



## **CalOptima Health OneCare Complete (HMO D-SNP), a Medicare Medi-Cal Plan**

### **2026 Prior Authorization Criteria**

**(Requirements for approval for certain drugs)**

**Please read:** This document contains information about the drugs we cover in this plan.

### **Criterios de autorización previa para 2026**

**(Requisitos para la aprobación de ciertos medicamentos)**

**Favor de leer:** Este documento contiene información sobre los medicamentos cubiertos en este plan.

### **Các Tiêu Chuẩn Về Sự Chấp Thuận Trước Trong Năm 2026**

**(Những yêu cầu để được chấp thuận cho các loại thuốc nhất định)**

**Vui lòng đọc:** Tài liệu này gồm có các thông tin về các loại thuốc chúng tôi đài thọ trong chương trình này.

### **شرایط دریافت مجوز قبلی برای سال 2026 (شرایط تأیید داروهای خاص)**

لطفاً مطالعه کنید: این نوشتار حاوی اطلاعات مهمی درباره داروهایی است که در این برنامه تحت پوشش داریم.

### **2026 사전 승인 기준**

**(특정 의약품의 승인 조건)**

**읽어 주십시오:** 본 문서는 본 플랜에서 보장하는 의약품 정보를 포함하고 있습니다.

## معايير الحصول على تصريح مسبق لعام 2026

(متطلبات الموافقة على أدوية معينة)

يرجى القراءة: هذه الوثيقة تتضمن معلومات بخصوص الأدوية التي نقوم بتغطيتها في هذه الخطة.

### 2026年預先授權標準

(特定藥物的批准要求)

請閱讀：本文件包含關於本計劃所承保藥物的資訊。

### Критерии для получения предварительного разрешения на 2026 г.

(Требования для получения одобрения на определенные лекарственные препараты.)

Пожалуйста, прочитайте! Этот документ содержит информацию о препаратах, покрываемых этим планом.

## **ABSSSI 2 WEEK**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DALBAVANCIN HCL

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Labs with culture and sensitivity information.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

2 weeks

### **OTHER CRITERIA**

Medical justification specifying that ONE oral antibiotic and IV vancomycin have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **ABSSSI 6 DAY**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

SIVEXTRO

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Labs with culture and sensitivity information.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

6 days

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **ACTEMRA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ACTEMRA 162 MG/0.9 ML SYRINGE, ACTEMRA ACTPEN

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: RA, PJIA, SJIA, GCA, SSc-ILD: 6 months. CRS: 1 month. COC: 12 MONTHS.

## **OTHER CRITERIA**

Initial- For Rheumatoid Arthritis (RA): One of the following: (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Orencia. For Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Orencia, Rinvoq, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PJIA. For Systemic Juvenile Idiopathic Arthritis (SJIA): (1) Trial of or contraindication to one of the following preferred agents: Tyenne, and (2) No concurrent use with another systemic biologic or targeted small molecule for SJIA. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES



# ADHD

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

DEXTROAMPHETAMINE-AMPHETAMINE, DEXTROAMP-AMPHET ER 10 MG CAP, DEXTROAMP-AMPHET ER 15 MG CAP, DEXTROAMP-AMPHET ER 20 MG CAP, DEXTROAMP-AMPHET ER 25 MG CAP, DEXTROAMP-AMPHET ER 30 MG CAP, DEXTROAMP-AMPHET ER 5 MG CAP, DEXTROAMPHETAMINE 10 MG TAB, DEXTROAMPHETAMINE 5 MG TAB, DEXTROAMPHETAMINE SULFATE ER, METHYLPHENIDATE, METHYLPHENIDATE ER 10 MG TAB, METHYLPHENIDATE ER 18 MG TAB, METHYLPHENIDATE ER 20 MG TAB, METHYLPHENIDATE ER 27 MG TAB, METHYLPHENIDATE ER 36 MG TAB, METHYLPHENIDATE ER 54 MG TAB, METHYLPHENIDATE ER 72 MG TAB, METHYLPHENIDATE ER (LA), METHYLPHENIDATE 10 MG/5 ML SOL, METHYLPHENIDATE 10 MG TABLET, METHYLPHENIDATE 20 MG TABLET, METHYLPHENIDATE 5 MG/5 ML SOLN, METHYLPHENIDATE 5 MG TABLET, METHYLPHENIDATE HCL CD, METHYLPHENIDATE HCL ER (CD), METHYLPHENIDATE LA, METHYLPHENIDATE SR

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

If the patient is receiving concomitant sedatives (ramelteon, zaleplon, zolpidem) or benzodiazepines (alprazolam, chlordiazepoxide, clobazam, clonazepam, diazepam, estazolam, flurazepam, lorazepam, oxazepam, quazepam, temazepam, triazolam), justification as to why both agents are medically

necessary.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# **AFICAMTEN**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

MYQORZO

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

PENDING CMS APPROVAL

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Cardiology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Dose does not exceed 20 mg per day

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# ALINIA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

NITAZOXANIDE

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Clinical information documenting infection with giardia or cryptosporidium species

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

2 weeks

## OTHER CRITERIA

For treatment of giardiasis: medical justification specifying why tinidazole could not be used.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# ALYFTREK

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

ALYFTREK

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

New: (1) Baseline FEV1, and (2) Documentation confirming at least one F508del mutation in the CFTR or a CFTR gene responsive based on in vitro data. COC: (1) Information provided that member has had an improved clinical response as indicated by improvement in FEV1, reduced number of pulmonary exacerbations, or improvement in body mass index (BMI).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with Pulmonology or a Cystic Fibrosis expert.

## COVERAGE DURATION

Initial: 6 months. COC: 1 year.

## OTHER CRITERIA

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# AMIKACIN

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

ARIKAYCE

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Labs with culture and sensitivity information.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

6 months

## OTHER CRITERIA

Documented failure with a multidrug background regimen therapy.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **ANDEMBRY**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ANDEMBRY AUTOINJECTOR

## **EXCLUSION CRITERIA**

Age less than 12 years old

## **REQUIRED MEDICAL INFORMATION**

(1) Documentation of HAE confirmed by lab work (HAE I: low C4 level AND low C1-INH antigenic level, HAE II: low C4 level AND normal or elevated C1-INH antigenic level AND low C1-INH function level, HAE III: low C4 level AND normal C1-INH antigenic level AND normal C1-INH function level AND documentation of a family history of HA or FXII mutation).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an Allergist, Immunologist, or physician who specializes in the treatment of HAE

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Member is not receiving medications that can worsen the severity or frequency of angioedema episodes (estrogen-containing products, angiotensin-converting enzyme [ACE] inhibitors, others).  
COC: (1) documentation or record of disease state improvement (such as decrease in the number, severity, and/or duration of the acute HAE attacks) within the last 6 months, and (2) member is receiving only one agent for HAE attacks.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **ANDROGENS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

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

### **EXCLUSION CRITERIA**

Testosterone levels within normal range (range for the lab doing the testing). Female patients (except for palliation of inoperable metastatic (skeletal) mammary cancer or gender dysphoria). Men with carcinoma of the breast or suspected carcinoma of the prostate. Use to enhance athletic ability.

### **REQUIRED MEDICAL INFORMATION**

For patients initiating testosterone replacement therapy: Testosterone levels (total or free) within the previous 3 months. Require either ONE low total testosterone level OR ONE low free testosterone level. (normal ranges as provided by office or clinic performing labs).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Approved until end of plan year.

### **OTHER CRITERIA**

Maximum recommended daily dosage.

### **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

## **ANTIBACTERIALS, OTHER BROAD-SPECTRUM**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

AVYCAZ, BLUJEP, LINEZOLID, LINEZOLID-D5W, ORLYNVAH, TIGECYCLINE

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Labs with culture and sensitivity information.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

6 weeks

### **OTHER CRITERIA**

Medical justification specifying that one formulary antibacterial indicated for the respective diagnosis within the listed antibacterial class of beta lactams, macrolides, fluoroquinolones, aminoglycosides or glycopeptides has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **ANTICGRP**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

AIMOVIG AUTOINJECTOR, AJOVY AUTOINJECTOR, AJOVY AUTOINJECTOR (3 PACK), AJOVY SYRINGE, EMGALITY PEN, EMGALITY SYRINGE, EMGALITY 300 MG (100 MG X 3 SYRINGE)

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

New: Patient must have at least 4 migraine days per month. COC: Physician attestation that the patient continues to benefit from the medication.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **ANTIFUNGAL**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

AMPHOTERICIN B LIPOSOME, CASPOFUNGIN ACETATE, ERAXIS, POSACONAZOLE 200 MG/5 ML SUSP, POSACONAZOLE DR 100 MG TABLET, VORICONAZOLE 200 MG VIAL, VORICONAZOLE 200 MG TABLET, VORICONAZOLE 40 MG/ML SUSP, VORICONAZOLE 50 MG TABLET, VORICONAZOLE 200 MG VIAL

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months (1 year if immunocompromised)

### **OTHER CRITERIA**

Medical justification specifying that one applicable formulary alternative (Oral Clotrimazole, Oral Fluconazole, Oral Flucytosine, Griseofulvin, Oral Itraconazole, Oral Ketoconazole, Oral Nystatin, or Oral Terbinafine) has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **ANTINAUSEA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

APREPITANT, GRANISETRON HCL 1 MG TABLET

## **EXCLUSION CRITERIA**

Excluded under Part D if meets coverage criteria under Part B.

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

3 months

## **OTHER CRITERIA**

Medical justification specifying that one applicable formulary alternative (Metoclopramide, Ondansetron, Tetrahydrocannabinol [Dronabinol]) has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# ANTINEOPLASTICS

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## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

ALECENSA, ALUNBRIG, AUGTYRO, AVMAPKI-FAKZYNJA, BALVERSA, BESREMI, BOSULIF, COMETRIQ, COPIKTRA, DANZITEN, DASATINIB, DAURISMO, ENSACOVE, ERIVEDGE, ERLOTINIB HCL, FIRMAGON, FOTIVDA, FRUZAQLA, GAVRETO, GEFITINIB, GILOTRIF, HERNEXEOS, HYRNUO, IBTROZI, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMKELDI, INLYTA, INQOVI, INREBIC, ITOVEBI, IWILFIN, JAYPIRCA, KOSELUGO, KRAZATI, LAPATINIB, LAZCLUZE, LENALIDOMIDE, LONSURF, LORBRENA, LUMAKRAS, LYTGABI, MODEYSO, NERLYNX, NILOTINIB D-TARTRATE, NILOTINIB HCL, ODOMZO, OGSIVEO 100 MG TABLET, OGSIVEO 150 MG TABLET, OJJAARA, ONUREG, ORSERDU, PAZOPANIB HCL 200 MG TABLET, PEMAZYRE, PHYRAGO, PIQRAY, QINLOCK, RETEVMO, REVUFORJ, REZLIDHIA, ROZLYTREK, SCEMBLIX, SORAFENIB, STIVARGA, SUNITINIB MALATE, TAGRISSO, TALZENNA, TEPMETKO, TIBSOVO, TOREMIFENE CITRATE, TRUQAP, TUKYSA, TURALIO, VANFLYTA, VENCLEXTA, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VORANIGO, WELIREG, XALKORI, XOSPATA, XPOVIO, ZEJULA 100 MG TABLET, ZEJULA 200 MG TABLET, ZEJULA 300 MG TABLET, ZYKADIA

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Systemic mastocytosis: Allergy/Immunology, or Hematology/Oncology. Neurofibromatosis: Neurology.  
Other Dx: Hematology/Oncology.

## COVERAGE DURATION

1 year

## OTHER CRITERIA

N/A

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

## **ANTINEOPLASTICS-MULTI**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ABIRATERONE ACETATE, ABIRTEGA, AYWAKIT, BRAFTOVI 75 MG CAPSULE, CALQUENCE, COTELLIC, ERLEADA, EULEXIN, EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 2 MG TAB FOR SUSP, EVEROLIMUS 3 MG TAB FOR SUSP, EVEROLIMUS 5 MG TAB FOR SUSP, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, FLUOROURACIL 2% TOPICAL SOLN, FLUOROURACIL 5% TOPICAL SOLN, GOMEKLI, IMBRUVICA 140 MG CAPSULE, IMBRUVICA 140 MG TABLET, IMBRUVICA 280 MG TABLET, IMBRUVICA 420 MG TABLET, IMBRUVICA 70 MG CAPSULE, IMBRUVICA 70 MG/ML SUSPENSION, JAKAFI, LOMUSTINE, MEKINIST, MEKTOVI, NUBEQA, OJEMDA, ORGOVYX, ROMVIMZA, TAFINLAR, TORPENZ, VALCHLOR, XTANDI, YONSA, ZELBORAF

### **EXCLUSION CRITERIA**

Excluded under Part D if meets coverage criteria under Part B.

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **APTIOM**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ESLICARBAZEPINE ACETATE

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medical justification must be received why Formulary Alternatives carbamazepine or oxcarbazepine cannot be used.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **AQNEURSA**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

AQNEURSA

### **EXCLUSION CRITERIA**

Weight less than 15 kg.

### **REQUIRED MEDICAL INFORMATION**

(1) Diagnosis has been genetically confirmed by mutation analysis of NPC1 and NPC2 genes, and (2) Not used in combination with Miplyffa.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Niemann-Pick disease type C (NPC)- Initial: Prescribed by or in consultation with Neurology or Genetics.

### **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

### **OTHER CRITERIA**

COC- For NPC: (1) Improvement or slowing of disease progression.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# ARCALYST

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

ARCALYST

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

New: Cryopyrin-Associated Periodic Syndromes (CAPS)- (1) Genetic testing has confirmed a mutation in the IL1RN gene. Pericarditis- (1) Patient has recurrent pericarditis (history of at least three episodes of pericarditis). COC: Physician attestation that the patient continues to benefit from the medication.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Cryopyrin-Associated Periodic Syndromes: Prescriber by or in consultation with Rheumatology, Geneticist, Allergist/Immunology, or Dermatology. Deficiency of Interleukin-1 Receptor Antagonist: Prescriber by or in consultation with Rheumatology, Geneticist, Dermatologist, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis: Prescriber by or in consultation with Cardiology or Rheumatology.

## COVERAGE DURATION

New: CAPS/Deficiency of Interleukin-1 Receptor Antagonist- 6 mos. Pericarditis- 3 mos. COC: 1 year.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# **ATTRUBY**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ATTRUBY

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Cardiomyopathy of wild type or variant transthyretin-mediated amyloidosis (ATTR-CM): Initial- (1) New York Heart Association (NYHA) Class I, II, or III heart failure, and (2) Diagnosis confirmed by (2A) bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99M-PYP, or (2B) biopsy of tissue of affected organ(s) to confirm amyloid presence and chemical typing to confirm presence of transthyretin (TTR) protein.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

The medication is prescribed by or in consultation with Cardiology.

## **COVERAGE DURATION**

1 year.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **ATYPICALS**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ASENAPINE MALEATE, CAPLYTA, COBENFY, COBENFY STARTER PACK, FANAPT 10 MG TABLET, FANAPT 12 MG TABLET, FANAPT 1 MG TABLET, FANAPT 2 MG TABLET, FANAPT 4 MG TABLET, FANAPT 6 MG TABLET, FANAPT 8 MG TABLET, FANAPT TITRATION PACK, FANAPT TITRATION PACK A, LYBALVI, 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

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Medical justification specifying that two formulary alternatives (aripiprazole, olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone) have been tried and failed, are contraindicated, or would not be medically appropriate for the patient. Rexulti will not require prior therapy when being used for agitation associated with dementia in Alzheimer's disease.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Psychiatry

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# AUVELITY

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

AUVELITY ER 45-105 MG TABLET

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation or record of the symptoms and duration of the episode. For treatment of depression, the depression rating scale and score are required.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medical justification specifying that two of the formulary alternatives (citalopram, desvenlafaxine, escitalopram, fluoxetine, paroxetine, sertraline or venlafaxine) have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# AVYCAZ

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

VABOMERE, ZERBAXA

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Labs with culture and sensitivity information.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

2 weeks

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

## **AZITHROMYCIN 600 MG ORAL TABLET**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

AZITHROMYCIN 600 MG TABLET

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Medical justification why other strengths cannot be used if the diagnosis is not treatment or prophylaxis of Mycobacterium avium complex (MAC). Up to 1200mg per week for prophylaxis or 600mg per day for treatment.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **BAXDELA**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

BAXDELA

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Labs with culture and sensitivity information.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Infectious Disease

### **COVERAGE DURATION**

14 days

### **OTHER CRITERIA**

Medical justification specifying that two applicable formulary antibacterials in the class of Beta Lactams, Macrolides, Quinolones, Sulfonamides or Tetracyclines have been tried and failed, are contraindicated, or would not be medically appropriate for the patient, or upon hospital discharge.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **BEXAROTENE**

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

BEXAROTENE

## **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **BIMZELX**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

BIMZELX, BIMZELX AUTOINJECTOR

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

Initial- For PSO: Trial of or contraindication to two of the following preferred agents (where ages align): Cosentyx, Humira, Simlandi, Skyrizi, Tremfya, Otezla, Selarsdi, Steqeyma, Yesintek. For Psoriatic Arthritis (PSA): Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Skyrizi, Tremfya, Orencia, Otezla, Selarsdi, Steqeyma, Yesintek. For Ankylosing Spondylitis (AS): (1) Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Xeljanz IR/XR, Rinvoq, and (2) No concurrent use of another small biologic or targeted small molecule for AS. For NR-AXSPA: (1) Trial of or contraindication to two of the following preferred agents: Cosentyx, Rinvoq, Cimzia, and (2) No concurrent use of another small biologic or targeted small molecule for NR-AXSPA. For Hidradenitis Suppurativa (HS): (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Cosentyx, and (2) No concurrent use with another systemic biologic or targeted small molecule for HS. COC: Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **BRINSUPRI**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

BRINSUPRI

## **EXCLUSION CRITERIA**

Age less than 12 years old

## **REQUIRED MEDICAL INFORMATION**

Diagnosis of non-cystic fibrosis bronchiectasis (NCFB) confirmed by high-resolution chest CT scan.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by, or in consultation with, a pulmonologist or infectious disease specialist

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

COC: Physician attestation that the patient has experienced a beneficial clinical response.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **BRONCHODILATORS, SYMPATHOMIMETIC**

---

### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ARFORMOTEROL TARTRATE, LEVALBUTEROL CONCENTRATE, LEVALBUTEROL HCL

### **EXCLUSION CRITERIA**

Excluded under Part D if meets coverage criteria under Part B.

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Medical justification why a beta agonist inhaler cannot be used.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **BRUKINSA**

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

BRUKINSA 160 MG TABLET

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Mantle Cell Lymphoma (MCL): The member has a history of failure, contraindication, or reason(s) for intolerance to one prior first line therapy, such as CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone), R-CHOP, B-R (bendamustine and rituximab), R-DHAP (rituximab, dexamethasone, cytarabine, and cisplatin), or VcR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, and prednisone). Marginal Zone Lymphoma (MZL): The member has received at least one prior anti-CD20 based therapy.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **BUTALBITAL**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

BUTALBITAL-ACETAMINOPHEN-CAFFEINE 50-325-40 MG TABLET

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

3 months

## **OTHER CRITERIA**

For enrollees age 65 and over, the prescriber must acknowledge that medication benefits outweigh potential risks. For continuation of care beyond the initial 3 months: Butalbital-acetaminophen-caffeine is not recommended for extended and repeated use. Please provide a medical justification statement as to the need for continued therapy.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **CABLIVI**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

CABLIVI 11 MG VIAL KIT

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: (1) Diagnosis of aTTP confirmed with a PLASMIC score of 6 to 7, (2) Prescribed in combination with plasma exchange therapy (PEX), and (3) Prescribed in combination with immunosuppressive therapy (i.e., glucocorticoids, rituximab). COC: (1A) If request is for a new treatment cycle, member has experienced no more than two recurrences while taking Cablivi, and prescribed in combination with plasma exchange and immunosuppressive therapy (i.e., glucocorticoids, rituximab), or (1B) If request is for treatment extension, documentation or record of a positive clinical response to therapy (e.g., improvement in any of the following: increase in platelet counts, reduction in neurological symptoms, or improvements in organ-damage markers [lactate dehydrogenase, cardiac troponin I, and serum creatinine]).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Hematology

## **COVERAGE DURATION**

3 months

## **OTHER CRITERIA**

Member cannot receive more than 58 days of Cablivi therapy after completion of plasma exchange therapy.

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# **CABOMETYX**

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

CABOMETYX

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

For diagnosis of hepatocellular carcinoma (HCC): member has history of failure, contraindication, or reason(s) for intolerance to sorafenib (Nexavar).

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# CANNABIDIOL

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

EPIDIOLEX 100 MG/ML SOLUTION

## **EXCLUSION CRITERIA**

Age less than 1 years old

## **REQUIRED MEDICAL INFORMATION**

Clinical information provided to support the following: (1) a diagnosis of Lennox-Gastaut syndrome, Dravet syndrome, or Tuberous sclerosis complex, (2) patient will continue treatment with at least one other antiepileptic drug, and (3) patient's weight and labs including AST/ALT and bilirubin levels within the past 30 days.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Neurology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **CARBAGLU**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

CARGLUMIC ACID

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Laboratory results which confirm the diagnosis, such as enzyme analysis of liver biopsy.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# CENEGERMIN

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

OXERVATE

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

New: Clinical information to support diagnosis of neurotrophic keratitis. COC: clinical information to indicate complete or improved corneal healing.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Ophthalmology

## COVERAGE DURATION

8 weeks

## OTHER CRITERIA

Dose does not exceed 1 vial per affected eye per day.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# CHOLBAM

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

CHOLBAM

## EXCLUSION CRITERIA

Used to treat extrahepatic manifestations (such as but not limited to neurologic symptoms) of single enzyme defect-associated bile acid synthesis disorders or peroxisomal disorders.

