



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

### **2025 Prior Authorization Criteria**

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

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

### **Crerios de autorizaci3n previa para 2025**

**(Requisitos para la aprobaci3n de ciertos medicamentos)**

**Favor de leer:** Este documento contiene informaci3n sobre los medicamentos cubiertos en este plan.

### **C3c Ti3u Chu3n V3 S3 Ch3p Thu3n Tru3c Trong N3m 2025**

**(Nh3ng y3u cầu đ3 đư3c ch3p thu3n cho các lo3i thu3c nh3t đ3nh)**

**Vui lòng đ3c:** Tài li3u này g3m có các thông tin về các lo3i thu3c chúng tôi đ3i th3 trong chương trình này.

**شرايط دريافت مجوز قبلي براي سال 2025**

**(شرايط تاييد داروهاي خاص)**

**لطفأ مطالعه كنيد:** اين نوشتار حاوي اطلاعات مهمي درباره داروهائي است كه در اين برنامه تحت پوشش داريم.

### **2025 사전 승인 기준**

**(특정 의약품의 승인 조건)**

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

## معايير الحصول على تصريح مسبق لعام 2025

(متطلبات الموافقة على أدوية معينة)

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

### 2025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。

## **ABSSSI 2 WEEK**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DALVANCE

### **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**

PENDING CMS APPROVAL

### **PART B PREREQUISITE**

N/A

## **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

# **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**

PENDING CMS APPROVAL

## **PART B PREREQUISITE**

N/A

# ADHD

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

DEXTROAMPHETAMINE 10 MG TAB, DEXTROAMPHETAMINE 5 MG TAB, DEXTROAMPHETAMINE SULFATE ER, 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-AMPHETAMINE, 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 TABLET, METHYLPHENIDATE 10 MG/5 ML SOL, METHYLPHENIDATE 20 MG TABLET, METHYLPHENIDATE 5 MG TABLET, METHYLPHENIDATE 5 MG/5 ML SOLN, 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

## **ADLARITY**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ADLARITY

### **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 rivastigmine patch and donepezil tablet cannot not be used.

### **PART B PREREQUISITE**

N/A



# **AEMCOLO**

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

AEMCOLO

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

3 days

## **OTHER CRITERIA**

Medical justification that two formulary alternatives (Azithromycin, Ciprofloxacin, Levofloxacin) have been tried and failed or are contraindicated, or would not be medically appropriate for the patient.

## **PART B PREREQUISITE**

N/A

# 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

# 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

# ANDROGENS

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

METHYLTESTOSTERONE, TESTOSTERONE 10 MG GEL PUMP, TESTOSTERONE 1% (25MG/2.5G) PK, TESTOSTERONE 1% (50 MG/5 G) PK, TESTOSTERONE 1.62% (2.5 G) PKT, TESTOSTERONE 1.62% GEL PUMP, TESTOSTERONE 1.62%(1.25 G) PKT, TESTOSTERONE 12.5 MG/1.25 GRAM, 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, TESTOSTERON CYP 2,000 MG/10 ML, TESTOSTERONE CYP 1,000 MG/10ML, TESTOSTERONE CYP 1,000 MG/5 ML, TESTOSTERONE CYP 100 MG/ML, TESTOSTERONE CYP 2,000 MG/10ML, TESTOSTERONE CYP 200 MG/ML, TESTOSTERONE CYP 500 MG/2.5 ML, TESTOSTERONE CYP 500 MG/5 ML, TESTOSTERONE CYP 6,000 MG/30ML, 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. For brand-name testosterone products, medical justification must be provided documenting why generic testosterone products cannot be used.

**PART B PREREQUISITE**

N/A

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

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

AVYCAZ, LINEZOLID, LINEZOLID-D5W, TEFLARO, 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

## **ANTICGRP**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

AIMOVIG AUTOINJECTOR, AJOVY AUTOINJECTOR, 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. Patient must have an inadequate response, contraindication, or intolerance to one different migraine prevention therapies from different classes such as antiepileptics (divalproex, topiramate, valproate, gabapentin, carbamazepine), beta blockers (propranolol, metoprolol, timolol, atenolol, nadolol), antidepressants (amitriptyline, nortriptyline, venlafaxine), calcium channel blocker (nicardipine, verapamil), angiotensin receptor II blockers ARB/Angiotensin-converting enzyme inhibitors (ACEIs) (candesartan, lisinopril) or antihistamine (cyproheptadine). For treatment of episodic cluster headache, patient must have an inadequate response, contraindication, or intolerance to at least one triptan (subcutaneous or intranasal sumatriptan) and dihydroergotamine. Renewal: 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





