PAS II, RAPID3, SDAI) or patient-reported dz sx. PsA—approve tabs if the following are met: 1. Init—approve if pt meets a and b: a. Currently experiencing 1 of the following (i, ii, iii, iv or v): i. Actively inflamed joints, ii. Dactylitis, iii. Enthesitis, iv. Axial disease, v. Active skin and/or nail involvement, b. Active mod to severe dz and meets i or ii: i. Pt has had a 3 mo trial of at least 1 TNFi or was unable to tolerate a 3 mo trial, ii. Member has predominantly axial dz, 2. Cont therapy—approve if there is documentation of pos clinical response to tx as evidenced by improvement in i, ii or iii: i. Number of swollen joints, ii. Number of tender joints, iii. Dactylitis, iv. Enthesitis, v. Axial dz. Mod to severely active UC—approve tabs if following are met: 2. Init: Approve if pt meets a or b: a. Had a 3 mo trial of at least 1 TNFi or was unable to tolerate a 3 mo trial, b. Pt meets i and ii: i. Pt has pouchitis AND ii. Pt has tried an abx, probiotic, corticosteroid enema, or mesalamine enema. 1. Cont therapy: Approve if pt meets BOTH i and ii: i. Pt has been established on the med for at least 5 mo, ii. Pt has experienced a positive clinical response compared to baseline as evidenced by improvement on endoscopy or using an objective scoring system (e.g. MMS, Truelove and Witts criteria). pJIA: approve IR tabs or sol if the following are met: 1. Init—approve if pt meets a, b and c: a. JIA/JRA dx as evidenced by 5 or more joints with active arthritis b. Documented baseline cJADAS-10, c. pt had a 3 mo trial of at least 1 TNFi or was unable to tolerate a 3 mo trial 1. Cont—approve if pt has experienced improvement in dz response based on 1 of the following (i, ii, iii or iv): i. Number of tender and swollen joint counts, ii. Reduction of CRP, iii. Improvement of pt global assessment, iv. Improvement in cJADAS-10 score. AS—approve tabs if following are met: Init—approve if pt meets a and b: a. Confirmed dx of AS as defined by presence of active dz for at least 4 weeks defined by any dz specific functional scoring tool (i.e. a BASDAI Index of at least 4, HAQ, MHAQ, etc.) and an expert opinion based on clinical features, acute phase reactants or imaging modalities, b. Pt had a 3 month trial of at least 1 TNFi or was unable to tolerate a 3 mo trial. Cont—approve if the patient has experienced a positive clinical response to therapy as evidenced by at least one objective measure compared to baseline (e.g. ASDAS, ASQoL, BASDAI, BASFI, BAS-G, BASMI, DFI, HAQ-S, and/or serum markers (e.g. CRP, ESR))

## PART B PREREQUISITE

N/A

## **XENAZINE**

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### **MEDICATION(S)**

TETRABENAZINE

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Tardive dyskinesia (TD). Tourette syndrome. Hyperkinetic dystonia. Hemiballism.

### **EXCLUSION CRITERIA**

Impaired hepatic function, concomitant use of monoamine oxidase inhibitors (minimum of 14 days should elapse after stopping MAOI and starting tetrabenazine), Concomitant use of reserpine (minimum of 20 days should elapse after stopping reserpine and before starting tetrabenazine), Concomitant use with Austedo or Ingrezza, current suicidality, untreated or inadequately treated depression, Non-Huntington's disease related chorea

### **REQUIRED MEDICAL INFORMATION**

Diagnosis, TD: AIMS or DISCUS score, HD reauth: positive clinical response

### **AGE RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

TD – initial 4 months, continuation 1 year, all others: 1 year

### **OTHER CRITERIA**

1.Chorea associated with Huntington's disease: a.Initial: approve if the patient's diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36), b. Continuation: Approve if patient meets both of the following (i and ii): i.If new to plan, patient met initial criteria at time of starting medication, ii. Patient has had a positive clinical response to therapy 2. Tardive Dyskinesia: a. Initial: Approve if patient meets all of the following (i, ii, and iii): i. Patient has had

at least 60 days of stable (drug and dose) medication exposure to one of the following (1, 2 or 3):

1. Typical or first generation antipsychotic agents (e.g. chlorpromazine, haloperidol, fluphenazine) 2.

Atypical or second-generation antipsychotic agents (e.g. clozapine, risperidone, olanzapine) 3.