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 3 months. Continuation: 1 year

## OTHER CRITERIA

For initial therapy: (A) Diagnosis of bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs) including but not limited to 3 beta-hydroxy-delta 5-C27-steroid oxidoreductase defects OR (B) Diagnosis of peroxisomal disorders (PDs) including but not limited to Zellweger spectrum disorders AND (C) Individual has one of the following: (a) Manifestations of liver disease (for example, jaundice, hepatomegaly) (b) steatorrhea (c) Complications from decreased fat soluble vitamin (such as but not limited to vitamin D and K) absorption (for example, rickets, hypocalcemia, bleeding). For maintenance therapy: Meets the initial request criteria AND has had a clinical improvement (symptoms, lab values) in liver function and/or cholestasis AND has not developed a complete biliary obstruction.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# CIMZIA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

CIMZIA 2X200 MG/ML SYRINGE KIT, CIMZIA (2 PACK), CIMZIA (2 PACK)

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- For Non-radiographic axial spondyloarthritis (NR-AXSPA): 1) C-reactive protein levels above the upper limit of normal, or 2) sacroiliitis on MRI. For Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. COC: 1 year.

## OTHER CRITERIA

Initial- For Rheumatoid Arthritis (RA): For Rheumatoid Arthritis (RA): One of the following: (1) Patient is (i) pregnant, breastfeeding, or trying to become pregnant, or (ii) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Orencia. For Psoriatic Arthritis (PSA): (1) Patient is (i) pregnant, breastfeeding, or trying to become pregnant, or (ii) Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Skyrizi, Tremfya, Orencia, Otezla, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSA. For PSO: (1) Patient is (i) pregnant, breastfeeding, or trying to become pregnant, or (ii) Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Skyrizi, Tremfya, Otezla, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use with another systemic biologic or targeted small molecule for PSO. For Ankylosing Spondylitis (AS): (1) Patient is (i) pregnant,

breastfeeding, or trying to become pregnant, or (ii) Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Xeljanz IR/XR, Rinvoq, and (2) No concurrent use with another systemic biologic or targeted small molecule for AS. For Crohns Disease (CD): (1) Patient is (i) pregnant, breastfeeding, or trying to become pregnant, or (ii) Trial of or contraindication to one of the following preferred agents: Humira, Simlandi, Rinvoq, Skyrizi, Tremfya, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use with another systemic biologic or targeted small molecule for CD. For NR-AXSPA: (1) Trial of or contraindication to an NSAID, and (2) No concurrent use with another systemic biologic or targeted small molecule for NR-AXSPA. For Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) Patient is (i) pregnant, breastfeeding, or trying to become pregnant, or (ii) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Rinvoq, Xeljanz IR, Orencia, and (2) No concurrent use with another systemic biologic or targeted small molecule for PJIA. COC: Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **CORLANOR**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

IVABRADINE HCL

## **EXCLUSION CRITERIA**

Individual has a heart rate maintained exclusively by a pacemaker. Individual has severe hypotension (blood pressure less than 90/50 mmHg). Individual has severe hepatic impairment (Child-Pugh Class C).

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Cardiology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Individual is using for the treatment of New York Heart Association (NYHA) class II, III or IV heart failure symptoms

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **CORTICOTROPIN**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ACTHAR, ACTHAR SELFJECT, CORTROPHIN, CORTROPHIN

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For all indications except infantile spasms, documentation of limited/unsatisfactory response or intolerance (i.e., severe anaphylaxis) to two corticosteroids (e.g., IV methylprednisolone, IV dexamethasone, or high dose oral steroids).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Neurologist for infantile spasm

### **COVERAGE DURATION**

Multiple sclerosis: 21 days. Other approved indications: 28 days.

### **OTHER CRITERIA**

For acute exacerbations of multiple sclerosis (MS), patients must be receiving concurrent immunomodulator therapy (e.g., interferon beta 1a, glatiramer acetate, dimethyl fumarate, fingolimod, or teriflunomide). For proteinuria in nephrotic syndrome, trial/failure or contraindication to calcineurin inhibitors (e.g., cyclosporine or tacrolimus) must be documented. For gout, an intolerance or contraindication to at least two first-line gout therapies (e.g., allopurinol, probenecid, or colchicine) must be documented. For continuation of care beyond the initial 28 days, medical documentation is required demonstrating positive effectiveness. Part B before Part D Step Therapy.

### **PART B PREREQUISITE**

YES

### **PREREQUISITE THERAPY REQUIRED**

YES

# COSENTYX

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

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

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- For Non-radiographic axial spondyloarthritis (NR-AXSPA): 1) C-reactive protein levels above the upper limit of normal, or 2) sacroiliitis on MRI. For Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial- HS: 1 year, All other indications: 6 months. COC- 1 year.

## OTHER CRITERIA

Initial- For PSO: (1) One of the following: (i) trial of at least a 3 month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus), or PUVA (phototherapy) for the treatment of PSO, (ii) Contraindication or intolerance to both immunosuppressant and PUVA therapy, or (iii) Patient is switching from a different biologic, PDE-4 inhibitor, or JAK inhibitor for PSO, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSO. For Psoriatic Arthritis (PSA): No concurrent use with another systemic biologic or targeted small molecule for PSA. For Ankylosing Spondylitis (AS): (1) Trial or contraindication to an NSAID, and (2) No concurrent use with another systemic biologic or targeted small molecule for AS. NR-AXSPA: (1) Trial or contraindication to an NSAID, and (2) No concurrent use with another systemic biologic or targeted small molecule for NR-AXSPA. For Enthesitis-Related Arthritis (ERA): trial of or

contraindication to an NSAID, sulfasalazine, or methotrexate. For Hidradenitis Suppurativa (HS): (1) No concurrent use with another systemic biologic or targeted small molecule for HS. COC- For all indications: Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **CRENESSITY**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

CRENESSITY 100 MG CAPSULE, CRENESSITY 50 MG CAPSULE

## **EXCLUSION CRITERIA**

Member under 4 years of age.

## **REQUIRED MEDICAL INFORMATION**

(1) Member has a diagnosis of classic CAH confirmed by ONE of the following (1A) elevated 17-hydroxyprogesterone, (1B) confirmed CYP21A2 genotype, (1C) positive newborn screening with confirmatory second-tier testing, OR (1D) diagnostic results after cosyntropin stimulation, and (2) the medication will be taken in combination with a systemic glucocorticoid (e.g. hydrocortisone, prednisone, prednisolone, dexamethasone).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

The medication is prescribed by or in consultation with endocrinology, or a physician who specializes in the treatment of adrenal hyperplasia.

## **COVERAGE DURATION**

1 year.

## **OTHER CRITERIA**

COC: Documentation that the member continues to benefit from the medication (e.g., reduced androstenedione levels, decreased 17-hydroxyprogesterone, or reduction in glucocorticoid dose from baseline)

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A



# **CRESEMBA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

CRESEMBA 186 MG CAPSULE, CRESEMBA 74.5 MG CAPSULE

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Fungal culture and sensitivity (C&S) results within 60 days.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an infectious disease specialist

## **COVERAGE DURATION**

3 months

## **OTHER CRITERIA**

Medical justification specifying that ONE applicable formulary alternative (Voriconazole, Posaconazole, Amphotericin B injection, Caspofungin injection, or Anidulafungin injection) has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **CROFELEMER**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

MYTESI

## **EXCLUSION CRITERIA**

Infectious diarrhea

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

6 months

## **OTHER CRITERIA**

Medical justification specifying why a formulary alternatives loperamide or diphenoxylate-atropine cannot be used.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **CSF**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

FULPHILA, FYLNETRA, GRANIX 300 MCG/0.5 ML SAFE SYR, GRANIX 300 MCG/0.5 ML SYRINGE, GRANIX 300 MCG/ML VIAL, GRANIX 480 MCG/0.8 ML SAFE SYR, GRANIX 480 MCG/0.8 ML SYRINGE, LEUKINE, NEULASTA 6 MG/0.6 ML SYRINGE, NEUPOGEN, NIVESTYM, NYVEPRIA, RELEUKO 300 MCG/0.5 ML SYRINGE, RELEUKO 480 MCG/0.8 ML SYRINGE, STIMUFEND, UDENYCA, UDENYCA AUTOINJECTOR, ZARXIO, ZIEXTENZO

### **EXCLUSION CRITERIA**

Neutrophil count higher than 100,000/mm<sup>3</sup>.

### **REQUIRED MEDICAL INFORMATION**

Patient's weight, CBC with differential drawn within the past 2 weeks.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

If any of the following is true, CSFs will be covered only if additional medical documentation establishes medical necessity in the individual case: (1) the neutrophil count is higher than 1,000/mm<sup>3</sup> in patients with neutropenia other than chemotherapy-induced, (2) the neutrophil count is higher than 5,000/mm<sup>3</sup> in patients receiving myelosuppressive chemotherapy, or (3) Filgrastim: dosing exceeds 10mcg/kg.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A



## **CTEXLI**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

CTEXLI

### **EXCLUSION CRITERIA**

Age less than 18 years old.

### **REQUIRED MEDICAL INFORMATION**

Diagnosis is established by both of the following: (A) a molecular genetic test demonstrating a pathogenic variant in the CYP27A1 gene, AND (B) lab result demonstrating elevated serum cholestanol levels.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with Neurology, Metabolic Specialists, or Genetics

### **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

### **OTHER CRITERIA**

New: baseline ALT, AST, and bilirubin. COC: (1) ALT, AST, and bilirubin within the past 6 months and (2) Physician attestation that the patient continues to benefit from the medication.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **DAE SFU**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

GLIMEPIRIDE 1 MG TABLET, GLIMEPIRIDE 2 MG TABLET, GLIMEPIRIDE 4 MG TABLET, GLYBURIDE, GLYBURIDE-METFORMIN HCL

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Prescriber must acknowledge that medication benefits outweigh potential risks in patients 65 years of age or older.

### **AGE RESTRICTION**

PA required for enrollees age 65 and over. No PA required for enrollees under age 65.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Approved until end of plan year.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **DAWNZERA**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DAWNZERA

### **EXCLUSION CRITERIA**

Age less than 12 years old

### **REQUIRED MEDICAL INFORMATION**

(1) Documentation of HAE confirmed by lab work (HAE I: low C4 level AND low C1-INH antigenic level, HAE II: low C4 level AND normal or elevated C1-INH antigenic level AND low C1-INH function level, HAE III: low C4 level AND normal C1-INH antigenic level AND normal C1-INH function level AND documentation of a family history of HA or FXII mutation).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an Allergist, Immunologist, or physician who specializes in the treatment of HAE

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Member is not receiving medications that can worsen the severity or frequency of angioedema episodes (estrogen-containing products, angiotensin-converting enzyme [ACE] inhibitors, others).  
COC: (1) documentation or record of disease state improvement (such as decrease in the number, severity, and/or duration of the acute HAE attacks) within the last 6 months, and (2) member is receiving only one agent for HAE attacks.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# DAYBUE

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

DAYBUE, DAYBUE STIX

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Initial: Patient has a diagnosis of Rett syndrome (RTT) with generic analysis confirming mutation in the MECP2 gene.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Geneticist, Pediatric neurology, Neurology, Metabolic neurology

## **COVERAGE DURATION**

Initial: 6 months, COC: 1 year.

## **OTHER CRITERIA**

COC: Documentation of positive clinical response (as measured by an appropriate rating scale) to Daybue therapy.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **DEMECLOCYCLINE**

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

DEMECLOCYCLINE HCL

## **EXCLUSION CRITERIA**

Drug-induced SIADH.

## **REQUIRED MEDICAL INFORMATION**

Labs including eGFR, and SCr, drawn within the past 90 days.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

3 months

## **OTHER CRITERIA**

Drug-induced SIADH should be treated by withdrawal of the offending drug and fluid restriction. Medical justification criteria must be provided including why a formulary alternative such as furosemide cannot be used.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **DERMATITIS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

PIMECROLIMUS, TACROLIMUS 0.03% OINTMENT, TACROLIMUS 0.1% OINTMENT

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

Medical justification as to why topical corticosteroids cannot be used.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **DERMATOLOGICAL AGENTS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DICLOFENAC SODIUM 3% GEL, DOXEPIN 5% CREAM, TAZAROTENE 0.05% CREAM, TAZAROTENE 0.05% GEL, TAZAROTENE 0.1% CREAM, TAZAROTENE 0.1% GEL, TRETINOIN 0.01% GEL, TRETINOIN 0.025% CREAM, TRETINOIN 0.025% GEL, TRETINOIN 0.05% CREAM, TRETINOIN 0.05% GEL, TRETINOIN 0.1% CREAM

### **EXCLUSION CRITERIA**

Cosmetic use.

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Psoriasis/Acne: 1 year, Other: 3 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **DIAGNOSTIC USE**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ATROPINE 1% EYE DROP

### **EXCLUSION CRITERIA**

Diagnostic use

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **DICLOFENAC**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DICLOFENAC EPOLAMINE, DICLOFENAC 2% SOLUTION PUMP

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

New: Documentation that at least ONE oral formulary NSAID has been tried and failed within the previous 6 months. COC: Physician attestation that the patient continues to benefit from the medication.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

6 months

### **OTHER CRITERIA**

Statement of medical justification for concomitant therapy with another nonsteroidal anti-inflammatory drug (NSAID). For continued therapy beyond 6 months, documented evaluation for gastrointestinal (GI) adverse events.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **DIRECT RENIN INHIBITOR**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ALISKIREN

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Medical justification specifying that two applicable formulary angiotensin II receptor antagonists (ARBs) have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **DOJOLVI**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DOJOLVI

### **EXCLUSION CRITERIA**

Concomitant use with other medium-chain triglyceride products.

### **REQUIRED MEDICAL INFORMATION**

New: Patient has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder based on: (1) Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma, (2) Enzyme activity assay (in cultured fibroblasts or lymphocytes) below the lower limit of the normal reference range for the reporting laboratory, or (3) Genetic testing demonstrating pathogenic mutation in a gene associated with long-chain fatty acid oxidation disorders. COC: Documentation of positive clinical response to therapy (e.g., increased cardiac efficiency, decreased left ventricular wall mass, decreased incidence of rhabdomyolysis, etc.).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **DOPTELET**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

DOPTELET

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Platelet Count (Drawn within last 30 days) indicating platelets less than  $50 \times 10^9/L$ .

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

ITP: 1 year. Other: 3 months

### **OTHER CRITERIA**

For treatment of thrombocytopenia in patients with chronic liver disease: documentation or record of a planned medical or dental procedure within 10-13 days after starting Doptelet. This requirement does not apply for the treatment of other approved indications.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# DRIZALMA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

DRIZALMA SPRINKLE

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

Medical justification for why generic duloxetine delayed release capsule could not be used.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

## **DRY EYE**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

EYSUVIS

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation is provided indicating an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods: (a) Tear break-up time (less than 10 seconds) OR (b) Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes OR (c) Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes) OR (d) Fluorescein clearance test/tear function index OR (e) Tear osmolarity (indicating tear film instability) OR (f) Tear lactoferrin concentrations in the lacrimal gland (decreased).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Eysuvis: 2 weeks

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **DUPIXENT**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

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

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Initial- For treatment of atopic dermatitis (AD): Body surface area (BSA) involvement equal to or greater than 10% or affecting crucial body areas such as the hands, feet, face, genitals, or intertriginous areas. For Eosinophilic esophagitis (EoE): Diagnosis confirmed by esophagogastroduodenoscopy (EGD) with biopsy. For Eosinophilic asthma: Blood eosinophil level of 150 to 1,500 cells/mcl within the past 12 months.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: AD, CRSwNP, CSU, EOE, PN- 6 months, Asthma, BP, COPD- 1 year. COC: All indications- 1 year.

## **OTHER CRITERIA**

Initial- For AD (in patients 2 years and older): (1) Trial of or contraindication to one topical (corticosteroid, calcineurin inhibitor, PDE4 inhibitor, or JAK inhibitor), and (2) No concurrent use of other systemic biological/JAK inhibitor for AD. PN: (1) Chronic pruritis (more than 6 weeks), multiple pruriginous lesions, and history or sign of a prolonged scratching behavior. For Asthma: (1) Concurrent therapy with a medium, high-dose or maximally-tolerated dose of an inhaled corticosteroid (ICS) and one other maintenance medication, (2) One asthma exacerbation requiring systemic corticosteroid burst lasting 3 or more days within the past 12 months, or one serious exacerbation requiring hospitalization or ER visit with the past 12 months, or poor symptom control despite current therapy as evidence by at least 3 of the following within the past 4 weeks: daytime asthma symptoms more than

twice per week, any night waking due to asthma, SABA reliever for symptoms more than twice per week, any activity limitations due to asthma, and (3) no concurrent use of Xolair or other Anti-IL5 biologics when used for asthma. For Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP): (1) a 56-day trial of one topical nasal corticosteroid, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. For COPD: (1) Used in combination with a LAMA/LABA/ICS, and (2) No concurrent use with another systemic biologic or targeted small molecules for eosinophilic COPD. For COC- AD: Members condition is stable or showing clinical improvement, and (2) No concurrent use with other systemic biologics or JAK inhibitors for AD. CRSwNP/EOE/PN: Improvement while on therapy. Asthma: (1) no concurrent use of Xolair, or other anti-IL5 biologic for asthma, (2) continued use of ICS and one other maintenance medication, and (3) clinical response as evidence by: (A) reduction in asthma exacerbations from baselines, (B) decrease utilization of rescue medications, (C) increase in percent predicted FEV1 from pretreatment baselines, or (D) reduction in severity or frequency of asthma-related symptoms. COPD: (1) Used in combination with a LAMA/LABA/ICS, (2) No concurrent use with another systemic biologic or targeted small molecules for eosinophilic COPD, and (3) Members condition is stable or showing clinical improvement.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# DUVYZAT

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

DUVYZAT

## EXCLUSION CRITERIA

(1) Concurrent use with exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vondys 53 (golodirsen)], (2) Patient has received gene therapy for DMD [e.g., Elevidys (delandistrogene moxparvovec-rokl)].

## REQUIRED MEDICAL INFORMATION

Initial: (1A) Confirmed presence of a mutation in the DMD gene or (1B) Muscle biopsy documenting absent dystrophin, (2) Clinical signs and symptoms of DMD (e.g., proximal muscle weakness, Gowers's maneuver, elevated serum creatine kinase level), (3) Patient is ambulatory, and (4) Baseline evaluation with one of the following standardized assessments of motor function: 4 Standard Stairs (4SC) Climb, Rise From Floor, Total North Star Ambulatory Assessment (NSAA), or Six-minute walk test (6MWT).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders.

## COVERAGE DURATION

Initial: 6 months, COC: 1 year

## OTHER CRITERIA

COC: (1) Physician attestation that the patient would benefit from continued administration.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# EGRIFTA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

EGRIFTA SV, EGRIFTA WR

## EXCLUSION CRITERIA

1. Active malignancy. 2. Disruption of the hypothalamic-pituitary axis (due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or trauma). 3. Pregnancy. 4. Weight loss management

## REQUIRED MEDICAL INFORMATION

Documentation of active antiretroviral therapy (at least 8 weeks). Baseline visceral adipose tissue (VAT), waist circumference, waist to hip ratio, fasting blood glucose, and body mass index (BMI) are required. For continuation therapy, current VAT is also required.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Lipodystrophy due to HIV: 1 year. COC: 1 year.

## OTHER CRITERIA

For initial therapy: Waist circumference greater than or equal to 37 inches (94 cm), waist to hip ratio greater than or equal to 0.94 for men or 0.88 for women, fasting blood glucose less than 150 mg/dL, and BMI greater than 20 kg/m<sup>2</sup>. For continuation, individual must demonstrate there is a clear response in reduction of visceral adipose tissue measured by waist circumference or computed tomography (CT) scan.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

## **ELAMIPRETIDE**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

FORZINITY

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Results of genetic test confirming diagnosis of Barth syndrome (presence of TFAZZIN mutation or MLCL/CL ratio of 0.30 or higher)

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with cardiology, genetics, metabolic specialist, or neurology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **ELYXYB**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ELYXYB

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Neurology, or Headache/migraine specialist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Medical justification that at least ONE oral triptan has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **EMFLAZA**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DEFLAZACORT, JAYTHARI, KYMBEE 18 MG TABLET, KYMBEE 30 MG TABLET, KYMBEE 36 MG TABLET, KYMBEE 6 MG TABLET, PYQUVI

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation indicating a diagnosis of Duchenne muscular dystrophy (DMD) confirmed by genetic testing.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with Neurology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Member must have tried and failed or have a contraindication or intolerance to Prednisone. For continuation: Physician attestation that the patient is showing improvement or slowing of disease progression.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **EMPAVELI**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

EMPAVELI

## **EXCLUSION CRITERIA**

Unresolved infection caused by Haemophilus influenzae, Neisseria meningitidis, or Streptococcus pneumoniae. Excluded under Part D if meets coverage criteria under Part B.