## **ANTIFUNGAL**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

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

### **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 (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

# **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

## **ANTINEOPLASTICS**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ALECENSA, ALUNBRIG, AUGTYRO, BALVERSA, BESREMI, BOSULIF, COMETRIQ, COPIKTRA, DAURISMO, ERLOTINIB HCL, FIRMAGON, FOTIVDA, FRUZAQLA, GAVRETO, GEFITINIB, GILOTRIF, ICLUSIG, IDHIFA, IMATINIB MESYLATE, INLYTA, INQOVI, INREBIC, IWILFIN, JAYPIRCA, KOSELUGO, KRAZATI, LAPATINIB, LENALIDOMIDE, LONSURF, LORBRENA, LUMAKRAS, LYTGObI, NERLYNX, ODOMZO, OGSIVEO, OJJAARA, ONUREG, ORSERDU, PAZOPANIB HCL, PEMAZYRE, PIQRAY, QINLOCK, RETEVMO, REZLIDHIA, ROZLYTREK, SCEMBLIX, SORAFENIB, SPRYCEL, STIVARGA, SUNITINIB MALATE, TAGRISSO, TALZENNA, TASIGNA, TAZVERIK, TEPMETKO, TIBSOVO, TOREMIFENE CITRATE, TRUQAP, TUKYSA, TURALIO 125 MG CAPSULE, VANFLYTA, VENCLEXTA, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, WELIREG, XALKORI, XOSPATA, XPOVIO, ZEJULA 100 MG TABLET, ZEJULA 200 MG TABLET, ZEJULA 300 MG TABLET, ZYDELIG, ZYKADIA

### **EXCLUSION CRITERIA**

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

### **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



## **ANTINEOPLASTICS-MULTI**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ABIRATERONE ACETATE, AYVAKIT, BRAFTOVI 75 MG CAPSULE, CALQUENCE, COTELLIC, ERLEADA, EVEROLIMUS 10 MG TABLET, EVEROLIMUS 2 MG TAB FOR SUSP, EVEROLIMUS 2.5 MG TABLET, EVEROLIMUS 3 MG TAB FOR SUSP, EVEROLIMUS 5 MG TAB FOR SUSP, EVEROLIMUS 5 MG TABLET, EVEROLIMUS 7.5 MG TABLET, FLUOROURACIL 2% TOPICAL SOLN, FLUOROURACIL 5% TOPICAL SOLN, GLEOSTINE, 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, MEKINIST, MEKTOVI, NUBEQA, OJEMDA, ORGOVYX, 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

# **APTIOM**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

APTIOM

## **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

# 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

## **ATYPICALS**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ASENAPINE MALEATE, CAPLYTA, FANAPT, 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.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Psychiatry

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



# AUVELITY

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

AUVELITY

## **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

# 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

## **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

# **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

# **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

# **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, or genital area.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months. Renewal: 1 year.

## **OTHER CRITERIA**

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

## **PART B PREREQUISITE**

N/A

## **BRONCHODILATORS, SYMPATHOMIMETIC**

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### **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

## **BRUKINSA**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

BRUKINSA

### **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



# **BUTALBITAL**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

BUTALBITAL-ACETAMINOPHEN-CAFFE

## **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

# CABLIVI

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

CABLIVI

## 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

# **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

# CANNABIDIOL

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

EPIDIOLEX

## **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**

3 months

## **OTHER CRITERIA**

Dose does not exceed 20mg/kg/day.

## **PART B PREREQUISITE**

N/A

# **CARBAGLU**

---

## **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

# CENEGERMIN

---

## 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

# CHOLBAM

---

## 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

# CIMZIA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

CIMZIA 200 MG VIAL KIT, CIMZIA 2X200 MG/ML SYRINGE KIT, CIMZIA 2X200 MG/ML(X3)START KT

## 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, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. Renewal: 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, Enbrel, Xeljanz, Rinvoq, or (2) Trial of a TNF inhibitor and physician has indicated the patient cannot use a JAK inhibitor due to the black box warning (increased risk of mortality, malignancies, and serious CV events). For Psoriatic Arthritis (PSA): Trial of or contraindication to two of the following preferred agents: Humira, Cosentyx, Stelara, Enbrel, Xeljanz, Tremfya, Rinvoq, Skyrizi. For PSO: Trial of or contraindication to two of the following preferred agents: Humira, Cosentyx, Stelara, Enbrel, Skyrizi, Tremfya. For Ankylosing Spondylitis (AS): Trial of or contraindication to two of the following preferred agents: Enbrel, Humira, Cosentyx, Xeljanz, Rinvoq. For Crohns Disease (CD): Trial of or contraindication to two of the following preferred agents: Humira, Rinvoq, Stelara, Skyrizi. For NR-AXSPA: Trial of or contraindication to two of the following



preferred agents: Cosentyx, Rinvoq. COC: Physician attestation that the patient continues to benefit from the medication.