Dopamine receptor-blocker used in treatment of nausea and gastroparesis (e.g. prochlorperazine, promethazine, metoclopramide), iii. Symptoms persist despite one of the following (1 or 2): 1.

Discontinuation or reduction in dose of offending agent(s) 2. Discontinuation or reduction in dose of offending agent(s) is not possible, iv. Patient has presence of involuntary athetoid or choreiform

movements lasting at least 30 days b. Continuation: Approve if patient meets all of the following (i and

ii): i. If new to plan, patient met initial criteria at time of starting medication, i. Following at least 3

months of therapy, patient has experienced an improvement or maintenance of symptoms while on therapy based on reduction in abnormal involuntary movement scale (AIMS) or Dyskinesia

Identification System: Condensed User Scale (DISCUS) from baseline. 3. Tourette's syndrome a. Initial

– Approve if patient has diagnosis of Tourette's Syndrome b. Continuation – Approve if patient has had

disease stabilization or improvement in signs and symptoms of Tourette's Syndrome due to

tetrabenazine therapy

## **PART B PREREQUISITE**

N/A

## **XERMELO**

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### **MEDICATION(S)**

XERMELO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **XGEVA**

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### **MEDICATION(S)**

XGEVA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **XIFAXAN**

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### **MEDICATION(S)**

XIFAXAN

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Small Intestinal Bacterial Overgrowth (SIBO)

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Diagnosis

### **AGE RESTRICTION**

Travelers diarrhea: 12 years of age or older. HE, IBS-D, SIBO: 18 years of age or older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

HE: 1 year. IBS-D: 14 days. Travelers' diarrhea: 3 days. SIBO: Initial and Cont 14 days.

### **OTHER CRITERIA**

1. Hepatic encephalopathy: trial/failure, intolerance or contraindication to lactulose.
2. Travelers' diarrhea: trial/failure, intolerance or contraindication to ciprofloxacin, levofloxacin, ofloxacin or azithromycin.
3. IBS-D - member meets all of the following (a, b and c):
  - a. Moderate to severe disease, including bloating without constipation,
  - b. Inadequate response to an antispasmodic (e.g. dicyclomine) AND an antidiarrheal agent (e.g. loperamide, diphenoxylate/atropine),
  - c. Dose is limited to 550 mg three times daily for 14 days. Retreatment is limited to patients with a positive response with a maximum of two, 14-day treatments.
4. Small Intestinal Bacterial Overgrowth (SIBO):
  - a. Initial Criteria: Patient meets all of the following (i, ii and iii):
    - i. Documentation of one of the following (1, 2 or 3):

1. Endoscopic culture with greater than 10<sup>3</sup> bacteria colony forming units/mL
2. Positive lactulose or glucose breath test with hydrogen increase of 20 ppm or greater above baseline within 90 minutes
3. Positive lactulose or glucose breath test for methane (10 ppm or greater at any point during testing)
- ii. Member must have a history of trial and failure to two of the following systemic antibiotics (alternatively, patient must have intolerance and/or contraindication to all of the following systemic antibiotics):
  1. Amoxicillin/clavulanic acid
  2. Ciprofloxacin
  3. Doxycycline
  4. Metronidazole
  5. Neomycin
  6. Sulfamethoxazole/trimethoprim
  7. Tetracycline
- iii. For methane-predominant bacterial overgrowth, must be used in combination with neomycin
- b. Continuation Criteria: Patient must meet both of the following (i and ii):
  - i. There must be documented, significant improvement with prior courses of treatment
  - ii. Retreatment is limited to once every 90 days

#### **PART B PREREQUISITE**

N/A



## **XOLAIR**

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### **MEDICATION(S)**

XOLAIR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with an interleukin (IL) antagonist monoclonal antibody

### **REQUIRED MEDICAL INFORMATION**

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

### **AGE RESTRICTION**

Moderate to severe persistent asthma-6 years and older. CIU-12 years and older. Nasal polyps - 18 years and older. IgE-mediated food allergy - 1 year or older.