## **REQUIRED MEDICAL INFORMATION**

For Paroxysmal nocturnal hemoglobinuria: (1) diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-AP) demonstrated by: (1A) At least 5% PNH cells, or (1B) At least 21% GPI-AP polymorphonuclear cells, and (2) Hemoglobin level of less than 10 g/dL. For C3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis: (1) diagnosis was confirmed by kidney biopsy.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Hematology, or Nephrology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Initial: Documentation of vaccine administration for Haemophilus influenzae, Neisseria meningitidis, and Streptococcus pneumoniae ordered, or vaccination status appropriate for patient with complement deficiency. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **ENBREL**

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## **COVERED USES**

All FDA-Approved Indications

## **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

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New requests for Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

Initial- For Rheumatoid arthritis (RA): (1) previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug). Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PJIA. For Psoriatic Arthritis (PSA): (1) No concurrent use with another systemic biologic or targeted small molecule for PSA. For Ankylosing Spondylitis (AS): (1) trial of or contraindication to an NSAID, and (2) No concurrent use with another systemic biologic or targeted small molecule for AS. For PSO: (1) One of the following: (i) trial of at least a 3 month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus), or PUVA (phototherapy) for the treatment of PSO, (ii) Contraindication or intolerance to both immunosuppressant and PUVA therapy, or (iii) Patient is switching from a different biologic, PDE-4 inhibitor, or JAK inhibitor for PSO, and (2) No concurrent use with another systemic biologic or targeted small molecule for PSO. For COC- All indications: Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# ENSPRYNG

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

ENSPRYNG

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

New: Clinical information provided showing (1) ONE of the following: Optic neuritis, Acute myelitis, Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting, Acute brainstem syndrome, Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions and (2) positive for the anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies. COC: (1) Documentation showing a positive response from baseline such as reduction in the number and/or severity of relapses, reduction in signs and symptoms of NMOSD, or reduction/discontinuation of corticosteroid or other supportive therapies.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

History of greater than or equal to 1 relapse during the previous 12 months

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A



## **ENZYME REPLACEMENTS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

CYSTAGON, GLYCEROL PHENYLBUTYRATE, JAVYGTOR, SAPROPTERIN DIHYDROCHLORIDE, SODIUM PHENYLBUTYRATE, YARGESA

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# EPCLUSA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

EPCLUSA 150-37.5 MG PELLETT PKT, EPCLUSA 200-50 MG PELLETT PACK, EPCLUSA 200 MG-50 MG TABLET, SOFOSBUVIR-VELPATASVIR

## EXCLUSION CRITERIA

Patients concurrently using any of the following medications not recommended by the manufacturer: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz (e.g., ATRIPLA, SUSTIVA), rosuvastatin at doses greater than 10mg daily, tipranavir/ritonavir, or topotecan.

## REQUIRED MEDICAL INFORMATION

HCV RNA level within past 6 months. Previous hepatitis C treatment history (if any). Other medications that will be used with current AASLD/IDSA protocol (if any). Presence or absence of cirrhosis.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

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

## OTHER CRITERIA

Criteria will be applied consistent with current AASLD/IDSA guidance. HCV RNA level within the past 6 months. Combination therapy with ribavirin is required for patients with decompensated cirrhosis, unless the patient is ribavirin ineligible.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A



# EPO

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

ARANESP 100 MCG/0.5 ML SYRINGE, ARANESP 100 MCG/ML VIAL, ARANESP 10 MCG/0.4 ML SYRINGE, 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, EPOGEN 20,000 UNIT/2 ML VIAL, EPOGEN 20,000 UNITS/ML VIAL, EPOGEN 2,000 UNITS/ML VIAL, EPOGEN 3,000 UNITS/ML VIAL, EPOGEN 4,000 UNITS/ML VIAL, PROCRI, RETACRIT

## **EXCLUSION CRITERIA**

Excluded under Part D if meets coverage criteria under Part B.

## **REQUIRED MEDICAL INFORMATION**

Labs including Hgb, Hct, serum ferritin, serum transferrin saturation drawn within the past 60 days.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Anemia due to chronic kidney disease or zidovudine: 1 year. Other: 3 months

## **OTHER CRITERIA**

Dose reduction or interruption is required if hemoglobin exceeds 10 g/dL (adult CKD not on dialysis, cancer), 11 g/dL (CKD on dialysis), 12 g/dL (pediatric CKD).

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **ETRIPAMIL**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

CARDAMYST

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Cardiology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **EUCRISA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

EUCRISA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

For patients over 2 years of age: Medical justification as to why topical corticosteroids and topical calcineurin inhibitors cannot be used.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **EXJADE**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DEFERASIROX 125 MG TB FOR SUSP, DEFERASIROX 250 MG TB FOR SUSP, DEFERASIROX 500 MG TB FOR SUSP, DEFERIPRONE, DEFERIPRONE (3 TIMES A DAY), FERRIPROX 100 MG/ML SOLUTION

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Current weight, lab values for serum ferritin, SCr, ALT/AST drawn within the past 30 days.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Hematology/Oncology

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

Dose cannot exceed 99mg/kg/day for deferiprone or 40mg/kg/day for deferasirox products. For transfusional iron overload: serum ferritin must consistently be greater than 1000 mcg/L.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **FABHALTA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

FABHALTA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Initial: For Paroxysmal nocturnal hemoglobinuria: (1) diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-AP) demonstrated by: (1A) At least 5% PNH cells, or (1B) At least 21% GPI-AP polymorphonuclear cells, and (2) Hemoglobin level of less than 10 g/dL. For C3 glomerulopathy or immunoglobulin A nephropathy: (1) diagnosis was confirmed by kidney biopsy.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Hematology, or Nephrology.

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **FASENRA**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

FASENRA, FASENRA PEN

### **EXCLUSION CRITERIA**

Excluded under Part D if meets coverage criteria under Part B. (Syringe will be reviewed under Part B).

### **REQUIRED MEDICAL INFORMATION**

For Asthma New Start: Documentation or record of persistent airflow obstruction as indicated by (1A) pre-bronchodilator FEV1 less than 80% predicted (for adults) or (1B) pre-bronchodilator FEV1 less than 90% predicted (for adolescent), and (2) Blood eosinophil at least 150 cells/uL within 4 weeks. For Asthma COC: Baseline blood eosinophil at least 150 cells/uL prior to treatment AND Clinical information documenting that member has experienced a reduction in at least ONE of the following: (1) reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath, (2) decrease in administration of rescue medication, (3) decrease in exacerbation frequency or (4) increase in predicted FEV1 from the pretreatment baseline.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

For Asthma New Start: (1) member has had 1 or more asthma exacerbations in the past 12 months requiring corticosteroid treatment and (2) clinical documentation of poor asthma control despite usage of maximal dosages of an inhaled corticosteroid (ICS) or combination ICS with long-acting beta-2 agonist or has documented intolerance or contraindications to ICS or ICS/LABA usage. For EGPA New Start: Patient is currently receiving a systemic corticosteroid. For EGPA COC: Documentation of positive clinical response to therapy (e.g. reduction in the frequency and/or severity of symptoms and exacerbations, reduction in the daily maintenance oral corticosteroid dose).

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# FILSPARI

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

FILSPARI

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial: (1) diagnosis confirmed by biopsy, (2) patient is at high risk of disease progression, defined by meeting both of the following criteria: a) Patient has proteinuria greater than 0.5 g/day or a urine protein-to-creatinine ratio greater than or equal to 1.5 g/g, and b) Patient has received the maximum or maximally tolerated dose of one Angiotensin converting enzyme (ACE) inhibitor (e.g. enalapril, lisinopril, perindopril, ramipril) or Angiotensin receptor blocker (ARB) (e.g. losartan, olmesartan, valsartan) for greater than or equal to 12 weeks prior to starting Filspari. COC: (1) diagnosis has been confirmed by biopsy, and (2) the patient has had a response to therapy (i.e. reduction in proteinuria from baseline).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Nephrology

## COVERAGE DURATION

Initial: 9 months, COC: 1 year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES



# FILSUVEZ

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

FILSUVEZ

## **EXCLUSION CRITERIA**

Concurrent use with Vyjuvek

## **REQUIRED MEDICAL INFORMATION**

Confirmation of a genetic mutation associated with DEB or JEB (i.e., COL7A1, LAMA3, LAMB3, LAMC2, COL17A1, ITGA6, ITGB4, ITGA3)

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Dermatology, Wound care specialist

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **GALAFOLD**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

GALAFOLD

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: Documentation or record of in vitro assay data indicating an amenable galactosidase alpha gene (GLA) variant, or (for males) Biochemical assay of alpha-galactosidase (GLA) enzyme activity in leukocytes of less than 20% of normal activity COC: documentation of disease stability or improvement in symptoms.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta).

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **GIMOTI**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

GIMOTI

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Medical justification that oral metoclopramide has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 weeks

## **OTHER CRITERIA**

For COC: documentation or statement from prescriber confirming improvement of gastroparesis symptoms and the absence of tardive dyskinesia symptoms.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **GLP1-GIP**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

MOUNJARO, OZEMPIC, RYBELSUS, TRULICITY

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **GNRH**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ELIGARD, ELIGARD 22.5 MG SYRINGE, ELIGARD 30 MG SYRINGE, ELIGARD 45 MG SYRINGE, ELIGARD 7.5 MG SYRINGE, LEUPROLIDE ACETATE, LEUPROLIDE DEPOT, LUPRON DEPOT, LUPRON DEPOT (LUPANETA), LUPRON DEPOT-PED 11.25 MG 3MO, LUPRON DEPOT-PED 45 MG 6MO KIT, LUPRON DEPOT-PED 7.5 MG KIT, SYNAREL, TRELSTAR

### **EXCLUSION CRITERIA**

Infertility treatment.

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **GROWTH HORMONE**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

GENOTROPIN, HUMATROPE 12 MG CARTRIDGE, HUMATROPE 24 MG CARTRIDGE, HUMATROPE 6 MG CARTRIDGE, INCRELEX, NORDITROPIN FLEXPRO 10 MG/1.5, NORDITROPIN FLEXPRO 15 MG/1.5, NORDITROPIN FLEXPRO 5 MG/1.5, OMNITROPE, SKYTROFA, SOGROYA, ZOMACTON

### **EXCLUSION CRITERIA**

Coverage is excluded for adults without demonstrated GH deficiency. Coverage is excluded for use to enhance body mass or strength for professional, recreational or social reasons.

### **REQUIRED MEDICAL INFORMATION**

Copies of recent results (within 3 months) from at least one GH stimulation test: Insulin tolerance test or Arginine plus GHRH. Copies of labs with: Dehydroepiandrosterone (DHEA), Thyroid-stimulating hormone (TSH), Thyroid (free T3 and free T4), Follicle-stimulating hormone (FSH), Luteinizing hormone (LH), Insulin-like growth factor (IGF-1), Hemoglobin A1c level, For males: testosterone levels (total and free), For females: estradiol levels. Patient weight.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Maximum recommended daily dose. For initiation of treatment of growth hormone (GH) deficiency in adults, GH deficiency must be demonstrated with at least one of the following: (1) insulin tolerance test (ITT) with serum GH less than 5.1ng/mL, or (2) IGF-I level less than the age-specific lower limit. Must first try Norditropin or provide medical justification why it would not be medically appropriate.

### **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **GROWTH HORMONE ANTAGONISTS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

SOMAVERT

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Serum IGF-I level drawn within the past 30 days.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Maximum recommended daily dose. Diagnosis of acromegaly AND a prescriber affirmation statement that member has had an inadequate response to surgery and/or radiation OR that surgery and/or radiation therapy are not an option (such as but not limited to, individual is an inappropriate candidate for surgical or radiation-based therapy).

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# HAE

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

HAEGARDA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Clinical information provided documenting the frequency and severity of HAE attacks.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

6 months

## **OTHER CRITERIA**

Dose does not exceed FDA approved dosage.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# HARVONI

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

LEDIPASVIR-SOFOSBUVIR

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

HCV RNA level within past 6 months. Confirmation of hepatitis C genotype. Previous hepatitis C treatment history (if any). Other medications that will be used with current AASLD/IDSA protocol (if any). Presence or absence of cirrhosis.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

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

## **OTHER CRITERIA**

Criteria will be applied consistent with current AASLD/IDSA guidance. No approval for requests where provider attests that patient has life expectancy less than 12 months due to non-liver related comorbid conditions (per AASLD/IDSA treatment guideline recommendation). Patient is not concurrently taking any of the following: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, sofosbuvir (as a single agent), or tipranavir/ritonavir.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **HBV**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ADEFOVIR DIPIVOXIL, BARACLUDE 0.05 MG/ML SOLUTION, LAMIVUDINE 100 MG TABLET, LAMIVUDINE 100 MG TABLET, VEMLIDY

### **EXCLUSION CRITERIA**

Antiviral treatment is not indicated in patients with inactive chronic hepatitis B (CHB), defined as: HBV DNA undetectable AND EITHER (1) HBsAg negative for greater than 6 months OR (2) HBsAg positive, HBeAg negative, anti-HBe positive and normal ALT.

### **REQUIRED MEDICAL INFORMATION**

For new HBV treatment: baseline HBsAg (greater than 6 months ago) AND HBV DNA, HBsAg, HBeAg, and LFT within 6 months. For continuation HBV treatment: anti-HBe (HBeAb), HBV DNA, HBsAg, HBeAg, and LFT within 6 months. For prophylaxis of HBV reactivation: documentation or record of previous HBV infection and current condition or therapy causing immunosuppression.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

**PREFERRED DRUGS:** Must have a history of failure, contraindication, or intolerance to entecavir or adefovir before lamivudine HBV is approved. Must have a history of failure, contraindication, or intolerance to Viread (tenofovir) before Vemlidy is approved. Combination therapy will be approved with documented resistance. **SPECIAL POPULATIONS:** Criteria will be applied consistent with AASLD guidelines. This includes hepatitis D virus, coinfection with HIV or HCV, concomitant immunosuppressive therapy, concomitant cytotoxic therapy, virologic failure, transplant (liver or non-liver solid organ), pregnancy, or pediatric. **SYMPTOMATIC ACUTE HEPATITIS (HBsAg positive for less than 6 months):** antiviral treatment is only indicated in patients with acute liver failure or protracted

severe course (defined by total bilirubin greater than 3 mg/dL, direct bilirubin greater than 1.5 mg/dL, INR greater than 1.5, encephalopathy, or ascites). CHRONIC HEPATITIS B (CHB) TREATMENT DURATION: [1] HBeAg-negative at baseline, treat indefinitely. [2] CHB with cirrhosis, treat indefinitely. [3] For patients with HBeAg positive infection without cirrhosis, discontinue therapy after HBsAg loss or after treatment consolidation (treat persistently normal ALT and undetectable HBV DNA for 12 months or longer after seroconversion to anti-HBe). [4] For continued therapy beyond the recommended duration, medical justification is required documenting the benefit of continued treatment outweighs the risk of discontinuation. CHB TREATMENT INDICATIONS (HBsAg positive for at least 6 months, without cirrhosis): [A] HBeAg positive, ALT at least 2XULN (ULN for ALT is 35 U/L for males and 25 U/L for females), HBV DNA greater than 20,000 IU/mL, treat. [B] HBeAg positive, ALT at least 2XULN, HBV DNA between 2,000-20,000 IU/mL, evaluate ALT. [C] HBeAg positive, ALT above ULN but below 2XULN, HBV DNA above 2,000 IU/mL, evaluate ALT. [D] HBeAg positive, ALT below ULN, HBV DNA above 20,000 IU/mL, do not treat. [E] HBeAg positive, ALT below ULN, HBV DNA between 2,000-20,000 IU/mL, consider treatment discontinuation. [F] HBeAg negative, ALT at least 2XULN, HBV DNA at least 2,000 IU/mL, treat. [G] HBeAg negative, ALT at least 2XULN, HBV DNA below 2,000 IU/mL, evaluate ALT. [H] HBeAg negative, ALT above ULN but below 2XULN, HBV DNA above or below 2,000 IU/mL, evaluate ALT. [I] HBeAg negative, ALT below ULN, HBV DNA above 2,000 IU/mL, monitor. [J] HBeAg negative, ALT below ULN, HBV DNA below 2,000 IU/mL, do not treat. EVALUATE ALT: Rule out other causes of ALT elevation and treat if age is greater than 40 years old OR evidence of liver necroinflammation (A3 or higher) or fibrosis (F2 or higher) is identified via noninvasive testing or biopsy.

#### **PART B PREREQUISITE**

N/A

#### **PREREQUISITE THERAPY REQUIRED**

YES

# HEMADY

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

HEMADY

## 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

## PREREQUISITE THERAPY REQUIRED

N/A

# HETLIOZ

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

TASIMELTEON

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: (Non-24 disorder) documentation or record of a diagnosis of Non-24. (SMS) results of genetic testing showing a microdeletion of chromosome 17p11.2. COC: Documentation showing response to therapy (improvement in sleep quality or time)

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

New: 6 months. COC: 1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **HIGH POTENCY ER OPIOID**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

MORPHINE SULFATE ER 100 MG CAP, MORPHINE SULFATE ER 120 MG CAP, MORPHINE SULF ER 100 MG TABLET, MORPHINE SULF ER 200 MG TABLET

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Medical justification specifying that pain is intractable (constant and debilitating pain, potent enough to interfere with sleep, and not controlled on other treatments).

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **HOFH**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

JUXTAPID 10 MG CAPSULE, JUXTAPID 20 MG CAPSULE, JUXTAPID 30 MG CAPSULE,  
JUXTAPID 5 MG CAPSULE

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Lipid panel, ALT, AST drawn within the past 30 days.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Must currently take a statin (unless contraindicated) or provide a medical justification as to why its usage would not be medically appropriate (e.g., statin intolerance) for the patient.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# HUMIRA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

HUMIRA, HUMIRA(CF), HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PSOR-UV-ADOL HS, HUMIRA PEN

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

New requests for Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: HS: 12 months, All other indications: 6 months. COC: 1 year.

## OTHER CRITERIA

Initial- For Rheumatoid arthritis (RA): (1) previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug). Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PJIA. For Psoriatic Arthritis (PSA): (1) No concurrent use with another systemic biologic or targeted small molecule for PSA. For Ankylosing Spondylitis (AS): (1) trial of or contraindication to an NSAID, and (2) No concurrent use with another systemic biologic or targeted small molecule for AS. For PSO: (1) One of the following: (i) trial of at least a 3 month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus), or PUVA (phototherapy) for the treatment of PSO, (ii) Contraindication or intolerance to both immunosuppressant and PUVA therapy, or (iii) Patient is switching from a different biologic, PDE-4 inhibitor, or JAK inhibitor for PSO, and (2) No concurrent use with another systemic biologic or targeted small molecule for PSO. For Uveitis: no isolated anterior uveitis. For Crohns Disease (CD): (1) No concurrent use with another systemic biologic or targeted small molecule for CD.

For Ulcerative Colitis (UC): (1) No concurrent use with another systemic biologic or targeted small molecule for UC. For Hidradenitis Suppurativa (HS): (1) No concurrent use with another systemic biologic or targeted small molecule for HS. For COC- All indications: Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **HYFTOR**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

HYFTOR

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Definitive diagnosis of tuberous sclerosis complex by meeting one of the following: 1) Identification of a pathogenic variant in the tuberous sclerosis complex 1 (TSC1) gene or tuberous sclerosis complex 2 (TSC2) gene by genetic testing, or 2) 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. (Major features- angiofibroma or fibrous cephalic plaque, angiomyolipomas, cardiac rhabdomyoma, hypomelanotic macules, lymphangiomyomatosis, multiple cortical tubers and/or radial migration lines, multiple retinal hamartomas, Shagreen patch, subependymal giant cell astrocytoma, subependymal nodule, or ungula fibromas. Minor feature criteria involve "confetti" skin lesions, dental enamel pits (three or more), intraoral fibromas, multiple renal cysts, nonrenal hamartomas, retinal achromic patch, and sclerotic bone lesions).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Dermatology

## **COVERAGE DURATION**

New: 3 months. COC: 1 year.

## **OTHER CRITERIA**

COC: Documentation or statement from prescriber confirming positive clinical response to therapy (e.g., improvement in skin lesions)

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# IBS

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

MOVANTIK

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medical justification for the concomitant use of antidiarrheals or non-opioid constipating medications.  
Medical justification as why bulk or osmotic laxatives are not appropriate. For opioid-induced constipation, clinical information indicating concurrent opioid use.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# ILUMYA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

ILUMYA

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For Plaque psoriasis (PSO): Psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a dermatologist.

## COVERAGE DURATION

Initial: 6 months. COC: 1 year.

## OTHER CRITERIA

Initial- For PSO: (1) Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Skyrizi, Tremfya, Otezla, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSO. COC: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# INLURIYO

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## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

INLURIYO

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Hematology/Oncology.

## COVERAGE DURATION

1 year

## OTHER CRITERIA

Medical justification specifying that one of the formulary endocrine therapy alternatives (e.g. tamoxifen, toremifene) have been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **INTRAROSA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

INTRAROSA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Approved until end of plan year.

## **OTHER CRITERIA**

Medical justification specifying that formulary alternatives without age restrictions (e.g., estradiol 0.01% cream, or estradiol/yuvafem vaginal tablet) have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **IQIRVO**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

IQIRVO

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: Diagnosis is confirmed by two of the following: (1) Elevated alkaline phosphatase (ALP) lab results within past 6 months, (2A) The presence of antimitochondrial antibodies (AMA) at a titer of 1:40 or higher, (if AMA is negative, presence of other PBC-specific autoantibodies, including SP 100 or GP210), or (2B) Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts, and (3) confirmation member does not have decompensated cirrhosis. COC: (1) No concurrent use with another second-line therapy for PBC, and (2) documentation of positive clinical response.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Initial- PBC: Prescribed by or in consultation with gastroenterology or hepatology.

## **COVERAGE DURATION**

New: 6 months, COC: 1 year.

## **OTHER CRITERIA**

(1) Medical justification that Ursodiol has been tried and failed (at a dosage of 13-15mg/kg/day, or maximally tolerated dose, for at least one year), is contraindicated, or would not be medically appropriate for the patient, and (2) Iqirvo will be used in combination with ursodiol (unless contraindicated, or not medically appropriate for the patient).