**PART B PREREQUISITE**

N/A

# **CORLANOR**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

CORLANOR 5 MG/5 ML ORAL SOLN, 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

# **CORTICOTROPIN**

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

ACTHAR, ACTHAR SELFJECT, 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

# 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, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. Renewal: 1 year.

## OTHER CRITERIA

Initial- For PSO: trial of or contraindication to one conventional therapy such as phototherapy ultraviolet light A (PUVA), ultraviolet light B (UVB), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine. For Psoriatic Arthritis (PSA): previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. For Ankylosing Spondylitis (AS) / NR-AXSPA: trial of or contraindication to an NSAID. For Enthesitis-Related Arthritis (ERA): trial of or contraindication to an NSAID, sulfasalazine, or methotrexate. COC- For all indications: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

# **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

# CSF

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## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

FULPHILA, FYLNETRA, GRANIX, LEUKINE, NEULASTA, 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

## **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**

Medical justification specifying that at least two formulary alternatives without age restrictions (glipizide or non-sulfonylurea agents) have been tried and failed, are contraindicated, or would not be medically appropriate for the patient.

### **PART B PREREQUISITE**

N/A



# DALIRESP

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ROFLUMILAST

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Individual is currently or will be concomitantly using with a long-acting bronchodilator.

## **PART B PREREQUISITE**

N/A

# DAYBUE

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

DAYBUE

## **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

# **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

## **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

# DERMATOLOGICAL AGENTS

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

DICLOFENAC SODIUM 3% GEL, DOXEPIN 5% CREAM, TAZAROTENE 0.05% GEL, TAZAROTENE 0.1% GEL, TAZORAC 0.05% CREAM, 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

3 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **DIAGNOSTIC USE**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

ATROPINE 1% EYE DROPS

### **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

# DICLOFENAC

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

DICLOFENAC EPOLAMINE, DICLOFENAC 2% SOLUTION PUMP

## EXCLUSION CRITERIA

Myocardial infarction (MI) or coronary artery bypass graft (CABG) in the previous year.

## REQUIRED MEDICAL INFORMATION

New: Documentation or record that diclofenac 1% gel AND at least ONE oral formulary NSAID has been tried and failed within the previous 6 months. Renewal: 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

## **DIRECT RENIN INHIBITOR**

---

### **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



# 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

# **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**

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

## **DRIZALMA**

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### **MEDICATION(S)**

DRIZALMA SPRINKLE

**PENDING CMS APPROVAL**

## **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**

PENDING CMS APPROVAL

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **DUPIXENT**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

DUPIXENT PEN, DUPIXENT 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 percent 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 greater than or equal to 150 to 1,500 cells/mcl within the past 12 months.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: AD, CRSwNP, EOE, PN- 6 months, Asthma- 4 months. COC: All indications- 12 months.

## **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, (2) Trial of or contraindication to one topical (corticosteroid or calcipotriol). 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) evidence of nasal polyps, 2) inadequately controlled disease as determined by use of systemic steroids in the past 2 years or endoscopic sinus surgery, and (3) a 56-day trial of one topical nasal corticosteroid. For renewal- 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: Improvement while on therapy. PN: Improvement or reduction of pruritis or pruriginous lesions. 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.

**PART B PREREQUISITE**

N/A

# EGRIFTA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

EGRIFTA SV

## 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

Initial: 3 months. Continuation: 6 months.

## 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

## **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



## **EMFLAZA**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DEFLAZACORT

### **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**

Initial: 6 months. Continuation: 1 year

### **OTHER CRITERIA**

Member must have tried and failed or have a contraindication or intolerance to Prednisone. Requested dose does not exceed 0.9mg/kg/day. For continuation: documentation of positive response to therapy (i.e., improved muscle strength or pulmonary function).

### **PART B PREREQUISITE**

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**

Renewal: Physician attestation that the patient continues to benefit from the medication. 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, or genital area.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months. Renewal: 1 year.