### **PRESCRIBER RESTRICTION**

Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist. Nasal polyps if prescribed by or in consultation with an allergist, immunologist or otolaryngologist. IgE-mediated food allergy: prescribed by or in consultation with an allergist or immunologist.

### **COVERAGE DURATION**

Asthma/CIU Initial: 4 mo. Nasal polyps initial: 6 mo. Food allergy: 1 yr. Cont tx all dx: 12 months.

## **OTHER CRITERIA**

Moderate to severe persistent asthma approve if pt meets criteria 1 and 2: 1) pt has received at least 3 months of combination therapy with an inhaled corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2) patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS for at least 3 months. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For CIU cont tx - must have responded to therapy as determined by the prescribing physician. For Nasal polyps (a, b AND c): a) Patient is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell AND b) patient is currently receiving therapy with intranasal corticosteroid AND c) patient has received treatment with a systemic corticosteroid for chronic rhinosinusitis with nasal polyps within the previous 2 years OR has a contraindication to systemic corticosteroid therapy OR patient has had prior surgery for nasal polyps. Nasal polyps cont tx: Approve if patient continues to receive therapy with an intranasal corticosteroid and has responded to therapy. IgE-mediated food allergy (a, b, c and d): a. Baseline IgE greater than or equal to 30 IU/ml, b. Pos skin prick test to 1 or more foods and positive in vitro test for IgE to 1 or more foods, c. H/o allergic rxn that met all of the following: pt demonstrated s/s of a sign systemic allergic rxn, rxn occurred w/in a short period of time following a known ingestion of food, prescriber deemed rxn significant enough to require a Rx for an epinephrine auto-injector, d. Pt has been prescribed an epinephrine auto-injector.

## **PART B PREREQUISITE**

N/A

## **XOSPATA**

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### **MEDICATION(S)**

XOSPATA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **XPOVIO**

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### **MEDICATION(S)**

XPOVIO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **XTANDI**

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### **MEDICATION(S)**

XTANDI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ZEJULA**

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### **MEDICATION(S)**

ZEJULA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ZELBORAF**

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### **MEDICATION(S)**

ZELBORAF

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ZEPATIER**

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### **MEDICATION(S)**

ZEPATIER

### **PA INDICATION INDICATOR**

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

### **OFF LABEL USES**

Indications consistent with current AASLD/IDSA guidance

### **EXCLUSION CRITERIA**

Combination use with other direct acting antivirals, excluding Sovaldi and ribavirin.

### **REQUIRED MEDICAL INFORMATION**

Hep C genotype, concurrent medications, medication history to include preferred product as outlined in other criteria

### **AGE RESTRICTION**

12 years or older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation w/ GI, hepatologist, ID, or liver transplant MD.

### **COVERAGE DURATION**

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

### **OTHER CRITERIA**

Criteria will be applied consistent with current AASLD/IDSA guidance. Harvoni, Epclusa, Sovaldi, Vosevi and Mavyret are the preferred products. Authorization for Zepatier requires that the member must have confirmation of one of the following: A documented failure to one of the preferred products, OR A documented intolerance to one the preferred products, OR A documented contraindication to one of the preferred products, OR A documented adverse reaction to one of the preferred products.

### **PART B PREREQUISITE**

N/A



## **ZEPOSIA**

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### **MEDICATION(S)**

ZEPOSIA 0.92 MG CAPSULE, ZEPOSIA STARTER KIT (28-DAY), ZEPOSIA STARTER PACK (7-DAY)

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

UC - Concurrent Use with a Biologic or with a Targeted Synthetic Disease-modifying Antirheumatic Drug (DMARD) for Ulcerative Colitis

### **REQUIRED MEDICAL INFORMATION**

MS: Diagnosis, UC: The member must have a confirmed diagnosis of moderately to severely active ulcerative colitis confirmed by endoscopy and/or an objective score (e.g. modified Mayo score [MMS], Truelove and Witts criteria). Trial of preferred products. Reauth: Improvement on endoscopy or objective score.