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**  
YES

# ISTURISA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

ISTURISA 1 MG TABLET, ISTURISA 5 MG TABLET

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

New: (1) Clinical information indicating pituitary surgery is not an option or has not been curative and (2) baseline 24-hour urinary free cortisol (UCF) level. COC: Labs within past 30 days documenting 24-hour urinary free cortisol (UFC) level has decreased from baseline.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Endocrinology

## COVERAGE DURATION

1 year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# **IVIG**

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

BIVIGAM, GAMMAGARD LIQUID, GAMMAGARD LIQUID ERC, GAMMAGARD S-D, GAMMAKED 1 GRAM/10 ML VIAL, GAMMAPLEX, GAMUNEX-C 1 GRAM/10 ML VIAL, OCTAGAM, PANZYGA, PRIVIGEN, QIVIGY, YIMMUGO

## **EXCLUSION CRITERIA**

Excluded under Part D if meets coverage criteria under Part B (primary immunodeficiency disease).

## **REQUIRED MEDICAL INFORMATION**

Prescribed dose and dosing frequency. Patient's weight and weight-based dose.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

CIDP, PHI, or patients with solid organ transplant: 1 year. Other Dx: 3 months

## **OTHER CRITERIA**

Medical justification must be provided to support the prescribed dosage if it exceeds the FDA-approved maximum daily dose.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **IXAZOMIB**

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

NINLARO

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Hematology/Oncology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

The member is (1) Using concomitant therapy with lenalidomide (Revlimid) and dexamethasone, (2) Has previously received at least one of the following Immunomodulators (e.g., lenalidomide (Revlimid), pomalidomide (Pomalyst), or thalidomide (Thalomid)), Liposomal doxorubicin (Doxil), cyclophosphamide (Cytoxan), melphalan (Alkeran), or Panobinostat (Farydak), Corticosteroids (e.g., dexamethasone, prednisone) or Radiation, and (3) Has a history of failure, contraindication, or reason(s) for intolerance to bortezomib (Velcade).

## **PART B PREREQUISITE**

YES

## **PREREQUISITE THERAPY REQUIRED**

YES

# JADENU

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

DEFERASIROX 180 MG TABLET, DEFERASIROX 360 MG TABLET, DEFERASIROX 90 MG TABLET

## **EXCLUSION CRITERIA**

Dosing not to exceed the 28 mg/kg/day recommendations. Jadenu is contraindicated in patients with serum creatinine greater than 2 times the age-appropriate ULN or CrCl less than 40 mL/min, poor performance status, high-risk myelodysplastic syndromes, advanced malignancies, and platelet counts less than  $50 \times 10^9/L$ .

## **REQUIRED MEDICAL INFORMATION**

Current weight, lab values drawn within the past 30 days for serum ferritin level, CPT score/class, serum creatinine, platelet count, and ALT/AST. For transfusional iron overload (transfusional hemosiderosis), also provide the length of time on blood transfusions, and date of last blood transfusion. For non-transfusion dependent thalassemia syndromes, also provide liver iron concentration (LIC).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Hematology/Oncology

## **COVERAGE DURATION**

6 months

## **OTHER CRITERIA**

Serum ferritin must consistently be greater than 1000 mcg/L for transfusional iron overload. Serum ferritin must consistently be greater than 300 mcg/L for non-transfusion-dependent thalassemia syndromes. Dose cannot exceed 28mg/kg/day.

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# JASCAYD

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

JASCAYD

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Clinical information provided to support the following: (1A) Confirmation of a diagnosis of IPF by ruling out other ILDs via radiologic evidence of lung fibrosis, (1B) Histological or radiographic evidence confirming the diagnosis of IPF, and (1C) Liver function tests, or (2A) a diagnosis of progressive pulmonary fibrosis confirmed by presence of ILD other than IPF with radiologic evidence of lung fibrosis AND (2B) two of the following signs of fibrotic disease progression within the previous 12 months without alternate explanation: absolute decline in forced vital capacity [FVC] 5 percent or greater predicted or absolute decline in diffusing capacity for carbon monoxide [DLCO] 10 percent or greater predicted, worsening respiratory symptoms, progression of radiologic fibrosis (increased extent or severity of reticular changes, lobar volume loss, or traction bronchiectasis/bronchiolectasis, new ground-glass opacities with traction bronchiectasis, or new/worsening honeycombing), OR (2C) a relative decline in FVC of greater than 10 percent or DLCO greater than 15 percent over 8 to 16 months.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Pulmonology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medical justification that Ofev and pirfenidone have been tried and failed, is contraindicated, or is not medically appropriate for the patient.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# JOENJA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

JOENJA

## EXCLUSION CRITERIA

(1) Member under 12 years or age, or (2) Member weight less than 45 kg.

## REQUIRED MEDICAL INFORMATION

Initial: (1) Member weight, (2) Member has a genetic phosphoinositide 3-kinase delta mutation with a variant in PIK3CD and/or PIK3R1 genes, and (3) Member has clinical manifestations compatible with APDS (e.g., history of repeated oto-sino-pulmonary infections, lymphoproliferation, autoimmunity [e.g., cytopenia], enteropathy, organ dysfunction [e.g., lung, liver])

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Immunology, Pulmonology, Hematology or a physician who specializes in the treatment of APDS.

## COVERAGE DURATION

Initial: 6 months, COC: 1 year

## OTHER CRITERIA

COC: Member is experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., reduced lymph node size, increased naive B-cell percentage, decreased frequency or severity of infections, decreased frequency of hospitalizations).

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# JOURNAVX

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

JOURNAVX

## **EXCLUSION CRITERIA**

(1) Member under 18 years of age, (2) Concomitant use with strong CYP3A inhibitors, (3) Member with severe hepatic impairment (Child-Pugh Class C), (4) Member with severe renal impairment (eGFR less than 15mL/min), and (5) Treatment of chronic pain (defined as pain lasting one month duration or greater).

## **REQUIRED MEDICAL INFORMATION**

(1) Medication will not be used for longer than 14 days for any acute pain occurrence, and (2) Patient has a history of intolerance or contraindication to a prescription NSAIDs.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

14 days

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# JYNARQUE

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

TOLVAPTAN

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For tolvaptan (generic Jynarque): New therapy- documentation or record of a diagnosis of ADPKD, labs including LFTs and bilirubin in the past 30 days and presence of at least 2 risk factors associated with rapidly progressing disease such as a total kidney volume (TKV) of 750 mL or more, hypertension, presence of PKD1 gene, onset of ADPKD symptoms before the age of 30, presence of proteinuria as indicated by labs, high urinary sodium excretion as indicated by labs or increased fibroblast growth factor (FGF) 23. COC- Labs including LFTs and bilirubin in the past 90 days. For tolvaptan (generic Samsca): (1) medication is for continuation of care post hospital discharge (2) documentation confirming the diagnosis of hyponatremia such as serum sodium less than 125 mEq/L or less than 135 mEq/L and symptomatic (i.e., headache, nausea, vomiting, fatigue, gait disturbances or confusion) and (4) not currently receiving a strong CYP3A4 inhibitor per claims (clarithromycin, ketoconazole oral, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, or telithromycin)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Nephrology

## COVERAGE DURATION

Autosomal dominant polycystic kidney disease: 1 year. Other: 3 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# **KALYDECO**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

KALYDECO

## **EXCLUSION CRITERIA**

Patients who are homozygous for the F508del mutation in the CFTR gene

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Pulmonology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# KERENDIA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

KERENDIA

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For Chronic kidney disease associated with type 2 diabetes:(1) Receiving concurrent therapy with an angiotensin converting enzyme inhibitor (ACE inhibitor) or angiotensin receptor blocker (ARB) at maximally tolerated labeled dosage (unless contraindicated), or provide a medical justification as to why therapy would not be medically appropriate (e.g., intolerance). For risk reduction related to cardiovascular death, hospitalization for heart failure, and urgent heart failure vistic: (1) heart failure with left ventricular ejection fraction (LVEF) of at least 40%.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# KEVZARA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

KEVZARA

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Initial- Rheumatoid Arthritis (RA) / Polyarticular Juvenile Idiopathic Arthritis (PJIA): Prescribed by on in consultation with Rheumatology.

## COVERAGE DURATION

Initial: Polymyalgia Rheumatica (PMR): 12 months, All other indications: 6 months. COC: 1 year.

## OTHER CRITERIA

Initial- For RA: (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Orencia. For (PJIA): (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Orencia, Rinvoq, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PJIA. COC: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **KINERET**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

KINERET

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Initial- Rheumatoid Arthritis (RA): Prescribed by on in consultation with Rheumatology.

## **COVERAGE DURATION**

Initial- RA: 6 months, All other indications: 12 months. COC: 12 months.

## **OTHER CRITERIA**

Initial- For RA: (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Orencia. For Cryopyrin-Associated Periodic Syndromes (CAPS): (1) One of the following: (i) Genetic test for gain-of-function mutations in the NLRP3 gene, or (ii) Has inflammatory markers (i.e. elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins), and (2) Two of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities. For Deficiency of Interleikin-1 Receptor Antagonists (DIRA): (1) One of the following: (i) Genetic test for gain-of-function mutations in the IL1RN gene, or (ii) Has inflammatory markers (i.e. elevated CRP, ESR), and (2) One of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, onychomadesis. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**  
YES

# KORLYM

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

MIFEPRISTONE 300 MG TABLET

## **EXCLUSION CRITERIA**

Pregnancy

## **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

# KRISTALOSE

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

KRISTALOSE, LACTULOSE 10 GM PACKET, LACTULOSE 20 GM PACKET

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Medical justification why lactulose solution cannot be used.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

3 months

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **LECANEMAB**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

LEQEMBI IQLIK

## **EXCLUSION CRITERIA**

PENDING CMS APPROVAL

## **REQUIRED MEDICAL INFORMATION**

PENDING CMS APPROVAL

## **AGE RESTRICTION**

PENDING CMS APPROVAL

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with neurology, geriatrics, or psychiatry.

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

Not experiencing any severe, unstable, or symptomatic amyloid-related imaging abnormalities, intracerebral hemorrhage, or hypersensitivity reactions while on therapy.

## **PART B PREREQUISITE**

YES

## **PREREQUISITE THERAPY REQUIRED**

N/A

# LENVIMA

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## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

LENVIMA

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

For renal cell carcinoma (RCC): (1) Lenvima is being used in combination with pembrolizumab or (2) Lenvima is being used in combination with everolimus (Afinitor) and the member has a history of failure, contraindication, or reason(s) for intolerance to one anti-angiogenic therapy such as axitinib (Inlyta), bevacizumab (Avastin), everolimus (Afinitor), pazopanib (Votrient), sorafenib (Nexavar), or sunitinib (Sutent).

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# LEPTIN

---

## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

MYALEPT

## EXCLUSION CRITERIA

1) HIV related lipodystrophy. 2) Metabolic disease, without concurrent evidence of generalized lipodystrophy. 3) General obesity.

## REQUIRED MEDICAL INFORMATION

Documentation or record of congenital or acquired generalized lipodystrophy. Weight and height, or BMI.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Endocrinology

## COVERAGE DURATION

6 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# LEQSELVI

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

LEQSELVI

## EXCLUSION CRITERIA

Concurrent use of other JAK inhibitors, biologic immunomodulators, cyclosporine, other potent immunosuppressants, or moderate or strong CYP2C9 inhibitors

## REQUIRED MEDICAL INFORMATION

(1) Documentation or record of at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT), and (2) Negative Tuberculosis (TB) test result.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Dermatology

## COVERAGE DURATION

1 year

## OTHER CRITERIA

Medical justification that Litfulo and Olumiant have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# LEVORPHANOL

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

LEVORPHANOL TARTRATE

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

Clinical information specifying that two applicable formulary alternative short-acting opioid/opioid analgesic combinations (morphine IR, oxycodone, hydromorphone, hydrocodone, oxymorphone) have been tried and failed, is contraindicated, or would not be medically appropriate for the patient in the past 6 months.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# LITFULO

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

LITFULO

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

(1) Documentation or record of at least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT), and (2) Negative Tuberculosis (TB) test result.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Dermatology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Maximum dose of 50mg daily.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **LOFEXIDINE**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

LOFEXIDINE HCL

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

(1) Diagnosis of opioid use disorder as per DSM-5 criteria, (2) statement from the prescriber that the patient is currently undergoing abrupt opioid discontinuation within the next 7 days, (3) medical justification supporting why an opioid taper with buprenorphine could not be used, and (4) medical records or statement from the prescriber indicating patient will not be using opioid medications during withdrawal period.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Approved for 14 days of treatment.

## **OTHER CRITERIA**

One of the following must be provided: (1) lofexidine has already been initiated in an inpatient/ER setting or (2) medical justification for why clonidine could not be used. Maximum dosage does not exceed 16 tablets (2.88 mg) daily.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# LOKELMA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

LOKELMA

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

(1) labs from within past 30 days showing hyperkalemia (potassium level above 5 mEq/L).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

(1) Medications known to cause hyperkalemia (ACEIs, ARBs, NSAIDs, aldosterone antagonists) have been discontinued or reduced to lowest effective dose, and (2) Medical justification specifying that sodium polystyrene sulfonate has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# LYRICA

---

## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

PREGABALIN ER

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

For neuropathic pain associated with diabetic peripheral neuropathy (DPN), individual had a trial of one of the following: (1) SNRI (such as, Cymbalta (duloxetine HCl) or venlafaxine, (2) Tricyclic antidepressants (such as, amitriptyline, desipramine, nortriptyline), OR (3) Gabapentin. For post herpetic neuralgia, member had a trial of one of the following: (1) Gabapentin (2) Lidocaine patch (Lidoderm) or (3) Tricyclic antidepressants (such as, amitriptyline, desipramine, nortriptyline).

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

## **MAVACAMTEN**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

CAMZYOS

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

New: The member has 1) left ventricular ejection fraction (LVEF) of greater than or equal to 55%, 2) Valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or after provocation, 3) NYHA class II or III symptoms of heart failure, and 4) therapeutic failure or intolerance to ONE of the following: Non-vasodilating beta blocker (e.g., metoprolol, propranolol, atenolol) OR Non-dihydropyridine calcium channel blocker (e.g., verapamil, diltiazem). COC: Documentation of positive clinical response to therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Cardiology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Dose does not exceed 15 mg per day.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# MAVENCLAD

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## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

CLADRIBINE 10 MG X 10 TAB PK, CLADRIBINE 10 MG X 1 TB DAY PK, CLADRIBINE 10 MG X 2 TB DAY PK, CLADRIBINE 10 MG X 4 TABLET PK, CLADRIBINE 10 MG X 5 TABLET PK, CLADRIBINE 10 MG X 6 TABLET PK, CLADRIBINE 10 MG X 7 TABLET PK, CLADRIBINE 10 MG X 8 TABLET PK, CLADRIBINE 10 MG X 9 TABLET PK, MAVENCLAD

## EXCLUSION CRITERIA

1) Current malignancy, 2) Pregnant women, 3) HIV infection, 4) Active chronic infections (e.g., hepatitis or tuberculosis).

## REQUIRED MEDICAL INFORMATION

First treatment course: Baseline liver function test (LFTs) and complete blood count (CBC) with differential, including lymphocyte counts within normal limits must be provided. Second treatment course: Member has received one course treatment (1.75mg/kg) with Mavenclad 43 weeks prior, Liver function test (LFTs) and complete blood count (CBC) with differential, including lymphocyte counts of at least 800 cells/microliter must be provided.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

3 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

## **MAVYRET**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

MAVYRET

### **EXCLUSION CRITERIA**

Moderate or severe hepatic impairment (Child Pugh B or C)

### **REQUIRED MEDICAL INFORMATION**

HCV RNA level within past 6 months

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

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

### **OTHER CRITERIA**

Criteria will be applied consistent with current AASLD/IDSA guidance. Trial of a preferred formulary alternative including Harvoni ledipasvir/sofosbuvir or Epclusa when these agents are considered acceptable for treatment of the specific genotype per AASLD/IDSA guidance. Patient is not concurrently taking any of the following medications not recommended or contraindicated by the manufacturer: carbamazepine, rifampin, ethinyl estradiol-containing medication, atazanavir, darunavir, lopinavir, ritonavir, efavirenz, atorvastatin, lovastatin, simvastatin, rosuvastatin at doses greater than 10mg, or cyclosporine at doses greater than 100mg per day. Patient must not have prior failure of a DAA (direct-acting antiviral) regimen with NS5A-inhibitor and HCV protease inhibitor.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES



## **MAYZENT**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

MAYZENT 0.25MG START-1MG MAINT, MAYZENT 0.25 MG TABLET, MAYZENT 1 MG TABLET, MAYZENT 2 MG TABLET

### **EXCLUSION CRITERIA**

Patients with a CYP2C9\*3/ \*3 genotype.

### **REQUIRED MEDICAL INFORMATION**

Results of CYP2C9 genotype testing. NEW: Baseline liver function test (AST, ALT, bilirubin), complete blood count and documentation provided showing member has received cardiac evaluation (ECG) and ophthalmologic evaluation prior to starting Mayzent. COC: Documentation that member has demonstrated a response to therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Requested dose is within FDA approved recommendation based on member's CYP2C9 genotype.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **MEDICALLY ACCEPTED**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ACUTANE 10 MG CAPSULE, ACCUTANE 20 MG CAPSULE, ACCUTANE 40 MG CAPSULE, ACTIMMUNE, ACYCLOVIR 1,000 MG/20 ML VIAL, ACYCLOVIR 500 MG/10 ML VIAL, AMMONIUM LACTATE, AMNESTEEM, AMPHOTERICIN B, ATOVAQUONE, BENLYSTA 200 MG/ML AUTOINJECT, BENLYSTA 200 MG/ML SYRINGE, CLARAVIS, DIACOMIT, IMPAVIDO, ISOTRETINOIN 10 MG CAPSULE, ISOTRETINOIN 20 MG CAPSULE, ISOTRETINOIN 30 MG CAPSULE, ISOTRETINOIN 40 MG CAPSULE, LIDOCAINE 5% PATCH, POMALIDOMIDE, QUININE SULFATE, TETRABENAZINE, TRIDACAINE, TRIDACAINE II, XGEVA, ZENATANE

### **EXCLUSION CRITERIA**

Excluded under Part D if meets coverage criteria under Part B.

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

# MEGESTROL

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

MEGESTROL 20 MG TABLET, MEGESTROL 400 MG/10ML SUSP CUP, MEGESTROL 40 MG TABLET, MEGESTROL ACETATE 40MG/ML ORAL SUSPENSION

## EXCLUSION CRITERIA

Weight gain conditions excluded from Part D coverage

## REQUIRED MEDICAL INFORMATION

Prescriber must acknowledge that medication benefits outweigh potential risks in patients 65 years of age or older.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Approved until end of plan year.

## OTHER CRITERIA

Maximum recommended daily dose.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

## **MEPERIDINE**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

MEPERIDINE 100 MG/ML VIAL, MEPERIDINE 25 MG/ML VIAL, MEPERIDINE 50 MG/5 ML SOLUTION, MEPERIDINE 50 MG/ML VIAL

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Labs with SCr, BUN drawn within the past 30 days.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

Medical justification as to why two formulary alternatives such as hydromorphone, fentanyl, oxycodone or methadone cannot be used in patients with decreased renal function or over age 65.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **METHADONE**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

METHADONE 10 MG/5 ML SOLUTION, METHADONE 5 MG/5 ML SOLN CUP, METHADONE 5 MG/5 ML SOLUTION, METHADONE HCL 10 MG TABLET, METHADONE HCL 5 MG TABLET

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medical justification specifying why at least two long-acting formulary alternatives (Fentanyl patch, Kadian, Morphine ER, Oxycodone ER, or Oxymorphone ER) cannot be used. If the patient is currently receiving treatment with a long-acting opioid medication, a prescriber statement is required indicating all other long-acting opioid medications will be discontinued. For doses above 30mg of methadone daily, consultation with a pain management specialist is required.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **MIGLUSTAT**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

MIGLUSTAT

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: Clinical information confirming Gaucher Disease Type 1 by ONE of the following: (a) deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR (b) molecular genetic testing documenting glucocerebrosidase gene mutation AND evidence of ONE of the following: (a) anemia (hemoglobin level below testing laboratory's lower limit of the normal range based on age and gender OR (b) thrombocytopenia (platelet less than 100,000 per microliter) OR (c) hepatomegaly (as evidenced by increased liver volume upon radiological imaging OR (d) splenomegaly (as evidenced by increased spleen volume by radiological imaging) OR (e) growth failure (growth velocity below the standard mean for age) OR (f) evidence of bone disease with other causes ruled out. COC: Improvement in or stabilization from baseline of at least 1 of the following: decrease in spleen volume, decrease in liver volume, increase in hemoglobin level, increase in platelet count, improvement in growth or decrease in bone pain or crisis.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Geneticist, endocrinologist or specialist in treatment of Gaucher disease.

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

For doses above 300 mg per day, documentation the dose is insufficient due to no clinical improvement in spleen volume, liver volume, hemoglobin level or platelet count AND creatinine clearance is above 70 ml/min/1.73m<sup>2</sup> AND clinical information confirming no evidence of adverse reactions (peripheral neuropathy, tremors, diarrhea or decreased platelet counts).

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

## **MIPLYFFA**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

MIPLYFFA

### **EXCLUSION CRITERIA**

Age less than 2 years old.

### **REQUIRED MEDICAL INFORMATION**

(1) Diagnosis has been genetically confirmed by mutation analysis of NPC1 and NPC2 genes, (2) Prescribed in combination with miglustat, and (3) Not receiving in combination with Aqneursa.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Niemann-Pick disease type C (NPC)- Initial: Prescribed by or in consultation with Neurology or Genetics.