## **OTHER CRITERIA**

Initial- For Rheumatoid arthritis (RA) / Polyarticular Juvenile Idiopathic Arthritis (PJIA)/ Psoriatic Arthritis (PSA): previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. For Ankylosing Spondylitis (AS): trial of or contraindication to an NSAID. For PSO: trial of or contraindication to one conventional therapy such as phototherapy ultraviolet light A (PUVA), ultraviolet light B (UVB), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine. COC- All indications: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

# 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

## **ENZYME REPLACEMENTS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

CYSTAGON, JAVYGTOR, RAVICTI, SAPROPTERIN DIHYDROCHLORIDE, SODIUM PHENYL BUTYRATE, 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

# EPCLUSA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

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

# EPO

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

ARANESP 10 MCG/0.4 ML SYRINGE, ARANESP 100 MCG/0.5 ML SYRINGE, ARANESP 100 MCG/ML VIAL, ARANESP 150 MCG/0.3 ML SYRINGE, ARANESP 200 MCG/0.4 ML SYRINGE, ARANESP 200 MCG/ML VIAL, ARANESP 25 MCG/0.42 ML SYRING, ARANESP 25 MCG/ML VIAL, ARANESP 300 MCG/0.6 ML SYRINGE, ARANESP 40 MCG/0.4 ML SYRINGE, ARANESP 40 MCG/ML VIAL, ARANESP 500 MCG/1 ML SYRINGE, ARANESP 60 MCG/0.3 ML SYRINGE, ARANESP 60 MCG/ML VIAL, EPOGEN 2,000 UNITS/ML VIAL, EPOGEN 20,000 UNITS/2 ML VIAL, EPOGEN 20,000 UNITS/ML VIAL, EPOGEN 3,000 UNITS/ML VIAL, EPOGEN 4,000 UNITS/ML VIAL, PROCRT, 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**

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

## **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

# **FABHALTA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

FABHALTA

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

(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 poly-morphonuclear cells, and (2) Hemoglobin level of less than 10 g/dL.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Hematology

## **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



# **FASENRA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

FASENRA, FASENRA PEN

## **EXCLUSION CRITERIA**

Current respiratory disease other than asthma. On dual therapy with another monoclonal antibody for the treatment of asthma. Excluded under Part D if meets coverage criteria under Part B. (Syringe will be reviewed under Part B).

## **REQUIRED MEDICAL INFORMATION**

PENDING CMS APPROVAL

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 3 months. Continuation: 1 year

## **OTHER CRITERIA**

New: (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.

## **PART B PREREQUISITE**

N/A

# 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 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 Filspari. 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

## **FILSUVEZ**

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### **MEDICATION(S)**

FILSUVEZ

**PENDING CMS APPROVAL**

# **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**

Initial: 3 months. Continuation: 1 year

## **OTHER CRITERIA**

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

## **PART B PREREQUISITE**

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

**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

# **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, NUTROPIN AQ NUSPIN, 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**

3 months

## **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





## **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

# 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

# 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

## **HBV**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

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

# 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

# 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

## **HIGH POTENCY ER OPIOID**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

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

### **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



## **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**

3 months

### **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

# HUMIRA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

HUMIRA 40 MG/0.8 ML SYRINGE, HUMIRA PEN, HUMIRA(CF), HUMIRA(CF) PEN, HUMIRA(CF) PEN CROHN'S-UC-HS, HUMIRA(CF) PEN PEDIATRIC UC, HUMIRA(CF) PEN PSOR-UV-ADOL HS

## 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, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. Renewal: 1 year.

## OTHER CRITERIA

Initial- For Rheumatoid arthritis (RA) / Polyarticular Juvenile Idiopathic Arthritis (PJIA)/ Psoriatic Arthritis (PSA): previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. For Ankylosing Spondylitis (AS): trial of or contraindication to an NSAID. For PSO: trial of or contraindication to one conventional therapy such as phototherapy ultraviolet light A (PUVA), ultraviolet light B (UVB), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine. For Uveitis: no isolated anterior uveitis. For Crohns Disease (CD) / Ulcerative Colitis (UC): trial of or contraindication to one conventional therapy such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine. COC- All indications: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

# **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



# 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**

3 months

## **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

# 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, or genital area.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a dermatologist.

## **COVERAGE DURATION**

Initial: 6 months. Renewal: 1 year.

## **OTHER CRITERIA**

Initial- For PSO: (1) Trial of or contraindication to two of the following preferred agents: Humira, Cosentyx, Stelara, Enbrel, Skyrizi, Tremfya. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

# **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



# 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**

6 months

## **OTHER CRITERIA**

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

## **PART B PREREQUISITE**

N/A

# IVIG

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

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

## **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**

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

# **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

# 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



## **JOENJA**

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### **MEDICATION(S)**

JOENJA

**PENDING CMS APPROVAL**

# JYNARQUE

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

JYNARQUE, TOLVAPTAN

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For 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: (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

3 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A





# KALYDECO

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## **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

# KERENDIA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

KERENDIA

## EXCLUSION CRITERIA

Concomitant use with a strong CYP3A4 inhibitor or diagnosis of adrenal insufficiency