### **AGE RESTRICTION**

UC - 18 years and older

### **PRESCRIBER RESTRICTION**

UC - Prescribed by or in consultation with a gastroenterologist

### **COVERAGE DURATION**

UC initial: 1 year, All others: 3 years

### **OTHER CRITERIA**

UC: 1.Initial therapy: Approve if the patient meets one of the following (a or b):

a.Patient has had a trial of one systemic agent for ulcerative colitis (e.g. 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, corticosteroid. A trial of another biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis.)

b.Patient meets both of the following (i and ii):

i.Patient has pouchitis AND

- ii. Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema
- 2. Continuation therapy: Approve if the patient meets ALL of the following (a, b, c and d):
  - a. If patient is new to plan, meets initial criteria at time they had started the medication
  - b. Patient has been established on the requested medication for at least 5 months
  - c. Patient has experienced a positive clinical response compared to baseline as evidenced by improvement on endoscopy or improvement using an objective scoring system (e.g. modified Mayo score [MMS], Truelove and Witts criteria)
  - d. Documented dose and frequency are within the FDA approved Dosing and Frequency

**PART B PREREQUISITE**

N/A

## **ZIIHERA**

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### **MEDICATION(S)**

ZIIHERA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ZOLADEX**

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### **MEDICATION(S)**

ZOLADEX

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ZOLINZA**

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### **MEDICATION(S)**

ZOLINZA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

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**

Diagnosis, previous antiepileptic therapy, Reauth: positive response

### **AGE RESTRICTION**

2 years of age and older

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Seizures associated with CDKL5 deficiency disorder: 1. Initial criteria - approve if the patient meets the following criteria:

- a. Has a molecularly confirmed pathogenic or likely pathogenic mutation in the CDKL5 gene,
  - b. Documented inadequate response to two other antiepileptic drugs.
2. Continuation criteria – approve if the patient meets the following criteria:
- a. If patient is new to plan, meets initial criteria at time they had started the medication,
  - b. Documented Dose and Frequency are within the FDA approved Dosing and Frequency,
  - c. Patient has experienced beneficial clinical response (e.g. reduced seizure activity, frequency and/or duration)

### **PART B PREREQUISITE**

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**

Prior use of Zurzuvae for the current pregnancy

### **REQUIRED MEDICAL INFORMATION**

Depression score or documentation of severe depression (as referenced in other criteria)

### **AGE RESTRICTION**

18 years of age or older

### **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, a psychiatrist, Perinatal Psychiatry Access Program, or obstetrician

### **COVERAGE DURATION**

30 days

### **OTHER CRITERIA**

Postpartum depression: Member must meet all of the following: 1. Diagnosis of major depressive episode that began no earlier than the third trimester and no later than the first 4 weeks following delivery, as diagnosed by Structured Clinical Interview for DSM-5 2. Meets one of the following criteria (a, b, c, or d): a.HAMD score greater than or equal to 24 (severe depression) b.MADRS score greater than or equal to 35 (severe depression) c.PHQ-9 score greater than or equal to 20 (severe depression) d.If member does not have severe depression as demonstrated by one of the depression scores (a, b or c), documentation of severe depression as evidenced by a psychiatrist clinical interview 3. No more than 12 months have passed since member has given birth

### **PART B PREREQUISITE**



N/A

## **ZYDELIG**

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### **MEDICATION(S)**

ZYDELIG

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ZYKADIA**

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### **MEDICATION(S)**

ZYKADIA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ZYNLONTA**

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### **MEDICATION(S)**

ZYNLONTA

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ZYNYZ**

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### **MEDICATION(S)**

ZYNYZ

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A