### **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

### **OTHER CRITERIA**

Initial- For patients weighing at least 15kg: Medical justification specifying that Aqneursa has been tried and failed, is contraindicated, or would not be medically appropriate for the patient. COC- For NPC: (1) Improvement or slowing of disease progression, and (2) prescribed in combination with miglustat.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **MIRIBAVIR**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

LIVTENCITY

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

New: Clinical information provided by chart notes, historical pharmacy claims review or a physician statement documenting member is refractory to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Oncology, Transplant or infectious disease specialist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **MITAPIVAT**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

AQVESME

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

New: (1) Confirmation of alpha- or beta-thalassemia, and (2A) Labs within past 30 days showing hemoglobin level 10 g/dL or less OR (2B) evidence of 6 or more blood transfusions within the previous 52 weeks. COC: Labs within past 30 days showing hemoglobin level increased from the baseline or evidence that the number of blood transfusions has decreased from baseline.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Hematology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **MOVEMENT DISORDER**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

AUSTEDO, AUSTEDO XR, AUSTEDO XR TITR(12-18-24-30MG), INGREZZA, INGREZZA INITIATION PK(TARDIV), INGREZZA SPRINKLE

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Huntington Disease: Prescribed by or in consultation with a neurologist or movement disorder specialist. Tardive Dyskinesia: Prescribed by or in consultation with a neurologist, psychiatrist or movement disorder specialist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **MS STEP 1**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

AVONEX, AVONEX (4 PACK), AVONEX PEN, AVONEX PEN (4 PACK), BETASERON 0.3 MG INJECTION, DALFAMPRIDINE ER, DIMETHYL FUMARATE, FINGOLIMOD, GILENYA 0.25 MG CAPSULE, GLATIRAMER ACETATE, GLATOPA, REBIF, REBIF REBIDOSE, TASCENSO ODT, TERIFLUNOMIDE, VUMERITY

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **MYFEMBREE**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

MYFEMBREE

### **EXCLUSION CRITERIA**

A diagnosis of osteoporosis defined as a history of fragility fracture or T-score less than or equal to 2.5 standard deviations at any site based upon bone mineral density (BMD) measurement by dual-energy x-ray absorptiometry (DXA)

### **REQUIRED MEDICAL INFORMATION**

BMD measurement within the past 3 months

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

1) For treatment of heavy menstrual bleeding: medical justification that hormonal contraceptives and tranexamic acid have been tried and failed, are contraindicated, or would not be medically appropriate for the patient. 2) The cumulative approval duration is limited to a total 24 months in a patients lifetime.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **NARCOLEPSY**

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

ARMODAFINIL, MODAFINIL

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Results of a sleep study supporting the diagnosis. (armodafinil, modafinil): Narcolepsy- positive polysomnography (sleep study) for Narcolepsy and dose does not exceed FDA label maximum. (armodafinil, modafinil): Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS)- patient has positive polysomnography for OSAHS, and hypersomnolence score of at least 10 on the Epworth Sleepiness Scale and dose does not exceed FDA label maximum. (armodafinil, modafinil): Shift Work Sleep Disorder (SWSD)- patient is night shift worker with hours of 11pm-7am, early morning shift worker with starting hours between 4am -7am, or rotating shift worker with night shifts, and dose does not exceed FDA label maximum. (armodafinil, modafinil): Refractory Depression- prescribed or recommended by a psychiatrist OR patient has failed therapy with one prior antidepressant regimen and is experiencing symptoms of fatigue or excessive daytime sedation while on the current antidepressant regimen, and modafinil will be added to current regimen, and dose does not exceed FDA label maximum. (armodafinil, modafinil): Bipolar depression- dose does not exceed FDA label maximum.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

If the patient is receiving concomitant sedatives (ramelteon, zaleplon, zolpidem) or benzodiazepines (alprazolam, chlordiazepoxide, clobazam, clonazepam, diazepam, estazolam, flurazepam, lorazepam, oxazepam, quazepam, temazepam, triazolam), justification as to why both agents are medically

necessary.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# **NAYZILAM**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

NAYZILAM

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Clinical information provided that the member is on existing antiepileptic therapy and is experiencing acute, intermittent, or frequent seizure activity.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Neurology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **NEXLETOL**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

NEXLETOL, NEXLIZET

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Lipid panel drawn within the past 30 days. For diagnosis of clinical atherosclerotic cardiovascular disease, diagnosis confirmed by one of the following: acute coronary syndrome, coronary or other arterial revascularization, history of MI, peripheral arterial disease, angina, stroke, or TIA.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Clinical information provided that the patient is utilizing the maximally tolerated dose of any statin or a prescriber attestation of statin-intolerance, and history of previous failure with ezetimibe.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# NIACIN

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

NIACIN ER

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

AST, ALT, Uric Acid, Fasting Glucose or A1c drawn within the previous 3 months.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Approved until end of plan year.

## **OTHER CRITERIA**

Medical justification specifying that two formulary statins (atorvastatin, lovastatin, pravastatin, rosuvastatin, or simvastatin) or two formulary fibrates (fenofibrate or gemfibrozil) have been tried and failed, are contraindicated, or would not be medically appropriate (e.g., statin intolerance) for the patient.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **NORTHERA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

DROXIDOPA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

2 weeks

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# NUCALA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

NUCALA

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- Asthma: blood eosinophils of greater than or equal to 150 cells/mcL within part 12 months.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial- CRSwNP: 6 months. All other Dx: 1 year. COC: 1 year.

## OTHER CRITERIA

Initial- For Asthma: (1) Concurrent therapy with a medium, high-dose or maximally-tolerated dose of an inhaled corticosteroid (ICS) and one other maintenance medication, (2) One asthma exacerbation requiring systemic corticosteroid burst lasting 3 or more days within the past 12 months, or one serious exacerbation requiring hospitalization or ER visit with the past 12 months, or poor symptom control despite current therapy as evidence by at least 3 of the following within the past 4 weeks: daytime asthma symptoms more than twice per week, any night waking due to asthma, SABA reliever for symptoms more than twice per week, any activity limitations due to asthma, and (3) no concurrent use of Xolair, Dupixent, Tezspire, or any other Anti-IL5 biologics when used for asthma. For COPD: (1) blood eosinophils of greater than or equal to 150 cells/mcL at initiation of therapy (within 6 weeks of dosing) or blood eosinophils of greater than or equal to 300 cells/mcL within 12 months prior to initiation of therapy, (2) history of 2 or more moderate exacerbations (resulting in treatment with systemic glucocorticoids, antibiotics, or both), or 1 or more severe exacerbation (requiring hospitalization or an emergency medical care visit), within the past 12 months, and (3A) Member is currently receiving maintenance inhaled triple therapy (i.e., inhaled corticosteroid [ICS], long-acting

muscarinic antagonist [LAMA], and long-acting beta2-agonist [LABA]), or (3B) Member is currently receiving a LAMA and LABA, and has a contraindication to ICS, and (4) Dose does not exceed 100 mg every 4 weeks. For Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP): (1) a 56-day trial of one topical nasal corticosteroid, and (2) no concurrent use with another systemic biologic or targeted small molecules (e.g. JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. COC: Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **NUEDEXTA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

NUEDEXTA

## **EXCLUSION CRITERIA**

Not approved if the patient has any of the following: concomitant use with quinine, quinidine, or mefloquine, history of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions, known hypersensitivity to dextromethorphan, use with an MAOI or within 14 days of stopping an MAOI, prolonged qt interval, congenital long qt syndrome, history suggestive of torsades de pointes, or heart failure, complete av block without implanted pacemaker, or patients at high risk of complete at block, concomitant use with drugs that both prolong qt interval and are metabolized by cyp2d6 (e.g., thioridazine, pimozide).

## **REQUIRED MEDICAL INFORMATION**

Diagnosis of PBA and diagnostic test results supporting the dx of PBA such as center of neurology study-lability scale (cns-ls) result.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Neurology

## **COVERAGE DURATION**

Initial: 3 months. Continuation: 1 year

## **OTHER CRITERIA**

For re-authorization, the following are needed: documentation of improvement in response to therapy based on cns-ls score after 90 days of treatment and documentation of ongoing CBC, LFT and cardiac monitoring.

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# NURTEC

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

NURTEC ODT

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months, COC: 1 year

## OTHER CRITERIA

New therapy: Acute migraine treatment: trial of or contraindication to one triptan (e.g., sumatriptan, rizatriptan). Episodic migraine prevention: 1) no concurrent use with other C-GRP inhibitors for migraine prevention, and 2) trial of or contraindication to one of the following preventive migraine treatments: divalproex sodium, topiramate, propranolol, timolol. COC: Acute migraine treatment: 1) Improvement from baseline in a validated acute treatment patient-reported outcome questionnaire, or 2) therapy works consistently in majority of migraine attacks. Episodic migraine Prevention: 1) no concurrent use with other C-GRP inhibitors for migraine prevention, and 2) reduction in migraine or headache frequency, migraine severity, or migraine duration with therapy.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES



# **NYMALIZE**

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

NIMODIPINE 60 MG/20 ML SOLN, NYMALIZE 60 MG/ML ORAL SOLUTION

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

21 days

## **OTHER CRITERIA**

Clinical information provided that oral nimodipine capsules are not appropriate or otherwise contraindicated.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **OFEV**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

NINTEDANIB ESYLATE

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Clinical information provided to support the following: (1A) Confirmation of a diagnosis of IPF by ruling out history of environmental exposure known to cause pulmonary fibrosis or other causes of pulmonary fibrosis, (1B) Histological or radiographic evidence confirming the diagnosis of IPF, (1C) FVC between 50% and 90%, and (1D) Liver function tests, or (2A) a diagnosis of systemic sclerosis-associated interstitial lung disease confirmed by greater than 10% fibrosis on high-resolution computed tomography, (2B) a baseline FVC greater than or equal to 40%, and (2C) a baseline predicted diffusing capacity of the lung for carbon monoxide between 30 and 89%, or (3A) a diagnosis of chronic fibrosing interstitial lung disease confirmed by greater than 10% fibrosis on high-resolution computed tomography, (3B) a baseline FVC greater than or equal to 45%, (3C) a baseline predicted diffusing capacity of the lung for carbon monoxide between, 30 and 79%, and (3D) a progressive phenotype.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Pulmonology, or Rheumatology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# **OLUMIANT**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

OLUMIANT

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Initial- Rheumatoid Arthritis (RA): Prescribed by on in consultation with Rheumatology.

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

Initial- For RA: (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Orencia. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **OMVOH**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

OMVOH 200 MG/2 ML SYRINGE, OMVOH 300 MG DOSE - 2 SYRINGES, OMVOH 200 MG/2 ML PEN, OMVOH 300 MG DOSE - 2 PENS

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

### **OTHER CRITERIA**

Initial: For Ulcerative Colitis (UC)- (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Skyrizi, Tremfya, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for UC. For Crohns Disease (CD): (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Rinvoq, Skyrizi, Tremfya, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use with another systemic biologic or targeted small molecule for CD. COC: Physician attestation that the patient continues to benefit from the medication.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES



## **ONAPGO**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ONAPGO

### **EXCLUSION CRITERIA**

(1) Concurrently using any of the following medications not recommended by the manufacturer: 5HT-3 antagonists, including antiemetics (e.g., ondansetron, granisetron, dolasetron, palonosetron) or alosetron. Excluded under Part D if meets coverage criteria under Part B.

### **REQUIRED MEDICAL INFORMATION**

New: (1) The patient is established on levodopa treatment, and (2) The patient has motor symptoms that are currently uncontrolled (defined as an average "off" time of at least 3 hours per day).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Neurology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

NEW: (1) Medical justification specifying that adjunctive agents from at least TWO of the following different drug classes: (A) dopamine agonists, (B) catechol-O-methyltransferase (COMT) inhibitors, (C) monoamine oxidase type B (MAO-B) inhibitors, have been tried and failed, are contraindicated, or would not be medically appropriate for the patient. COC: Physician attestation that the patient continues to benefit from the medication.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES



## **OPHTHALMIC QUINOLONE**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

BESIFLOXACIN HCL, CILOXAN 0.3% OINTMENT

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 month

### **OTHER CRITERIA**

Medical justification specifying that two formulary alternatives without prior authorization restriction (ciprofloxacin, gatifloxacin, levofloxacin, or ofloxacin ophthalmic solution) have been tried and failed, are contraindicated, or are not medically appropriate for the patient, OR an ophthalmologist or optometrist has prescribed the medication or provided a consult to recommend the medication.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# OPIPZA

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

OPIPZA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medical justification specifying why Aripiprazole tablets and Aripiprazole disintegrating tablets could not be used.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **OPSYNVI**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

OPSYNVI

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

(1) Documentation of PAH diagnosis based on right heart catheterization and (2) WHO functional class II-III symptoms

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Cardiology or Pulmonology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

New: Tried and failed ONE endothelin receptor antagonists (ERA) such as ambrisentan, bosentan or macitentan and ONE phosphodiesterase 5 inhibitor (PDE5I) such as sildenafil or tadalafil taken as single agents. Continuation: Documentation that the medication has been effective (i.e., member is stable on current dose and/or no evidence of disease progression).

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **ORAL ALLERGENS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

GRASTEK, ODACTRA

### **EXCLUSION CRITERIA**

Uncontrolled Asthma, Eosinophilic esophagitis

### **REQUIRED MEDICAL INFORMATION**

New: Clinical information documenting a diagnosis confirmed by one of the following: positive skin prick test OR In vitro testing showing positive pollen-specific IgE antibodies. COC: Documentation of response to therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Allergy/Immunology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

(1) Medical justification specifying that two of the following classes have been tried and failed, are contraindicated, or would not be medically appropriate for the patient: oral antihistamines (cetirizine, loratadine, desloratadine, or fexofenadine), intranasal antihistamines (azelastine), intranasal corticosteroids (fluticasone, flunisolide or triamcinolone) or leukotriene inhibitor (montelukast). (2) Clinical information indicating the member has an epinephrine auto-injector/syringe prescription.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **ORAL SUSPENSION**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

GLOPERBA, SUBVENITE 10 MG/ML SUSPENSION, TOPIRAMATE 25 MG/ML SOLUTION, VIGABATRIN 500 MG POWDER PACKT, VIGAFYDE, ZONISADE

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Medical justification specifying why oral tablet or capsule formulation cannot be used.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **ORAL SUSPENSION-PB**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

SEVELAMER 0.8 GM POWDER PACKET, SEVELAMER 2.4 GM POWDER PACKET

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Excluded under Part D if meets coverage criteria under Part B.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Medical justification specifying why oral tablet or capsule formulation cannot be used.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **ORAL VANCO**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

VANCOMYCIN HCL 125 MG CAPSULE

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Labs with culture and sensitivity information.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

2 weeks

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# ORENCIA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

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

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial- RA/PJIA/PSA: 6 months. AGVHD: 1 month. COC: 12 months.

## OTHER CRITERIA

Initial- For Rheumatoid Arthritis (RA): (1) previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug). Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PJIA. For Psoriatic Arthritis (PSA): (1) No concurrent use with another systemic biologic or targeted small molecule for PSA. COC: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **ORIAHNN**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ORIAHNN

## **EXCLUSION CRITERIA**

A diagnosis of osteoporosis defined as a history of fragility fracture or T-score less than or equal to 2.5 standard deviations at any site based upon bone mineral density (BMD) measurement by dual-energy x-ray absorptiometry (DXA)

## **REQUIRED MEDICAL INFORMATION**

BMD measurement within the past 3 months

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

1) Medical justification that hormonal contraceptives and tranexamic acid have been tried and failed, are contraindicated, or would not be medically appropriate for the patient. 2) The cumulative approval duration is limited to a total 24 months in a patients lifetime.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **ORLADEYO**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ORLADEYO 110 MG CAPSULE, ORLADEYO 150 MG CAPSULE

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

New: (1) Documentation of HAE confirmed by lab work (HAE I: low C4 level AND low C1-INH antigenic level, HAE II: low C4 level AND normal or elevated C1-INH antigenic level AND low C1-INH function level, HAE III: low C4 level AND normal C1-INH antigenic level AND normal C1-INH function level AND documentation of a family history of HA or FXII mutation).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

6 months

### **OTHER CRITERIA**

Member is not receiving medications that can worsen the severity or frequency of angioedema episodes (estrogen-containing products, angiotensin-converting enzyme [ACE] inhibitors, others). Medical justification specifying that the member has a contraindication or intolerance to Haegarda. COC: (1) documentation or record of disease state improvement (such as decrease in the number, severity, and/or duration of the acute HAE attacks) within the last 6 months and (2) member is receiving only one agent for HAE attacks.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# OTEZLA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

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

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- For Mild Plaque psoriasis (PSO): One of the following: (1) psoriasis involving less than 3% of body surface area, (2) Static physician global assessment (SPGA) score of 2, or (3) Psoriasis area and severity index (PASI) score of 2 to 9. For Moderate to severe PSO: psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

For Psoriatic Arthritis (PSA): Prescribed by or in consultation with Dermatology or Rheumatology. PSO: Prescribed by or in consultation with a Dermatology. Behcets disease: Prescribed by or in consultation with a Rheumatology.

## COVERAGE DURATION

Initial: 6 months. COC: 1 year.

## OTHER CRITERIA

Initial- For PSA: (1) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSA. For mild PSO: (1) Trial of or contraindication to one conventional systemic agent (e.g., methotrexate, acitretin, cyclosporine) or one conventional topical agent (e.g., PUVA, UVB, topical corticosteroid). For moderate to severe PSO: (1) One of the following: (i) trial of at least a 3 month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus), or PUVA (phototherapy) for the treatment of PSO, (ii) Contraindication or intolerance to both immunosuppressant and PUVA therapy, or (iii) Patient is switching from a different biologic, PDE-

4 inhibitor, or JAK inhibitor for PSO, and (2) No concurrent use with another systemic biologic or targeted small molecule for PSO. For Behcets disease: (1) Patient has oral ulcers, or a history of recurrent oral ulcers based on clinical symptoms, and (2) Trial of or contraindication to one or more conservative treatment (e.g., colchicine, topical corticosteroid, oral corticosteroid). COC: Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

## **OXYBATE SALTS**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

SODIUM OXYBATE, XYWAV

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For Narcolepsy: results of a sleep study supporting the diagnosis and dose does not exceed FDA label maximum.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

If the patient is receiving concomitant sedatives (ramelteon, zaleplon, zolpidem) or benzodiazepines (alprazolam, chlordiazepoxide, clobazam, clonazepam, diazepam, estazolam, flurazepam, lorazepam, oxazepam, quazepam, temazepam, triazolam), justification as to why both agents are medically necessary.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **PACRITINIB**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

VONJO

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

New: Labs showing platelet counts less than 50,000. COC: Clinical documentation of continued benefit

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Hematology/Oncology

### **COVERAGE DURATION**

Initial: 6 months. COC: 1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# PAH

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

ADEMPAS, ALYQ, AMBRISENTAN, BOSENTAN, OPSUMIT, ORENITRAM ER, ORENITRAM MONTH 1 TITRATION KT, ORENITRAM MONTH 2 TITRATION KT, ORENITRAM MONTH 3 TITRATION KT, SILDENAFIL, SILDENAFIL 10 MG/ML ORAL SUSP, SILDENAFIL 20 MG TABLET, TADALAFIL 20MG TABLET (ADCIRCA GENERIC), TADLIQ

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

FDA approved functional class (WHO Group or NYHA class)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

For new requests: The diagnosis of PAH (pulmonary arterial hypertension) is confirmed by right heart catheterization, the pulmonary hypertension has progressed despite surgical treatment and/or maximal medical treatment of the underlying condition, and the medication used for treatment is consistent with its FDA approved functional class. For continuation of therapy: Physician attestation that the patient has experienced an improvement or slowing of disease progression. For initiation of combination therapy with 3 agents: Patient is refractory or poorly responsive to 2-drug combination therapy and the 3 agents must have different mechanisms of action.