## REQUIRED MEDICAL INFORMATION

New: (1) Labs within the past 30 days documenting serum potassium level of less than or equal to 5.0 mEq/L, estimated glomerular filtration rate of at least 25 mL/min/1.73m<sup>2</sup> and urine albumin-to-creatinine ratio (UACR) of at least 30 mg/g (2) Receiving concurrent therapy with angiotensin-converting enzyme inhibitor (ACE inhibitor) or angiotensin receptor blocker (ARB) at maximally tolerated labeled dosage, unless contraindicated (3) medical justification that a sodium-glucose cotransport-2 (SGLT2) inhibitor (Jardiance, Invokana, Farxiga, Steglatro) AND a steroidal mineralocorticoid receptor antagonist (spironolactone, eplerenone) have been tried and failed, are contraindicated, or would not be medically appropriate for the patient. COC: (1) Labs within the past 30 days documenting serum potassium level 5.5 mEq/L or less and estimated glomerular filtration rate of at least 25 mL/min/1.73m<sup>2</sup> and (2) approved prior authorization on file or lab showing UACR of at least 30 mg/g within past 30 days and (3) Physician attestation that the patient continues to benefit from the medication.

## AGE RESTRICTION

18 years of age or older

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 3 months. COC: 1 year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **KEVZARA**

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### **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): Prescribed by on in consultation with Rheumatology.

### **COVERAGE DURATION**

Initial: 6 months. Renewal: 1 year.

### **OTHER CRITERIA**

Initial- RA: (1) Trial of or contraindication to two of the following preferred agents: Humira, Enbrel, Xeljanz, Rinvoq, or (2) Trial of a TNF inhibitor and physician has indicated the patient cannot use a JAK inhibitor due to the black box warning (increased risk of mortality, malignancies, and serious CV events). COC: Physician attestation that the patient continues to benefit from the medication.

### **PART B PREREQUISITE**

N/A

# 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- RA: (1) Trial of or contraindication to two of the following preferred agents: Humira, Enbrel, Xeljanz, Rinvoq, or (2) Trial of a TNF inhibitor and physician has indicated the patient cannot use a JAK inhibitor due to the black box warning (increased risk of mortality, malignancies, and serious CV events). COC: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

# 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

# KRISTALOSE

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

KRISTALOSE, LACTULOSE 10 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

# LENVIMA

---

## 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



# 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

# 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

# **LIBERVANT**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

LIBERVANT

## **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**

Patient is 2 to 5 years of age.

## **PRESCRIBER RESTRICTION**

Neurology

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# LITFULO

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## **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

# **LOFEXIDINE**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

LUCEMYRA

## **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

# 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

# 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

# **MANNITOL**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

BRONCHITOL

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

New: Documentation indicating that the member has passed the Bronchitol Tolerance Test (BTT).

COC: Documentation showing response to therapy (improvement in lung function as determined by change in FEV1).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



## **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, 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

# MAVENCLAD

---

## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

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 12 months ago, 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

# 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

# MAYZENT

---

## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

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

3 months

## OTHER CRITERIA

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

## PART B PREREQUISITE

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, POMALYST, QUININE SULFATE, TETRABENAZINE, TRIDACINE 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

# **MEGESTROL**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

MEGESTROL 20 MG TABLET, MEGESTROL 40 MG TABLET, MEGESTROL ACET 40 MG/ML SUSP, MEGESTROL ACETATE

## **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

# MEPERIDINE

---

## 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

## **METHADONE**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

METHADONE 10 MG/5 ML SOLUTION, 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



# **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

## **MIRIBAVIR**

---

### **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**

PENDING CMS APPROVAL

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **MOVEMENT DISORDER**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

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

## **MS STEP 1**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

AVONEX 30 MCG/0.5 ML SYRINGE, AVONEX PREFILLED SYR 30 MCG KT, AVONEX PEN, BETASERON 0.3 MG INJECTION, DALFAMPRIDINE ER, DIMETHYL FUMARATE, FINGOLIMOD, GILENYA 0.25 MG CAPSULE, GLATIRAMER ACETATE, GLATOPA, PLEGRIDY 125 MCG/0.5 ML SYRING, PLEGRIDY 125 MCG/0.5 ML PEN, 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

## **MYCITE**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ABILIFY MYCITE 10 MG, ABILIFY MYCITE 15 MG, ABILIFY MYCITE 2 MG, ABILIFY MYCITE 20 MG, ABILIFY MYCITE 30 MG, ABILIFY MYCITE 5 MG

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 year

### **OTHER CRITERIA**

(1) Medical justification specifying that two formulary alternatives (olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone) have been tried and failed, are contraindicated, or would not be medically appropriate for the patient, (2) Evidence by paid pharmacy claims that member is currently prescribed aripiprazole and has no adverse effects to the drug, (3) Documented history of medication non-compliance, and (4) Evidence that patient and provider have access to technology that is sufficient for tracking the usage of Abilify Mycite.