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**  
YES

# **PALBOCICLIB**

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

IBRANCE 100 MG TABLET, IBRANCE 125 MG CAPSULE, IBRANCE 125 MG TABLET, IBRANCE 75 MG TABLET

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

The patient has not experienced disease progression following prior CDK inhibitor therapy.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **PALYNZIQ**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

PALYNZIQ

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

New: Baseline labs showing blood phenylalanine level is greater than 600 micromole/L within the past 30 days. Continuation: documentation of reduced phenylalanine levels from baseline.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Medical justification that Kuvan has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **PANCREATIC ENZYME**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

CREON, PANCREAZE, PERTZYE, VIOKACE, ZENPEP

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Test result confirming diagnosis such as one of the following: (1) Fecal elastase-1 less than 200mcg elastase/g fecal material. (2) Secretin tradition test result shows peak bicarbonate concentration less than 80mEq/L, (3) Secretin endoscopic test result shows peak bicarbonate concentration less than 80 mEq/L for the 1-hour method or less than 75 mEq/L for the shortened test, or (4) Fecal fat excretion greater than 7% of fat intake in 72-hour stool test.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **PARP INHIBITOR**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

AKEEGA, LYNPARZA, RUBRACA

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Hematology/Oncology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

The member has a deleterious or suspected deleterious BRCA mutation (as detected by an FDA approved test), or clinical information provided to support use consistent with FDA-approved labeling.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **PART D**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ALOSETRON HCL, ARALAST NP, BETAINE ANHYDROUS, BRIVARACETAM 100 MG TABLET, BRIVARACETAM 10 MG/ML ORAL SOL, BRIVARACETAM 10 MG TABLET, BRIVARACETAM 25 MG TABLET, BRIVARACETAM 50 MG TABLET, BRIVARACETAM 75 MG TABLET, CALCIPOTRIENE 0.005% CREAM, CALCIPOTRIENE 0.005% OINTMENT, CALCIPOTRIENE 0.005% SOLUTION, CINRYZE, CLOBAZAM, CROTAN, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG TABLET, DESVENLAFAXINE ER, DIAZOXIDE, DICHLORPHENAMIDE, DIHYDROERGOTAMINE 4 MG/ML SPRY, ELMIRON, EMSAM, FINTEPLA, FLUCYTOSINE, GARDASIL 9, GLASSIA, ICATIBANT, L-GLUTAMINE 5 GRAM POWDER PKT, NUPLAZID, OCTREOTIDE 1,000 MCG/5 ML VIAL, OCTREOTIDE 1,000 MCG/ML VIAL, OCTREOTIDE 5,000 MCG/5 ML VIAL, OCTREOTIDE ACET 0.05 MG/ML VL, OCTREOTIDE ACET 100 MCG/ML AMP, OCTREOTIDE ACET 100 MCG/ML VL, OCTREOTIDE ACET 200 MCG/ML VL, OCTREOTIDE ACET 500 MCG/ML AMP, OCTREOTIDE ACET 500 MCG/ML VL, OCTREOTIDE ACET 50 MCG/ML AMP, OCTREOTIDE ACET 50 MCG/ML VIAL, ORKAMBI, ORMALVI, PARICALCITOL 1 MCG CAPSULE, PARICALCITOL 2 MCG CAPSULE, PARICALCITOL 4 MCG CAPSULE, PHENOXYBENZAMINE HCL, PIRFENIDONE, PROLASTIN C, PRURADIK, PYRIMETHAMINE, RECOMBIVAX HB 10 MCG/ML VIAL, RUFINAMIDE, SAJAZIR, SIRTURO, SYMPAZAN, TRIENTINE HCL 250 MG CAPSULE, UPTRAVI 1,000 MCG TABLET, UPTRAVI 1,200 MCG TABLET, UPTRAVI 1,400 MCG TABLET, UPTRAVI 1,600 MCG TABLET, UPTRAVI 200 MCG TABLET, UPTRAVI 400 MCG TABLET, UPTRAVI 600 MCG TABLET, UPTRAVI 800 MCG TABLET, ZEMAIRA

### **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

**PREREQUISITE THERAPY REQUIRED**

N/A

## **PART D 3 MONTH**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

CYSTARAN, TOBI PODHALER

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **PART D 3 MONTH-E**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

CLINIMIX 4.25%-10% SOLUTION, CLINIMIX 4.25%-5% SOLUTION, CLINIMIX 5%-15% SOLUTION, CLINIMIX 5%-20% SOLUTION, CLINIMIX E 2.75%-5% SOLUTION, CLINIMIX E 4.25%-10% SOLUTION, CLINIMIX E 4.25%-5% SOLUTION, CLINIMIX E 5%-15% SOLUTION, CLINIMIX E 5%-20% SOLUTION, CLINISOL, CLINOLIPID, INTRALIPID, NUTRILIPID, PLENAMINE, PREMASOL, PROSOL, TRAVASOL, TROPHAMINE

### **EXCLUSION CRITERIA**

Excluded under Part D if meets coverage criteria under Part B.

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **PART D-E**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DRONABINOL 10 MG CAPSULE, DRONABINOL 2.5 MG CAPSULE, DRONABINOL 5 MG CAPSULE, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, HEPLISAV-B, RECOMBIVAX HB 10 MCG/ML SYR, RECOMBIVAX HB 40 MCG/ML VIAL, RECOMBIVAX HB 5 MCG/0.5 ML SYR, RECOMBIVAX HB 5 MCG/0.5 ML VL

### **EXCLUSION CRITERIA**

Excluded under Part D if meets coverage criteria under Part B.

### **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

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **PART D VS PART B**

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### **MEDICATION(S)**

ASTAGRAF XL, AZASAN, AZATHIOPRINE, CELLCEPT 200 MG/ML ORAL SUSP, CELLCEPT 250 MG CAPSULE, CELLCEPT 500 MG TABLET, CINACALCET HCL, CYCLOSPORINE 100 MG CAPSULE, CYCLOSPORINE 25 MG CAPSULE, CYCLOSPORINE MODIFIED, EVEROLIMUS 0.25 MG TABLET, EVEROLIMUS 0.5 MG TABLET, EVEROLIMUS 0.75 MG TABLET, EVEROLIMUS 1 MG TABLET, GENGRAF 100 MG CAPSULE, GENGRAF 25 MG CAPSULE, MYCOPHENOLATE 200 MG/ML SUSP, MYCOPHENOLATE 250 MG CAPSULE, MYCOPHENOLATE 500 MG TABLET, MYCOPHENOLIC ACID, MYFORTIC, MYHIBBIN, NEORAL, PROGRAF 0.2 MG GRANULE PACKET, PROGRAF 0.5 MG CAPSULE, PROGRAF 1 MG CAPSULE, PROGRAF 1 MG GRANULE PACKET, PROGRAF 5 MG CAPSULE, RAPAMUNE 1 MG TABLET, RAPAMUNE 2 MG TABLET, SANDIMMUNE 100 MG CAPSULE, SANDIMMUNE 25 MG CAPSULE, SIROLIMUS, 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), ZORTRESS

### **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.

# PCSK9

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

REPATHA SURECLICK, REPATHA SYRINGE

## EXCLUSION CRITERIA

Concurrent use with another PCSK9 agent (Praluent, Repatha) or a lipotropic agent (Juxtapid, Kynamro).

## REQUIRED MEDICAL INFORMATION

For Homozygous Familial Hypercholesterolemia (HoFH), confirmation of the diagnosis by LDLR DNA Sequence Analysis, LDLR Deletion/Duplication Analysis (only if the Sequence Analysis is negative), APOB and PCSK9 testing (if both of the above tests are negative but a strong clinical picture exists), or diagnosis by clinical criteria (LDL-C is greater than 560 mg/dl, LDL-C is greater than 400 mg/dl with xanthomas or aortic valve disease before 20 years of age, or LDL-C greater than or equal to 400 mg/dl with 1 or both parents diagnosed with FH). For Heterozygous Familial Hypercholesterolemia (HeFH), an adult with a LDL-C level suggestive of a diagnosis of heterozygous familial hypercholesterolemia (i.e. greater than 190 mg/dL for an adults, or greater than 130 mg/dL for pediatrics ). For Primary Hyperlipidemia, documented LDL-C must be 70mg/dL or higher while on the maximally tolerated statin therapy (unless contraindicated) or provide a medical justification as to why statin therapy would not be medically appropriate (e.g., statin intolerance).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

For all treatable medical conditions, must currently take high-intensity statin. If there has been a previous trial/failure of either atorvastatin or rosuvastatin, then must currently take maximally tolerated dose of any statin or provide a prescriber attestation of statin-intolerance. For continuation of therapy,

criteria have been satisfied AND there is confirmation of LDL reduction.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# PEGASYS

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

PEGASYS

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

HCV RNA level within past 6 months.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

48 weeks.

## OTHER CRITERIA

For requests for use of peginterferon as part of a combination regimen with other Hepatitis C virus (HCV) antiviral drugs: trial with preferred formulary alternative ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, or Mavyret where the regimen is listed as an acceptable regimen for the specific genotype per AASLD/IDSA guidance. No approval for requests where provider attests that patient has life expectancy less than 12 months due to non-liver related comorbid conditions (per AASLD/IDSA treatment guideline recommendation).

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **PERSERIS**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

PERSERIS, PERSERIS ER 90 MG SYRINGE KIT

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Psychiatry

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medical documentation establishing tolerability with oral risperidone before starting Perseris.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **PHOSBINDER**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

CALCIUM ACETATE 667 MG CAPSULE, CALCIUM ACETATE 667 MG GELCAP, SEVELAMER CARBONATE 800 MG TAB, SEVELAMER HCL

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Excluded under Part D if meets coverage criteria under Part B.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **PLOZASIRAN**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

REDEMPLO

## **EXCLUSION CRITERIA**

(1) Under 18 years of age.

## **REQUIRED MEDICAL INFORMATION**

PENDING CMS APPROVAL

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with Endocrinology, Gastroenterology, or Lipidology.

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

Initial: medical justification that Tryngolza has been tried and failed or would not be medically appropriate for the patient. COC: documentation supporting positive clinical response (such as a reduction in TG level from baseline or reduction in acute pancreatitis episodes).

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **POLYPHARMACY ANTIDEPRESSANTS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

AMITRIPTYLINE HCL, CLOMIPRAMINE HCL, DESIPRAMINE HCL, DOXEPIN 100 MG CAPSULE, DOXEPIN 10 MG CAPSULE, DOXEPIN 10 MG/ML ORAL CONC, DOXEPIN 150 MG CAPSULE, DOXEPIN 25 MG CAPSULE, DOXEPIN 50 MG CAPSULE, DOXEPIN 75 MG CAPSULE, IMIPRAMINE HCL, PAROXETINE HCL, PERPHENAZINE-AMITRIPTYLINE

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Prescriber must acknowledge that medication benefits outweigh potential risks in patients 65 years of age or older.

### **AGE RESTRICTION**

PA required for enrollees age 65 and over. No PA required for enrollees under age 65.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Approved until end of plan year.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **POLYPHARMACY OTHER**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

CYCLOBENZAPRINE 10 MG TABLET, CYCLOBENZAPRINE 5 MG TABLET, CYPROHEPTADINE HCL, DICYCLOMINE 10 MG/5 ML SOLN, DICYCLOMINE 10 MG CAPSULE, DICYCLOMINE 20 MG TABLET, DIPHENOXYLATE-ATROPINE, HYDROXYZINE 2 MG/ML ORAL SOLUTION, HYDROXYZINE 10 MG/5 ML SOLN, HYDROXYZINE 50 MG/25 ML CUP, HYDROXYZINE HCL 10 MG TABLET, HYDROXYZINE HCL 25 MG TABLET, HYDROXYZINE HCL 50 MG TABLET, HYDROXYZINE PAMOATE, ORPHENADRINE CITRATE ER, PROMETHAZINE 12.5 MG/10 ML CUP, PROMETHAZINE 12.5 MG TABLET, 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, SCOPOLAMINE

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Prescriber must acknowledge that medication benefits outweigh potential risks in patients 65 years of age or older.

### **AGE RESTRICTION**

PA required for enrollees age 65 and over. No PA required for enrollees under age 65.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Approved until end of plan year.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

## **POLYPHARMACY SLEEP**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ESZOPICLONE, OXAZEPAM, TEMAZEPAM 15 MG CAPSULE, TEMAZEPAM 30 MG CAPSULE, TRIAZOLAM, ZALEPLON, ZOLPIDEM TARTRATE 10 MG TABLET, ZOLPIDEM TARTRATE 5 MG TABLET, ZOLPIDEM TARTRATE ER

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Prescriber must acknowledge that medication benefits outweigh potential risks in patients 65 years of age or older.

### **AGE RESTRICTION**

PA required for enrollees age 65 and over. No PA required for enrollees under age 65.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Approved until end of plan year.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **PONVORY**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

PONVORY

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Trial of or contraindication to ONE sphingoside-1-phosphate receptor modulator and ONE other agent indicated for treatment of multiple sclerosis.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# PREVYMIS

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

PREVYMIS 240 MG TABLET, PREVYMIS 480 MG TABLET

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For is allogeneic hematopoietic stem cell transplant (HSCT), therapy will be initiated between day 0 and day 28 post-transplantation. For kidney transplant, therapy will be initiated between day 0 and day 7 post-transplantation. For continuation of treatment beyond 200 days, medical justification is required.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

6 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

## **PROGESTINS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

CRINONE

### **EXCLUSION CRITERIA**

Infertility treatment.

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Maximum recommended daily dose.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# **PROLIA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

PROLIA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For NEW treatment of osteoporosis: (1) BMD T-Score of less than or equal to -2.5 AND intolerance to ONE oral bisphosphonate OR IV zoledronic acid OR (2) history of fracture plus one or more risk factors for osteoporotic fracture. For NEW treatment of bone loss: has one or more risk factors for osteoporotic fracture and evidence of concurrent androgen deprivation therapy for prostate cancer OR adjuvant aromatase inhibitor therapy for breast cancer. Risk factors for fracture may include but are not limited to: (glucocorticoid daily dosage equivalent to 5 mg or greater of prednisone for at least 3 months, low body weight, smoking, alcohol intake of 3 or more drinks/day, rheumatoid arthritis, hypogonadism or premature ovarian failure, chronic liver disease or inflammatory bowel disease).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES



# PROMACTA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

ELTROMBOPAG OLAMINE

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For thrombocytopenia with persistent or chronic ITP New: (1) clinical information showing inadequate response or intolerant to corticosteroids, immunoglobulins or has undergone splenectomy and (2) platelet count at baseline is less than 30,000 platelets/microliter or platelet count at baseline is less than 50,000 platelets/microliter and patient has an increased risk for bleeding. For thrombocytopenia with chronic hepatitis C New: (1) patient will be receiving interferon-based therapy for chronic hepatitis C and (2) platelet count at baseline is less than 75,000 platelets/microliter. For aplastic anemia New: (1) clinical information showing inadequate response to immunosuppressive therapy or patient will be using eltrombopag with standard immunosuppressive therapy and (2) platelet count at baseline is less than 30,000 platelets/microliter (3) baseline labs for hemoglobin level and absolute neutrophil count.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

ITP or Aplastic Anemia: hematologist or oncologist. Chronic hepatitis: gastroenterologist, hepatologist or specialist in infectious disease.

## COVERAGE DURATION

ITP or Aplastic Anemia: 6 months. Chronic hepatitis C: 1 year

## OTHER CRITERIA

For thrombocytopenia with persistent or chronic ITP COC: clinical information documenting beneficial response by increased platelet counts, maintenance of platelet counts or decreased frequency of bleeding episodes. For thrombocytopenia with chronic hepatitis C COC: (1) clinical information documenting positive clinical response and (2) patient continues to be on antiviral interferon therapy for chronic hepatitis C. For aplastic anemia COC: clinical information documenting a positive clinical

response such as increased platelet counts, reduction in blood transfusions, increase in hemoglobin and/or increase in absolute neutrophil count.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

## **PTH ANALOG**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

BONSITY, TERIPARATIDE, TYMLOS

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

BMD (bone mineral density) measurements or fracture documentation.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Patient has one of the following: (A) Has been refractory to a trial of an oral bisphosphonate therapy OR (B) Intolerance or contraindications to oral bisphosphonate as defined by having at least one of the following: 1. Hypersensitivity to TWO oral bisphosphonates (one of which must be alendronate) 2. Inability to sit or stand upright for at least 30 minutes, 3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.). 4. Uncorrected hypocalcemia. 5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **PYRUKYND**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

PYRUKYND 20 MG TABLET, PYRUKYND 50 MG TABLET, PYRUKYND 5 MG TABLET, PYRUKYND

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: (1) Confirmation of pyruvate kinase deficiency, and (2A) Labs within past 30 days showing hemoglobin level 10 g/dL or less OR (2B) evidence of 6 or more blood transfusions within the previous 52 weeks. COC: Labs within past 30 days showing hemoglobin level increased from the baseline or evidence that the number of blood transfusions has decreased from baseline.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Hematology

## **COVERAGE DURATION**

New: 24 weeks, COC: 1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **QBREXA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

QBREXZA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: Hyperhidrosis Disease Severity Scale (HDSS) of 3 or 4. COC: Hyperhidrosis Disease Severity Scale (HDSS) of improved by 2 or more points.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **RADICAVA ORS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

RADICAVA ORS

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Neurology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Evidence that patient is currently on riluzole or has tried riluzole in the past.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **RALDESY**

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

RALDESY

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Clinical information provided that oral trazodone tablets are not appropriate or otherwise contraindicated.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# RAYALDEE

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

RAYALDEE

## EXCLUSION CRITERIA

Treatment of patients with secondary hyperparathyroidism with stage 5 chronic kidney disease or end-stage renal disease on dialysis.

## REQUIRED MEDICAL INFORMATION

Labs within past 30 days showing serum total 25-hydroxyvitamin D level is less than 30 ng/mL.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

Patient has had previous treatment, intolerance, or contraindication to a generic vitamin D analog (i.e., ergocalciferol, cholecalciferol, or calcitriol).

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **RECORLEV**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

RECORLEV

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: (1) Clinical information indicating pituitary surgery is not an option or has not been curative and (2) baseline 24-hour urinary free cortisol (UFC) level. COC: Labs within past 30 days documenting 24-hour urinary free cortisol (UFC) level has decreased from baseline.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Endocrinology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medical justification specifying that oral ketoconazole has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# RELISTOR

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

RELISTOR

## EXCLUSION CRITERIA

Individual has a known or suspected mechanical gastrointestinal obstruction.

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

Individual must have a previous trial of or insufficient response to a trial and inadequate response or intolerance to a preferred agent (Movantik/Amitiza) OR the preferred agent (Movantik/Amitiza) is not acceptable due to concomitant clinical situations, warnings or contraindications, such as but not limited to the following: (1) individual is taking a diphenylheptane opioid (e.g., methadone), where effectiveness has not been established in the treatment of OIC (Amitiza) OR (2) individual has disruption to the blood-brain barrier and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik) OR (3) individual is taking strong CYP3A4 inhibitors and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik).

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES



# REVCIVI

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

REVCIVI

## 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

## PREREQUISITE THERAPY REQUIRED

N/A

## **REZDIFFRA**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

REZDIFFRA

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Initial: confirmed diagnosis of MASH/NASH by (1) liver biopsy with evidence of stage F2 or F3 fibrosis and NAFLD Activity Score (NAS) of at least 4 OR (2) noninvasive tests including (2A) identification of liver steatosis by ultrasound, CT or MRI, and (2B) detection of advanced liver fibrosis via at least ONE of the following serological tests: (i) Fibrosis-4 (FIB-4) score 2.67 or more, or (ii) Enhanced Liver Fibrosis (ELF) test is 9.8 or more, AND (2C) ONE of the following noninvasive methods of imaging: (i) vibration-controlled transient elastography (VCTE) imaging of liver stiffness is 12kPa or more, or (ii) magnetic resonance elastography (MRE) of 3.63kPa or more. Noninvasive testing must be done within the past 12 months. COC: Clinical information or physician statement indicating there is no evidence of liver cirrhosis.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Hepatology, Gastroenterology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# REZUROCK

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

REZUROCK

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Medical justification specifying that at least 2 prior lines of systemic therapy have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# RIBAVIRIN

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

RIBAVIRIN 200 MG CAPSULE, RIBAVIRIN 200 MG TABLET

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

HCV RNA level (viral load), Hepatitis C Virus (HCV) genotype drawn within the past 6 months.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Hep C: Per current AASLD/IDSA guidance. Hep B: 16 wks. Other: 1 yr.

## **OTHER CRITERIA**

Criteria will be applied consistent with current AASLD/IDSA guidance

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **RIBOCICLIB**

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

KISQALI

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

The member is being treated in combination with (1) an aromatase therapy (e.g., anastrozole, letrozole, exemestane), or (2) fulvestrant (Faslodex).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Hematology/Oncology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Requires a trial of or contraindication to Verzenio or Ibrance where indications align.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **RIBOCICLIB-LETROZOLE**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

KISQALI FEMARA 400 MG CO-PACK, KISQALI FEMARA 600 MG CO-PACK

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Hematology/Oncology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Member has not had prior endocrine therapy.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

## **RINVOQ**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

RINVOQ, RINVOQ LQ

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Initial- For Non-radiographic axial spondyloarthritis (NR-AXSPA): 1) C-reactive protein levels above the upper limit of normal, or 2) sacroiliitis on MRI.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

### **OTHER CRITERIA**

Initial- For Rheumatoid Arthritis (RA): previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug). For Psoriatic Arthritis (PSA): No concurrent use of another small biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSA. For Polyarticular Juvenile Idiopathic Arthritis (PJIA): no concurrent use of another small biologic or targeted small molecule for PJIA. For Atopic Dermatitis (AD): 1) Atopic dermatitis covering at least 10% of body surface area or affecting the face, head, neck, hands, feet, groin, or intertriginous areas, 2) history of failure, contraindication, or reason(s) for intolerance to one of the following: topical corticosteroid, topical calcineurin inhibitors, topical PDE4 inhibitors, or topical JAK inhibitor, and 3) no concurrent use with another systemic biological for AD, or JAK inhibitor for any indication. For Crohns Disease (CD): no concurrent use with another systemic biologic or targeted small molecule for CD. For Ulcerative Colitis (UC): no concurrent use with another systemic biologic or targeted small molecule for UC. For Ankylosing Spondylitis (AS): 1) trial or contraindication to an NSAID, and 2) no concurrent use with another systemic biologic or targeted small molecule for AS. For NR-AXSPA: 1) trial or contraindication

to an NSAID, and 2) no concurrent use with another systemic biologic or targeted small molecule for NR-AXSPA. COC- For All Indications: Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# RIVFLOZA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

RIVFLOZA

## EXCLUSION CRITERIA

Concurrent use with Oxlumo (lumasiran).

## REQUIRED MEDICAL INFORMATION

New: (1A) Genetic test result showing a mutation in the alanine: glyoxylate aminotransferase (AGT or AGXT) gene or (1B) Liver biopsy confirming AGT enzyme deficiency, and (2) eGFR of greater than or equal to 30 mL/min/1.73 m<sup>2</sup>.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Nephrology, Genetics, or other healthcare provider who specializes in treating primary hyperoxaluria type 1 (PH1)

## COVERAGE DURATION

New: 6 months, COC: 1 year

## OTHER CRITERIA

COC: The patient has had a positive response to therapy (e.g., decrease or normalization in urinary and/or plasma oxalate levels, improvement in kidney function).