### **PART B PREREQUISITE**

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

6 months

## 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

# **NARCOLEPSY**

---

## **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

# **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

# **NEXLETOL**

---

## **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

# 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

## **NORTHERA**

---

### **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

# NUCALA

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

NUCALA

## **EXCLUSION CRITERIA**

Current respiratory disease other than asthma.

## **REQUIRED MEDICAL INFORMATION**

For severe asthma: 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.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **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

# NURTEC

---

## 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, Renewal: 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. Renewal: 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



# **NYMALIZE**

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## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

NYMALIZE 30 MG/5 ML ORAL SYRNG, NYMALIZE

## **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

# OCALIVA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

OCALIVA

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For new therapy: Diagnosis is confirmed by two of the following: (1) Alkaline phosphatase (ALP) level of at least 1.5x upper limit of normal (ULN), (2) The presence of antimitochondrial antibodies (AMA) at a titer of 1:40 or higher, or (3) Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

1 year

## OTHER CRITERIA

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

## PART B PREREQUISITE

N/A

# OFEV

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

OFEV

## 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

## COVERAGE DURATION

1 year

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **OLUMIANT**

---

## **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. Renewal: 1 year.

## **OTHER CRITERIA**

Initial- RA: Trial of or contraindication to two of the following preferred agents: Humira, Enbrel, Xeljanz, Rinvoq. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

# OMVOH

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

OMVOH 100 MG/ML SYRINGE, OMVOH PEN

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months. Renewal: 1 year.

## **OTHER CRITERIA**

Initial: For Ulcerative Colitis (UC)- Trial of or contraindication to two of the following preferred agents: Humira, Stelara, Xeljanz, Rinvoq. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

## **OPHTHALMIC QUINOLONE**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

BESIVANCE, 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

## **OPSYNVI**

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### **MEDICATION(S)**

OPSYNVI

**PENDING CMS APPROVAL**

## **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



## **ORAL SUSPENSION**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

EPRONTIA, GLOPERBA, VIGABATRIN 500 MG POWDER PACKT, VIGAFYDE, VIGPODER, 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

## **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

# 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: 12 months. COC: 12 months.

## 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, Enbrel, Xeljanz, Rinvoq, or (2) Trial of a TNF inhibitor and physician has indicated the patient cannot use a JAK inhibitor due to the black box warning (increased risk of mortality, malignancies, and serious CV events). For Polyarticular juvenile idiopathic arthritis (PJIA): Trial or contraindication to any TWO of the following preferred agents: Humira, Enbrel or Xeljanz. For Psoriatic Arthritis (PSA): Trial of or contraindication to two of the following preferred agents: Humira, Cosentyx, Stelara, Enbrel, Xeljanz, Tremfya, Rinvoq, Skyrizi. Renewal: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

## **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**

6 months

### **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

## **ORLADEYO**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ORLADEYO

### **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

# OTEZLA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

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

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Initial- For Mild Plaque psoriasis (PSO): One of the following: (1) psoriasis involving greater than or equal to 2% 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, 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 dermatologist. Behcets disease: prescribed by or in consultation with a rheumatologist.

## COVERAGE DURATION

Initial: 6 months. Renewal: 1 year.

## OTHER CRITERIA

Initial- For PSA: Trial of or contraindication to two of the following preferred agents: Humira, Cosentyx, Stelara, Enbrel, Xeljanz, Tremfya, Rinvoq, Skyrizi. For mild PSO: Trial of or contraindication to one conventional systemic agent (e.g., methotrexate, acitretin, cyclosporine) and one conventional topical agent (e.g., PUVA, UVB, topical corticosteroid). For moderate to severe PSO: Trial of or contraindication to two of the following preferred agents: Humira, Cosentyx, Stelara, Enbrel, Skyrizi, Tremfya. 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

# **OXBRYTA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

OXBRYTA 300 MG TABLET, OXBRYTA 500 MG TABLET

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

(1) Hemoglobin level drawn in the last 30 days with result between 5.5 and 10.5 mg/dL and (2) clinical information indicating a history of least 1 vaso-occlusive crisis within the previous 12 months.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

Information that member is either currently stable on hydroxyurea or that hydroxyurea has been tried and failed, is contraindicated, or would not be medically appropriate.