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# **RYDAPT**

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

RYDAPT

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Hematology/Oncology, Allergist

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

For Advanced Systemic Mastocytosis with KIT D816V mutation status negative/unknown, medical justification is required why Gleevec cannot be used.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# SAVELLA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

MILNACIPRAN HCL 100 MG TABLET, MILNACIPRAN HCL 12.5 MG TABLET, MILNACIPRAN HCL 25 MG TABLET, MILNACIPRAN HCL 50 MG TABLET, SAVELLA TITRATION PACK

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

For Fibromyalgia, individual had a trial of and insufficient response or intolerance to TWO of the following: (1) Cymbalta (duloxetine HCl) (2) Gabapentin (3) Tricyclic antidepressants (such as, amitriptyline, clomipramine, desipramine, nortriptyline), (4) Cyclobenzaprine OR (5) Fluoxetine.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **SIBEPRENIMAB**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

VOYXACT

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

PENDING CMS APPROVAL

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Nephrology

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

Medical justification that Vanrafia have been tried and failed or would not be medically appropriate for the patient.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **SIGNIFOR**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

SIGNIFOR

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Fasting plasma glucose, hemoglobin A1C, liver function tests, ECG, and gallbladder ultrasound.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Endocrinology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

For patients with Cushing's disease not due to pituitary tumor, medical justification is required.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **SILIQ**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

SILIQ

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For Plaque psoriasis (PSO): Psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

For PSO: Prescribed by or in consultation with a dermatologist.

### **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

### **OTHER CRITERIA**

Initial- For PSO: (1) Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Skyrizi, Tremfya, Otezla, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use of another small biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSO. COC- For PSO: Physician attestation that the patient continues to benefit from the medication.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## **SIMLANDI**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

SIMLANDI(CF) 20 MG/0.2 ML SYRG, SIMLANDI(CF) 40 MG/0.4 ML SYRG, SIMLANDI(CF) AUTOINJECTOR

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

New requests for Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

Initial: HS: 12 months, All other indications: 6 months. COC: 1 year.

### **OTHER CRITERIA**

Initial- For Rheumatoid arthritis (RA): (1) previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug). Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PJIA. For Psoriatic Arthritis (PSA): (1) No concurrent use with another systemic biologic or targeted small molecule for PSA. For Ankylosing Spondylitis (AS): (1) trial of or contraindication to an NSAID, and (2) No concurrent use with another systemic biologic or targeted small molecule for AS. For PSO: (1) One of the following: (i) trial of at least a 3 month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus), or PUVA (phototherapy) for the treatment of PSO, (ii) Contraindication or intolerance to both immunosuppressant and PUVA therapy, or (iii) Patient is switching from a different biologic, PDE-4 inhibitor, or JAK inhibitor for PSO, and (2) No concurrent use with another systemic biologic or targeted small molecule for PSO. For Uveitis: no isolated anterior uveitis. For Crohns Disease (CD): (1) No concurrent use with another systemic biologic or targeted small molecule for CD.

For Ulcerative Colitis (UC): (1) No concurrent use with another systemic biologic or targeted small molecule for UC. For Hidradenitis Suppurativa (HS): (1) No concurrent use with another systemic biologic or targeted small molecule for HS. For COC- All indications: Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **SIMPONI**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

SIMPONI

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

Initial- For Rheumatoid Arthritis (RA): For Rheumatoid Arthritis (RA): One of the following: (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Orencia. For Psoriatic Arthritis (PSA): (1) Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Skyrizi, Tremfya, Orencia, Otezla, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use of another small biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSA. For Ankylosing Spondylitis (AS): (1) Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Xeljanz IR/XR, Rinvoq, and (2) No concurrent use of another small biologic or targeted small molecule for AS. For Ulcerative Colitis (UC): Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Skyrizi, Tremfya, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use of another small biologic or targeted small molecule for UC. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# SKYCLARYS

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

SKYCLARYS

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

(1) Confirmed presence of a mutation in the frataxin (FXN) gene.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Neurology, Geneticist

## COVERAGE DURATION

1 year

## OTHER CRITERIA

COC: Documentation of positive clinical response to Skyclarys therapy.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# SKYRIZI

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

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

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- For Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. COC: 1 year.

## OTHER CRITERIA

Initial- For PSO: (1) One of the following: (i) trial of at least a 3 month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus), or PUVA (phototherapy) for the treatment of PSO, (ii) Contraindication or intolerance to both immunosuppressant and PUVA therapy, or (iii) Patient is switching from a different biologic, PDE-4 inhibitor, or JAK inhibitor for PSO, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSO. For Psoriatic Arthritis (PSA): No concurrent use of another small biologic or targeted small molecule for PSA. For Crohns Disease (CD): (1) No concurrent use of another small biologic or targeted small molecule for CD. For Ulcerative Colitis (UC): (1) No concurrent use of another small biologic or targeted small molecule for UC. COC- Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**  
YES

## **SNRI**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

EXXUA, FETZIMA, TRINTELLIX, VILAZODONE HCL

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation or record of the symptoms and duration of the episode. For treatment of depression, the depression rating scale and score are required.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Medical justification specifying that two of the formulary alternatives (citalopram, desvenlafaxine, escitalopram, fluoxetine, paroxetine, sertraline or venlafaxine) have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# SOHONOS

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

SOHONOS

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

New: (1) results of genetic test confirming mutation in activin A type 1 receptor (ACVR1) consistent with fibrodysplasia ossificans progressive (FOP) and (2) presence of heterotopic ossification (HO) as confirmed by radiologic testing such as X-ray, computed tomography (CT), magnetic resonance imaging (MRI) or positron emission tomography (PET) scans. COC: documentation of positive clinical response to therapy.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Endocrinologist, Rheumatologist, Orthopedist, Geneticist or primary provider in consult with an FOP specialist

## COVERAGE DURATION

1 year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# SOLOSEC

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

SOLOSEC

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 day

## OTHER CRITERIA

Medical justification specifying that tinidazole, clindamycin or metronidazole have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **SORIATANE**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ACITRETIN

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

COC: Physician attestation that the patient continues to benefit from the medication. New requests for plaque psoriasis: Psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a dermatologist.

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **SOTYKTU**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

SOTYKTU

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For Plaque psoriasis (PSO): Psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Psoriasis: prescribed by or in consultation with a dermatologist.

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

Initial- For PSO: Trial of or contraindication to two of the following preferred agents (where ages align): Cosentyx, Humira, Simlandi, Skyrizi, Tremfya, Otezla, Selarsdi, Steqeyma, Yesintek. COC- For PSO: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# SOVALDI

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

SOVALDI

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Confirmation of hepatitis C genotype. Previous hepatitis C treatment history (if any). Other medications that will be used with current AASLD/IDSA protocol (if any). Presence or absence of cirrhosis.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

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

## OTHER CRITERIA

Criteria will be applied consistent with current AASLD/IDSA guidance. Trial with preferred formulary alternative ledipasvir/sofosbuvir, sofosbuvir/velpatasvir, or Mavyret where that regimen is listed as an acceptable regimen for the specific genotype per AASLD/IDSA guidance. For patients on Sovaldi plus Daklinza regimens there will be no approvals for concurrent use of any of these (contraindicated or not recommended by the manufacturer) medications: amiodarone, carbamazepine, phenytoin, or rifampin. Requests for Sovaldi in combination with Daklinza will require that the patient also meets all criteria for Daklinza.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES



# **SPEVIGO**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

SPEVIGO 150 MG/ML SYRINGE, SPEVIGO 300 MG/2 ML SYRINGE

## **EXCLUSION CRITERIA**

(1) SAPHO syndrome, (2) Weight less than 40kg

## **REQUIRED MEDICAL INFORMATION**

(1) No current active infection, (2) Weight

## **AGE RESTRICTION**

12 years of age or older

## **PRESCRIBER RESTRICTION**

Generalized pustular psoriasis (GPP): Prescribed by or in consultation with Dermatology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

GPP- New: (1) History of GPP defined by presence of sterile, macroscopically visible pustules on non-acral skin, and (2) No concurrent use with another systemic biologic or targeted small molecules (e.g. JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication. COC: (1) Documentation that the member continues to benefit from the medication, and (2) No concurrent use with another systemic biologic or targeted small molecules (e.g. JAK inhibitor, PDE-4 inhibitor) for an autoimmune indication.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# STELARA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

STELARA 45 MG/0.5 ML VIAL, USTEKINUMAB 45MG/0.5ML SYRINGE, USTEKINUMAB 45 MG/0.5 ML VIAL, USTEKINUMAB 90 MG/ML SYRINGE, USTEKINUMAB-AAUZ

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- For Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. COC: 1 year.

## OTHER CRITERIA

Initial- For PSO: (1) One of the following: (i) trial of at least a 3 month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus), or PUVA (phototherapy) for the treatment of PSO, (ii) Contraindication or intolerance to both immunosuppressant and PUVA therapy, or (iii) Patient is switching from a different biologic, PDE-4 inhibitor, or JAK inhibitor for PSO, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSO. For Psoriatic Arthritis (PSA): (1) No concurrent use of another small biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSA. For Crohns Disease (CD): (1) No concurrent use of another small biologic or targeted small molecule for CD. For Ulcerative Colitis (UC): (1) No concurrent use of another small biologic or targeted small molecule for UC. COC- Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **SYMDEKO**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

SYMDEKO

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: Baseline FEV1 and recent laboratory report within the past 90 days showing ALT, AST, and bilirubin levels are within normal range. Confirmed genetic testing for homozygous F508del mutation of the CFTR gene or a CFTR (cystic fibrosis transmembrane conductance regulator) gene mutation that is responsive to the Symdeko per package labeling. COC: Confirmation that member has improvement of symptoms (i.e., improved FEV1, weight gain, or decreased exacerbation). Recent laboratory report (within last 90 days) for ALT, AST, and bilirubin are within normal range.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# TABRECTA

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

TABRECTA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Hematology/Oncology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Documentation of tumor mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA approved test

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# TADALAFIL

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

TADALAFIL 2.5 MG TABLET, TADALAFIL 5 MG TABLET

## **EXCLUSION CRITERIA**

(1) Treatment of erectile/sexual dysfunction, (2) Concomitant use of nitrate-based drugs (nitroglycerin) for heart conditions.

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Urology

## **COVERAGE DURATION**

26 weeks.

## **OTHER CRITERIA**

For initial therapy: Clinical documentation indicates the patient has symptomatic BPH. For continued therapy: clinical documentation indicates a reduction in symptoms.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# TAKHZYRO

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

TAKHZYRO

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

(1) Documentation of HAE confirmed by lab work (HAE I: low C4 level AND low C1-INH antigenic level, HAE II: low C4 level AND normal or elevated C1-INH antigenic level AND low C1-INH function level, HAE III: low C4 level AND normal C1-INH antigenic level AND normal C1-INH function level AND documentation of a family history of HA or FXII mutation).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year.

## OTHER CRITERIA

Member is not receiving medications that can worsen the severity or frequency of angioedema episodes (estrogen-containing products, angiotensin-converting enzyme [ACE] inhibitors, others). Medical justification specifying that the member has a contraindication or intolerance to Haegarda. COC: (1) documentation or record of disease state improvement (such as decrease in the number, severity, and/or duration of the acute HAE attacks) within the last 6 months, and (2) member is receiving only one agent for HAE attacks.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# TALTZ

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

TALTZ 80 MG/ML AUTOINJECTOR, TALTZ 80 MG/ML AUTOINJECTOR, TALTZ 80 MG/ML AUTOINJECTOR, TALTZ 80 MG/ML SYRINGE, TALTZ SYRINGE

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- For Non-radiographic axial spondyloarthritis (NR-AXSPA): 1) C-reactive protein levels above the upper limit of normal, or 2) sacroiliitis on MRI. For Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. COC: 1 year.

## OTHER CRITERIA

Initial- For PSO: (1) Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Skyrizi, Tremfya, Otezla, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSO. For Psoriatic Arthritis (PSA): Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Skyrizi, Tremfya, Orencia, Otezla, Selarsdi, Steqeyma, Yesintek. For Ankylosing Spondylitis (AS): (1) Trial of or contraindication to two of the following preferred agents: Cosentyx, Humira, Simlandi, Xeljanz IR/XR, Rinvoq, and (2) No concurrent use of another small biologic or targeted small molecule for AS. For NR-AXSPA: (1) Trial of or contraindication to two of the following preferred agents: Cosentyx, Rinvoq, Cimzia, and (2) No concurrent use of another small biologic or targeted small molecule for NR-AXSPA. COC: Physician

attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# TARPEYO

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

TARPEYO

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

(1) Diagnosis of primary IgAN confirmed by biopsy, (2) Member is currently receiving therapy with an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB), and (3) Confirmation of proteinuria as evidenced by equal to or greater than 0.5 g/day or a UPCR equal to equal to or greater than 0.8 g/g.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Nephrology or Immunology

## COVERAGE DURATION

10 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# TAVALISSE

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## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

TAVALISSE

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

New: Platelet count less than 30,000mm<sup>3</sup>. COC: ALT, AST, and bilirubin (drawn within the last 90 days) less than 3x the upper limit of normal. Documentation of either (1) lab work indicating platelet count greater than 30,000mm<sup>3</sup> (drawn within last 90 days), or (2) medical document showing that the platelet count increased compared to baseline demonstrating efficacy (although member may need an increase in dose).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Hematology, Oncology

## COVERAGE DURATION

Initial: 3 months. COC: 6 months.

## OTHER CRITERIA

New: Medical justification specifying that a formulary alternative (corticosteroid [e.g., prednisone, dexamethasone], Promacta, or rituximab (Rituxan)) has been tried and failed, is contraindicated, or would not be medically appropriate for the patient, or that the patient has had a splenectomy.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# TAVNEOS

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

TAVNEOS

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Clinical information documenting (1) LFTs within past 60 days (2) history of trial and failure (disease relapse or disease remission failure) or a contraindication to treatment with rituximab OR cyclophosphamide, AND glucocorticoids (methylprednisolone or prednisone).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

Documentation of concomitant use with a standard immunosuppressive therapy (rituximab OR cyclophosphamide)

## PART B PREREQUISITE

YES

## PREREQUISITE THERAPY REQUIRED

YES

# **TEDUGLUTIDE**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

GATTEX 5 MG INJECTION, GATTEX 5 MG INJECTION

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Approval for continued therapy with Gattex requires a decrease of parenteral nutritional volume. Quantity limited to #1 vial per day.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **TEFAMIDIS**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

VYNDAMAX

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Cardiology

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# THALOMID

---

## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

THALOMID 100 MG CAPSULE, THALOMID 50 MG CAPSULE

## 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

## PREREQUISITE THERAPY REQUIRED

N/A

# TIGLUTIK

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

TIGLUTIK 50 MG/10 ML SUSP, TIGLUTIK 50 MG/10 ML SUSP

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Neurology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Evidence that patient has tried riluzole tablet in the past

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **TIOPRONIN**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

TIOPRONIN, VENXXIVA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: One of the following: (1) stone analysis positive for cystine, (2) urinalysis positive for pathognomonic hexagonal cystine crystals, (3) family history of cystinuria with a positive cyanide-nitroprusside screen, or (4) 24-hour urine collection with urinary cystine greater than 500. COC: Documentation of positive clinical response to therapy.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **TOPICAL ANTIHERPETIC**

---

### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ACYCLOVIR 5% CREAM, ACYCLOVIR 5% OINTMENT, PENCICLOVIR

### **EXCLUSION CRITERIA**

Herpes zoster.

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 month

### **OTHER CRITERIA**

Dose does not exceed FDA label maximum.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# TREMFYA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

TREMFYA 100 MG/ML SYRINGE, TREMFYA 200 MG/2 ML SYRINGE, TREMFYA 100 MG/ML PEN, TREMFYA PEN, TREMFYA PEN, TREMFYA PEN INDUCTION (2 PEN)

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- For Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. COC: 1 year.

## OTHER CRITERIA

Initial- For PSO: (1) One of the following: (i) trial of at least a 3 month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus), or PUVA (phototherapy) for the treatment of PSO, (ii) Contraindication or intolerance to both immunosuppressant and PUVA therapy, or (iii) Patient is switching from a different biologic, PDE-4 inhibitor, or JAK inhibitor for PSO, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSO. For Psoriatic Arthritis (PSA): (1) No concurrent use of another small biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSA. For Crohns Disease (CD): (1) No concurrent use of another small biologic or targeted small molecule for CD. For Ulcerative Colitis (UC): (1) No concurrent use of another small biologic or targeted small molecule for UC. COC- All indications: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **TRIKAFTA**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

TRIKAFTA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: (1) Baseline FEV1, weight/ BMI, and (2) Documentation confirming at least one F508del mutation in the CFTR or a CTFR gene responsive based on in vitro data. COC: (1) Information provided that member has had an improved clinical response as indicated by improvement in FEV1, reduced number of pulmonary exacerbations, or improvement in body mass index (BMI).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# TRYNGOLZA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

TRYNGOLZA

## EXCLUSION CRITERIA

Member under 18 years of age.

## REQUIRED MEDICAL INFORMATION

Initial: (1) confirmation of the diagnosis by genetic testing (biallelic pathogenic variants in FCS-causing genes [such as LPL, GPIHBP1, APOA5, APO2, LMF1, GPD1, CREB3L3]), (2) labs showing fasting triglycerides (TG) level of 880mg/dL or more, and (3) prescriber attestation that patient has received diet counseling.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

The medication is prescribed by or in consultation with Endocrinology, Gastroenterology, or Lipidology.

## COVERAGE DURATION

Initial: 6 months, COC: 1 year.

## OTHER CRITERIA

COC: documentation supporting positive clinical response (such as a reduction in TG level from baseline or reduction in acute pancreatitis episodes)

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# **TYENNE**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

TYENNE 162 MG/0.9 ML SYRINGE, TYENNE AUTOINJECTOR

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

Initial- For Rheumatoid Arthritis (RA): (1) Trial or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Orencia. For Polyarticular Juvenile Idiopathic Arthritis (PJIA): (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Orencia, Rinvoq, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PJIA. For Systemic Juvenile Idiopathic Arthritis (SJIA): (1) No concurrent use with another systemic biologic or targeted small molecule for SJIA.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **TYRVAYA**

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

TYRVAYA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation is provided indicating an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods: (a) Tear break-up time (less than 10 seconds) OR (b) Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes OR (c) Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes) OR (d) Fluorescein clearance test/tear function index OR (e) Tear osmolarity (indicating tear film instability) OR (f) Tear lactoferrin concentrations in the lacrimal gland (decreased).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medical justification that cyclosporine and Xiidra eye drops have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **TYVASO DPI**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

TYVASO DPI 16-32-48 MCG TITRAT, TYVASO DPI 16 MCG CARTRIDGE, TYVASO DPI 32-64 MCG MAINT KIT, TYVASO DPI 32 MCG CARTRIDGE, TYVASO DPI 48-64 MCG MAINT KIT, TYVASO DPI 48 MCG CARTRIDGE, TYVASO DPI 64 MCG CARTRIDGE, TYVASO DPI 80 MCG CARTRIDGE

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

New requests for group 1 PAH: Confirmation of PAH based on right heart catheterization with results showing (1) mean pulmonary arterial pressure (mPAP) of greater than 20 mmHg and (1B) pulmonary vascular resistance (PVR) of 3 Wood units or more and (3) pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less AND (1) a baseline 6-minute walk distance (6MWD) test result AND (2) Clinical information documenting patient has World Health Organization (WHO) or New York Heart Association (NYHA) Functional Class III to IV symptoms. Renewal for group 1 PAH: Documentation of either (1) improvement of baseline 6MWD or (2) patient is stable from baseline 6MWD and the WHO/NYHA functional class has improved or remained stable. New requests for group 3 PH-ILD: Confirmation of PH based on (1A) right heart catheterization (with results showing mean pulmonary arterial pressure (mPAP) of greater than 20 mmHg, pulmonary vascular resistance (PVR) of 3 Wood units or more, and pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less), or (1B) an appropriate noninvasive test, and (2) a baseline 6-minute walk distance (6MWD) test result. Renewal for group 3 PH: Documentation of improvement or stable from baseline 6MWD.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Cardiologist or pulmonologist

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

For group 1 PAH only: (1) Tried and Failed TWO of the following ORAL agents from different drug classes: endothelin receptor antagonists (ambrisentan, bosentan or Opsumit), phosphodiesterase 5 inhibitors (sildenafil or tadalafil), oral guanylate cyclase stimulator (Adempas) OR (2) Functional Class III symptoms and documented rapid progression or poor prognosis OR (3) Functional Class IV symptoms and has tried and failed or has contraindication to IV/SQ epoprostenol or treprostinil.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# **UBRELVY**

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

UBRELVY

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Initial: Medical justification specifying that TWO formulary anti-migraine drugs from different classes have been tried and failed are contraindicated, or would not be medically appropriate. Classes include: (1) Analgesics- acetaminophen, aspirin, naproxen, ibuprofen, diclofenac, and (2) Triptans- sumatriptan, rizatriptan/rizatriptan ODT, naratriptan, or zolmitriptan/zolmitriptan ODT. COC: Documentation of positive clinical response to therapy.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonists (i.e., Nurtec ODT)

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# UCERIS

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

BUDESONIDE 2 MG RECTAL FOAM

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

6 weeks

## OTHER CRITERIA

Patient has clinical information supporting: (1) Active, mild to moderate ulcerative colitis, and (2) Failure, contraindication, or intolerance to a one-month course of aminosalicylates (e.g., sulfasalazine, mesalamine).

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

## **UREA SPLITTING URINARY INFECTION**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

LITHOSTAT

### **EXCLUSION CRITERIA**

Pregnancy or SCr less than 20mL/min

### **REQUIRED MEDICAL INFORMATION**

SCr is required. For women, pregnancy status is required. For continuation of therapy, CBC with reticulocyte count, platelet count, and white cell count within the past 30 days is required.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

3 months

### **OTHER CRITERIA**

Medical justification which documents the plan for curative treatment with surgical removal of stones and antibiotic therapy. Or medical justification which documents why curative treatment is not appropriate.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# USTEKINUMAB

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

SELARSDI 45 MG/0.5 ML SYRINGE, SELARSDI 45 MG/0.5 ML VIAL, SELARSDI 90 MG/ML SYRINGE, STEQEYMA 45 MG/0.5 ML SYRINGE, STEQEYMA 45 MG/0.5 ML VIAL, STEQEYMA 90 MG/ML SYRINGE, YESINTEK 45 MG/0.5 ML SYRINGE, YESINTEK 45 MG/0.5 ML VIAL, YESINTEK 90 MG/ML SYRINGE

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- For Plaque psoriasis (PSO): Moderate to severe psoriasis involving greater than or equal to 3% of body surface area or psoriatic lesions affecting the hands, feet, face, scalp, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. COC: 1 year.