## **PART B PREREQUISITE**

N/A



## **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

## **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

# 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, TRACLEER 32 MG TABLET FOR SUSP

## EXCLUSION CRITERIA

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

## 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: Documentation that the medication has been effective (i.e., member is stable on current dose and/or no evidence 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

## **PALBOCICLIB**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

IBRANCE

### **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

## **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

## **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

## **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

## **PART D**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ALOSETRON HCL, ARALAST NP 1,000 MG VIAL, BETAINE ANHYDROUS, BRIVIACT 10 MG TABLET, BRIVIACT 10 MG/ML ORAL SOLN, BRIVIACT 100 MG TABLET, BRIVIACT 25 MG TABLET, BRIVIACT 50 MG TABLET, BRIVIACT 75 MG TABLET, CALCIPOTRIENE 0.005% CREAM, CALCIPOTRIENE 0.005% OINTMENT, CALCIPOTRIENE 0.005% SOLUTION, CINRYZE, CLOBAZAM, CROTAN, CYCLOPHOSPHAMIDE 25 MG CAPSULE, CYCLOPHOSPHAMIDE 25 MG TABLET, CYCLOPHOSPHAMIDE 50 MG CAPSULE, CYCLOPHOSPHAMIDE 50 MG TABLET, DESVENLAFAXINE ER, DIAZOXIDE, DIHYDROERGOTAMINE 4 MG/ML SPRY, ELMIRON, EMSAM, ERGOLOID MESYLATES, FINTEPLA, FLUCYTOSINE, GARDASIL 9, GLASSIA, ICATIBANT, KEVEYIS, 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 50 MCG/ML AMP, OCTREOTIDE ACET 50 MCG/ML VIAL, OCTREOTIDE ACET 500 MCG/ML AMP, OCTREOTIDE ACET 500 MCG/ML VL, ORKAMBI, ORMALVI, PHENOXYBENZAMINE HCL, PIRFENIDONE, PROLASTIN C, PYRIMETHAMINE, RECOMBIVAX HB 10 MCG/ML VIAL, RUFINAMIDE, SAJAZIR, SYMPAZAN, 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, VALGANCICLOVIR 450 MG 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

## **PART D 3 MONTH**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

CYSTARAN, PARICALCITOL 1 MCG CAPSULE, PARICALCITOL 2 MCG CAPSULE, PARICALCITOL 4 MCG CAPSULE, REGRANEX, SIRTURO, TOBI PODHALER, TRIENTINE HCL 250 MG CAPSULE

### **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

## **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, INTRALIPID, NUTRILIPID, PLENAMINE, PREMASOL 10% IV SOLUTION, PROSOL, TRAVASOL, TROPHAMINE 10% IV SOLUTION

### **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

## **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, KYLEENA, LILETTA, MIRENA, 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, PULMOZYME, RAPAMUNE 1 MG TABLET, RAPAMUNE 1 MG/ML ORAL SOLN, RAPAMUNE 2 MG TABLET, SANDIMMUNE 100 MG CAPSULE, SANDIMMUNE 25 MG CAPSULE, SIROLIMUS, SKYLA, 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.

## **PART D-E**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

DRONABINOL, ENGERIX-B ADULT, ENGERIX-B PEDIATRIC-ADOLESCENT, HEPLISAV-B 20 MCG/0.5 ML SYRNG, PREHEVBRIO, 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

## **PCSK9**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

### **EXCLUSION CRITERIA**

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

### **REQUIRED MEDICAL INFORMATION**

PENDING CMS APPROVAL

### **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 cardiovascular risk reduction, LDL-C must be 70mg/dL or higher while on maximal treatment, and at least one of the following is required: acute coronary syndrome, coronary or other arterial revascularization, history of MI, peripheral arterial disease presumed to be of atherosclerotic origin, stable or unstable angina, stroke, or TIA. For continuation of therapy, criteria have been satisfied AND there is confirmation of LDL reduction.

### **PART B PREREQUISITE**

N/A

**COVERED USES**

All FDA-Approved Indications

**MEDICATION(S)**

NEUPRO, ONGENTYS, TOLCAPONE

**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 one formulary alternative (bromocriptine, pramipexole, or ropinirole, entacapone, or selegiline) has been tried and failed, is contraindicated, or would not be medically appropriate for the patient. When indicated as adjunct therapy, concomitant use with formulary alternatives will be approved.