## OTHER CRITERIA

Initial- For PSO: (1) One of the following: (1A) trial of at least a 3 month trial of one oral immunosuppressant (cyclosporine, methotrexate, tacrolimus), or PUVA (phototherapy) for the treatment of PSO, (1B) Contraindication or intolerance to both immunosuppressant and PUVA therapy, or (1C) Patient is switching from a different biologic, PDE-4 inhibitor, or JAK inhibitor for PSO, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSO. For Psoriatic Arthritis (PSA): (1) No concurrent use of another small biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSA. For Crohns Disease (CD): (1) No concurrent use of another small biologic or targeted small molecule for CD. For Ulcerative Colitis (UC): (1) No concurrent use of another small biologic or targeted small molecule for UC. COC- Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# VALTOCO

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

VALTOCO

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Neurology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **VANRAFIA**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

VANRAFIA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Initial: (1) diagnosis confirmed by biopsy, (2) patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73 m<sup>2</sup>, and (3) patient is at high risk of disease progression, defined by meeting both of the following criteria: a) Patient has proteinuria greater than 1.0 g/day or a urine protein-to-creatinine ratio greater than or equal to 1.5 g/g, AND b) Patient has received the maximum or maximally tolerated dose of one Angiotensin converting enzyme (ACE) inhibitor (e.g. enalapril, lisinopril, perindopril, ramipril) or Angiotensin receptor blocker (ARB) (e.g. losartan, olmesartan, valsartan) for greater than or equal to 12 weeks prior to starting Vanrafia. COC: (1) diagnosis has been confirmed by biopsy, (2) the patient has had a response to therapy (i.e. reduction in proteinuria from baseline), and (3) the patient has an estimated glomerular filtration rate greater than or equal to 30 mL/min/1.73 m<sup>2</sup>.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Nephrology

## **COVERAGE DURATION**

Initial: 9 months. COC: 1 year.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**  
YES

# VELSIPITY

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

VELSIPITY

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial- UC: 6 months, COC: 12 months

## OTHER CRITERIA

Initial: For UC: (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Skyrizi, Tremfya, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for UC. COC: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **VENLAFAXINE BESYLATE**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

VENLAFAXINE BESYLATE ER

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Clinical information that member has been on at least 75 mg of another venlafaxine extended release product for at least 4 days.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Medical justification for why venlafaxine hcl extended release capsule or tablet could not be used.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# VEOZAH

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

VEOZAH

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Menopausal Vasomotor Symptoms (VMS): Initial- (1) Experiences 7 or more hot flashes per day, and (2) Medical justification that one hormonal therapy (such as estradiol transdermal patch, oral conjugated estrogens, micronized progesterone) has been tried and failed or are contraindicated, or would not be medically appropriate for the patient. COC- Reduction in VMS frequency or severity due to Veozah treatment.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# VERQUVO

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

VERQUVO

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

Heart Failure (HF)- Initial: Trial of or contraindication to (1) one agent from any of the following standard of care classes: A) ACE inhibitor, ARB, or ARNI, B) Beta blocker (i.e., bisoprolol, carvedilol, metoprolol succinate), or C) Aldosterone antagonist (i.e., spironolactone, eplerenone), and (2) one SGLT-2 inhibitors. Initial/COC: not concurrently taking Adempas, or PDE-5 inhibitors.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# VIBERZI

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

VIBERZI

## **EXCLUSION CRITERIA**

Concurrent use of Lotronex, opioids, or anticholinergic medications.

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Gastroenterology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **VIJOICE**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

VIJOICE

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Clinical information indicating (1) patient has at least one severe clinical manifestation of PROS (examples of severe clinical manifestations include excessive tissue growth, blood vessel malformations, scoliosis, vascular tumors, cardiac or renal manifestations, and those that require systemic treatment) AND (2) confirmation of PIK3CA mutation

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# VOCLOSPORIN

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

LUPKYNIS

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: Labs showing eGFR is 45ml/min/1.73m<sup>2</sup> or higher and BP is less than 165/105. COC:  
Documentation of positive clinical response to therapy.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Nephrologist

## **COVERAGE DURATION**

6 months

## **OTHER CRITERIA**

Clinical information showing member is using mycophenolate mofetil (MMF) and a corticosteroid concurrently with Lupkynis.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# VOQUEZNA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

VOQUEZNA DUAL PAK, VOQUEZNA TRIPLE PAK

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Diagnosis of H. Pylori

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

2 weeks

## OTHER CRITERIA

Trial of a generic, guideline recommended, first-line regimen for H. pylori infection such as clarithromycin triple therapy (proton pump inhibitor (PPI) + clarithromycin + amoxicillin or metronidazole) or bismuth quadruple therapy (PPI + bismuth subcitrate or subsalicylate + tetracycline + metronidazole).

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# VOSEVI

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

VOSEVI

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

HCV RNA level within past 6 months

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

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

## OTHER CRITERIA

Trial with preferred formulary alternative Mavyret where Mavyret regimen is listed as an acceptable regimen for the specific genotype per AASLD/IDSA guidance. Patient is not concurrently taking any of the following medications not recommended by the manufacturer: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, cyclosporine, pitavastatin, pravastatin (doses above 40mg), rosuvastatin, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, or HIV regimen that contains efavirenz, atazanavir, lopinavir or tipranavir/ritonavir.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# VOWST

---

## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

VOWST

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

(1) The diagnosis of CDI has been confirmed by a positive stool test for C. difficile toxin.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Gastroenterology, or Infectious Disease Specialist.

## COVERAGE DURATION

3 days.

## OTHER CRITERIA

(1) Patient has had one or more recurrence(s) of CDI following an initial episode of CDI, and (2) Patient has completed at least 10 days of one of the following antibiotic therapies (oral vancomycin, Dificid) for rCDI 2 to 4 days prior to initiating Vowst.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# VOYDEYA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

VOYDEYA

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial: (1) Paroxysmal nocturnal hemoglobinuria diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-AP) demonstrated by: 1A) At least 5% PNH cells, or 1B) At least 21% GPI-AP polymorphonuclear cells, (2) Hemoglobin level of less than 10 g/dL, (3) Used with a C5 Complement inhibitor, and (4) No concurrent use with a C3 Complement inhibitor or Factor B inhibitor.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Hematology

## COVERAGE DURATION

Initial: 4 months. COC: 1 year.

## OTHER CRITERIA

COC: (1) Physician attestation that the patient continues to benefit from the medication, (2) Used with a C5 Complement inhibitor, and (3) No concurrent use with a C3 Complement inhibitor or Factor B inhibitor.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# VRAYLAR

---

## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

VRAYLAR 0.5 MG CAPSULE, VRAYLAR 0.75 MG CAPSULE, VRAYLAR 1.5 MG CAPSULE, VRAYLAR 3 MG CAPSULE, VRAYLAR 4.5 MG CAPSULE, VRAYLAR 6 MG CAPSULE

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

Medical justification that two formulary alternatives (Aripiprazole, Olanzapine, Paliperidone, Quetiapine, Risperidone, Ziprasidone, or Rexulti) have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# VTAMA

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

VTAMA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

For plaque psoriasis: Medical justification specifying why tazarotene and calcipotriene could not be used.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# VUITY

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

PILOCARPINE HCL 1.25% EYE DROP

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: physician statement for why corrective lenses could not be used. COC: physician statement documenting continued benefit with use and an improved vision related to reading performance

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Optometrist or Ophthalmologist

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

## **VYKAT XR**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

VYKAT XR

### **EXCLUSION CRITERIA**

Age less than 4 years old.

### **REQUIRED MEDICAL INFORMATION**

(1) Member has Prader-Willi Syndrome confirmed by genetic testing, and (2) Member has hyperphagia,.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with Endocrinology, or Genetics

### **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

### **OTHER CRITERIA**

COC: Physician attestation that the patient continues to benefit from the medication.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# VYVGART

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

VYVGART HYTRULO 1,000MG-10,000

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- For Myasthenia Gravis (MG): (1) Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy, and (2A) History of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.), or (2B) Patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/ plasma exchanges and/or intravenous immune globulin over the course of at least 12 months without symptom control. For Chronic inflammatory demyelinating polyneuropathy (CIDP): (1) Diagnosis of CIDP supported by electrodiagnostic studies, and (2A) Member has had an inadequate response or intolerable adverse event to immunoglobulins, corticosteroids, or plasma exchange, or (2B) Member has a documented clinical reason to avoid therapy with immunoglobulins, corticosteroids, or plasma exchange. COC- Physician attestation that the patient continues to benefit from the medication.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Neurology

## COVERAGE DURATION

1 year

## OTHER CRITERIA

For MG: Patient is not receiving Vyvgart Hytrulo in combination with another neonatal Fc receptor blocker (e.g., Imaavy, Rystiggo, Vyvgart) or a complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq). For CIDP: Patient is not receiving Vyvgart Hytrulo in combination with other biologic therapies or

immunoglobulin therapy for CIDP.

**PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

YES

# WAINUA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

WAINUA 45 MG/0.8 ML AUTOINJECT

## EXCLUSION CRITERIA

Wainua is not being used in combo with Amvuttra, Onpattro, Tegsedi, or a tafamidis product (Vyndamax, Vyndaqel).

## REQUIRED MEDICAL INFORMATION

New: (1) Diagnosis confirmed by detection of a mutation in the TTR gene, (2) Patient has symptomatic polyneuropathy (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction) (3) Member is not a liver transplant recipient, (4) Documentation confirming the presence of polyneuropathy characterized by either (4A) Baseline polyneuropathy disability (PND) score less than or equal to IIIb, (4B) Baseline familial amyloid polyneuropathy (FAP) Stage 1 or 2, or (4C) Neuropathy impairment (NIS) score of at least 10 but no more than 130.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Neurology, Genetics

## COVERAGE DURATION

New: 6 months. COC: 1 year.

## OTHER CRITERIA

COC: Response to treatment (e.g., improvement of neuropathy severity and rate of disease progression as demonstrated by the modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, manual grip strength).

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

## **WASTING**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

SEROSTIM

### **EXCLUSION CRITERIA**

Using to enhance athletic performance or physique.

### **REQUIRED MEDICAL INFORMATION**

Height, weight, body mass index (BMI), Body cell mass (BCM) by bioelectrical impedance analysis (BIA). Male recipients: a prescriber statement is required attesting treatment is not prescribed to enhance athletic performance or physique.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

For HIV-associated wasting, patients must have concomitant antiretroviral therapy and meet the following criteria. For HIV-associated wasting or cachexia associated with chronic disease: dose does not exceed FDA approved maximum and patient meets at least one of the following: weighs less than 90% ideal body weight, OR 10% or more unintentional weight loss within the preceding 12 months, OR 5% unintentional weight loss within the preceding six months, OR has a baseline BIA or total body DEXA showing body cell mass (BCM) below 40% in males and 35% in females, OR 5% BCM loss within the preceding six months, OR BMI less than 20 kg/m<sup>2</sup>. Reauthorization: improvement or stabilization in the body weight or body cell mass (BCM) compared to baseline.

### **PART B PREREQUISITE**

N/A

**PREREQUISITE THERAPY REQUIRED**

N/A

# WEGOVY

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

WEGOVY

## EXCLUSION CRITERIA

Part D does not cover this drug when used for treatment of obesity.

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

N/A

# WINREVAIR

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

WINREVAIR 45 MG VIAL, WINREVAIR 60 MG VIAL, WINREVAIR (2 PACK)

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial: (1) Diagnosis of PAH (pulmonary arterial hypertension) WHO group 1 is confirmed by right heart catheterization and (2) WHO Functional Class II or III and (3) Results of a baseline 6-minute walk distance (6MWD)

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Cardiology, Pulmonology, Hematology, Immunology, or Allergy

## COVERAGE DURATION

New: 6 months, COC: 1 year.

## OTHER CRITERIA

Initial: (1) On background PAH therapy for at least 3 months as evidenced by pharmacy claims or physician supporting statement with at least TWO of the following agents from different drug classes: (A) oral endothelin receptor antagonist (ambrisentan, bosentan or macitentan), (B) oral phosphodiesterase 5 inhibitors (sildenafil or tadalafil), (C) oral cGMP stimulator (riociguat), (D) prostacyclin agonist (epoprostenol, treprostinil, selexipag or iloprost), or (2) On ONE agent the above drug classes and has a contraindication or intolerance to all of the other drug classes. COC: Documentation that the medication has been effective by either (1) improvement in 6MWD from baseline or (2) improvement in WHO-FC group (e.g., patient has moved from WHO-FC group III to WHO-FC group II or WHO-FC group II to WHO-FC group I).

## PART B PREREQUISITE

N/A

**PREREQUISITE THERAPY REQUIRED**  
YES

## **XCOPRI**

---

### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

XCOPRI

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Medical justification specifying that two formulary alternatives (Carbamazepine, Clorazepate, Felbamate, Gabapentin, Lamotrigine, Levetiracetam, Oxcarbazepine, Pregabalin, Tiagabine, Topiramate, Valproic Acid, Zonisamide) have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

# **XDEMZY**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

XDEMZY

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Results of either standardized skin surface biopsy (SSSB) or direct microscopic examination (DME).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

One 10mL bottle per 365 days

## **OTHER CRITERIA**

Medical justification that metronidazole has been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **XELJANZ**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

XELJANZ, XELJANZ XR

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months. COC: 1 year.

## **OTHER CRITERIA**

Initial- For Rheumatoid Arthritis (RA): (1) Trial of or contraindication to one DMARD (disease modifying antirheumatic drug). For Psoriatic Arthritis (PSA): No concurrent use of another small biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for PSA. For Polyarticular Course Juvenile Idiopathic Arthritis (PCJIA): (1) No concurrent use of another small biologic or targeted small molecule for PCJIA. For Ankylosing Spondylitis (AS): (1) Trial or contraindication to an NSAID, and (2) No concurrent use with another systemic biologic or targeted small molecule for AS. For Ulcerative Colitis (UC): (1) No concurrent use of another small biologic or targeted small molecule for UC. COC- All indications: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES



# **XERMELO**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

XERMELO

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 3 months. Continuation: 1 year

## **OTHER CRITERIA**

For initial therapy: Individual is using in combination with somatostatin analog (SSA) therapy (such as but not limited to, lanreotide (Somatuline Depot), octreotide (Sandostatin)) AND individual has had an inadequate response on a stable dose of SSA monotherapy for at least 3 months. For continuation therapy: Individual has previously met the initiation criteria AND clinically significant improvements are confirmed after 12 weeks of treatment with Xermelo (telotristat ethyl) when added to SSA therapy.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# XIFAXAN

---

## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

XIFAXAN

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

N/A

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Travelers diarrhea: 3 days, Hepatic encephalopathy: 1 yr, IBS: 3 months, or SIBO: 14 days.

## OTHER CRITERIA

For hepatic encephalopathy must first try lactulose or metronidazole or provide medical justification.

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# **XOLAIR**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

XOLAIR

## **EXCLUSION CRITERIA**

Non-allergic asthma.

## **REQUIRED MEDICAL INFORMATION**

For IgE medicated allergic asthma: Perennial aeroallergen IgE levels, documented trial and failure of at least one inhaled corticosteroid (Beclomethasone, Budesonide, Ciclesonide, Flunisolide, Fluticasone, or Mometasone). For chronic idiopathic urticaria: Medical justification that an H1 antihistamine has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Maximum dose of 375mg every 2 weeks (for asthma) or 600mg every 2 weeks (for nasal polyps).

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# **XOLREMDI**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

XOLREMDI

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

(1) Genetic testing that shows confirmed variant of CXCR4 consistent with WHIM syndrome, and (2) Weight.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year.

## **OTHER CRITERIA**

(1) Is not on concurrent drug that is highly dependent on CYP2D6 for clearance.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **XROMI**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

XROMI

## **EXCLUSION CRITERIA**

Patients age 18 and over.

## **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

## **PREREQUISITE THERAPY REQUIRED**

N/A

# YORVIPATH

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

YORVIPATH

## EXCLUSION CRITERIA

Member under 18 years of age.

## REQUIRED MEDICAL INFORMATION

New: (1) diagnosis of hypoparathyroidism confirmed by: low albumin-corrected serum calcium (8.5mg/dL or less), undetectable or inappropriately low intact parathyroid hormone (PTH) concentration (less than 20pg/mL) by a second or third generation immunoassay, and serum magnesium level within normal limits and (2) member is currently on adequate supplemental calcium and active vitamin D (e.g. calcitriol) therapy (albumin-corrected serum calcium between 7.8-10.6mg/dL and serum 25(OH) vitamin D is within normal range).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

The medication is prescribed by or in consultation with Endocrinology, or Nephrology.

## COVERAGE DURATION

Initial: 6 months, COC: 1 year.

## OTHER CRITERIA

COC: Documentation of positive clinical response (e.g., albumin-corrected serum calcium level in normal range (8.3 – 10.6mg/dL), independence from conventional therapy).

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# ZAVZPRET

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

ZAVZPRET

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Medical justification specifying that TWO formulary anti-migraine drugs from different classes have been tried and failed are contraindicated, or would not be medically appropriate. Classes include: (1) CGRP- Ubrelvy, or Nurtec ODT, (2) Triptans- sumatriptan, rizatriptan/rizatriptan ODT, naratriptan, or zolmitriptan/zolmitriptan ODT. COC: Documentation of positive clinical response to therapy.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

New: 6 months. COC: 1 year

## OTHER CRITERIA

Medication will not be used in combination with another acute calcitonin gene-related peptide receptor (CGRP) antagonists (i.e., Ubrelvy, Nurtec ODT)

## PART B PREREQUISITE

N/A

## PREREQUISITE THERAPY REQUIRED

YES

# ZELSUVM

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ZELSUVM

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Dermatology

## **COVERAGE DURATION**

12 weeks

## **OTHER CRITERIA**

COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A

# **ZEPOSIA**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

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

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Initial- Ulcerative Colitis (UC): Prescribed by or in consultation with gastroenterology.

## **COVERAGE DURATION**

Initial- Multiple Sclerosis (MS): 12 months. UC: 6 months, COC: 12 months

## **OTHER CRITERIA**

Initial- For MS: (1) Trial of one sphingosine-1 phosphate receptor modulator (e.g., Fingolimod, Mayzent) and any one agent indicated for the treatment of MS. For UC: (1) Trial of or contraindication to two of the following preferred agents: Humira, Simlandi, Xeljanz IR/XR, Rinvoq, Skyrizi, Tremfya, Selarsdi, Steqeyma, Yesintek, and (2) No concurrent use with another systemic biologic or targeted small molecule (e.g. JAK inhibitor, PDE-4 inhibitor) for UC. COC- All indications: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

# ZEVTERA

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ZEVTERA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Labs with culture and sensitivity information.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Infectious Disease

## **COVERAGE DURATION**

6 weeks

## **OTHER CRITERIA**

Medical justification specifying that one formulary antibacterial indicated for the respective diagnosis within the listed antibacterial class of beta lactams, macrolides, fluoroquinolones, aminoglycosides or glycopeptides has been tried and failed, is contraindicated, or would not be medically appropriate for the patient.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **ZIFTOMENIB**

---

### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

KOMZIFTI

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Hematology/Oncology.

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# ZILBRYSQ

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

ZILBRYSQ

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- (1) Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy, (2) Patient has a Myasthenia Gravis Activities of Daily Living scale (MG-ADL) total score 6 or more at initiation of therapy, and (3A) History of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, etc.), or (3B) Patient has a history of failure of at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/ plasma exchanges and/or intravenous immune globulin over the course of at least 12 months without symptom control. COC- Clinical improvement demonstrated by (1) Improvement and/or maintenance of at least a 3-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Neurology

## COVERAGE DURATION

1 year

## OTHER CRITERIA

Patient is not receiving Zilbrysq in combination with another complement inhibitor (e.g., Soliris, Ultomiris) or a neonatal Fc receptor blocker (e.g., Rystiggo, Vyvgart, Vyvgart Hytrulo).

## PART B PREREQUISITE

YES

**PREREQUISITE THERAPY REQUIRED**  
YES

# ZORYVE

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

ZORYVE 0.3% CREAM, ZORYVE 0.3% FOAM

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

For plaque psoriasis: Medical justification specifying why tazarotene and calcipotriene could not be used.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

YES

## **ZORYVE-AD**

---

### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ZORYVE 0.05% CREAM, ZORYVE 0.15% CREAM

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

Atopic Dermatitis: Medical justification specifying why one topical corticosteroid or topical calcineurin inhibitor could not be used.

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

YES

## ZTALMY

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ZTALMY

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Clinical information confirming CDKL5 deficiency disorder.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

### **PREREQUISITE THERAPY REQUIRED**

N/A

# ZURZUVAE

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ZURZUVAE

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

(1) Diagnosis of postpartum depression (PPD) with an onset of depressive symptoms in the third trimester or within 4 weeks postpartum, documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.), and (2) Patient is currently less than 1 year postpartum.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Psychiatry or Obstetrician-Gynecologist (OB/GYN)

## **COVERAGE DURATION**

14 days

## **OTHER CRITERIA**

Member will not receive more than one 14-day course per 12 months.

## **PART B PREREQUISITE**

N/A

## **PREREQUISITE THERAPY REQUIRED**

N/A