**PART B PREREQUISITE**

N/A

# 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**

PENDING CMS APPROVAL

## **OTHER CRITERIA**

PENDING CMS APPROVAL

## **PART B PREREQUISITE**

N/A



# **PERSERIS**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

PERSERIS

## **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

## **POLYPHARMACY ANTIDEPRESSANTS**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

AMITRIPTYLINE HCL, CLOMIPRAMINE HCL, DESIPRAMINE HCL, DOXEPIN 10 MG CAPSULE, DOXEPIN 10 MG/ML ORAL CONC, DOXEPIN 100 MG CAPSULE, 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

## **POLYPHARMACY OTHER**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ACETAMINOPHEN-CODEINE 120-12 MG/5, ACETAMINOPHEN-CODEINE, CYCLOBENZAPRINE 10 MG TABLET, CYCLOBENZAPRINE 5 MG TABLET, CYPROHEPTADINE HCL, DICYCLOMINE 10 MG CAPSULE, DICYCLOMINE 10 MG/5 ML SOLN, DICYCLOMINE 20 MG TABLET, DIPHENOXYLATE-ATROPINE, HYDROXYZINE 10 MG/5 ML SOLN, HYDROXYZINE 10 MG/5 ML SYRUP, 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, PROCHLORPERAZINE MALEATE, PROMETHAZINE 12.5 MG TABLET, PROMETHAZINE 25 MG TABLET, PROMETHAZINE 50 MG TABLET, 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

## **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

## **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

# 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

## **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

# 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



# PROMACTA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

PROMACTA

## 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

## **PTH ANALOG**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

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

# **PYRUKYND**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

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

## **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

# **RANEXA**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ASPRUZYO 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 specifying why one formulary alternative cannot be used (acebutolol, atenolol, betaxolol, bisoprolol, carvedilol, labetalol, metoprolol, nadolol, pindolol, propranolol, timolol, diltiazem, verapamil, amlodipine, felodipine, isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin, or translingual nitroglycerin).

## **PART B PREREQUISITE**

N/A

# 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

# 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

6 months

## 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



# RELISTOR

---

## 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

PENDING CMS APPROVAL

## PART B PREREQUISITE

N/A

## **REVCovi**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

REVCovi

### **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

## **REZDIFFRA**

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### **MEDICATION(S)**

REZDIFFRA

**PENDING CMS APPROVAL**

# REZUROCK

---

## 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

# **RIBAVIRIN**

---

## **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

## **RIBOCICLIB**

---

### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

KISQALI

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

PENDING CMS APPROVAL

### **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

## **RIBOCICLIB-LETROZOLE**

---

### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

KISQALI FEMARA 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

## **RINVOQ**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

RINVOQ

### **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. Renewal: 1 year.

### **OTHER CRITERIA**

Initial- For Rheumatoid Arthritis (RA) and Psoriatic Arthritis (PSA): previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. For Atopic Dermatitis (AD): 1) Atopic dermatitis covering at least 10 percent 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 other systemic biological/jak inhibitor for the treatment of AD. For Crohns Disease (CD) / Ulcerative Colitis (UC): trial of or contraindication to one conventional therapy such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine. For NR-AXSPA: trial of or contraindication to an NSAID. COC- For RA/PSA/AS/NR-AXSPA: Physician attestation that the patient continues to benefit from the medication. For AD: 1) Physician attestation that the patient continues to benefit from the medication, and 2) no concurrent use with other systemic biological/jak inhibitor for the treatment of AD.



**PART B PREREQUISITE**

N/A

## **RIVFLOZA**

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### **MEDICATION(S)**

RIVFLOZA

**PENDING CMS APPROVAL**

# **RYDAPT**

---

## **COVERED USES**

All Medically-Accepted Indications

## **MEDICATION(S)**

RYDAPT

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

PENDING CMS APPROVAL

## **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

# SAVELLA

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

SAVELLA

## 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

# **SIGNIFOR**

---

## **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

## **SILIQ**

---

### **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, or genital area.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

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

### **COVERAGE DURATION**

Initial: 6 months. Renewal: 1 year.

### **OTHER CRITERIA**

Initial- For PSO: (1) Trial of or contraindication to two of the following preferred agents: Humira, Cosentyx, Stelara, Enbrel, Skyrizi, Tremfya. COC- For PSO: Physician attestation that the patient continues to benefit from the medication.

### **PART B PREREQUISITE**

N/A

# **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. Renewal: 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, Enbrel, Xeljanz, Rinvoq, or (2) Trial of a TNF inhibitor and physician has indicated the patient cannot use a JAK inhibitor due to the black box warning (increased risk of mortality, malignancies, and serious CV events). For Psoriatic Arthritis (PSA): Trial of or contraindication to two of the following preferred agents: Humira, Cosentyx, Stelara, Enbrel, Xeljanz, Tremfya, Rinvoq, Skyrizi. For Ankylosing Spondylitis (AS): Trial of or contraindication to two of the following preferred agents: Enbrel, Humira, Cosentyx, Xeljanz, Rinvoq. For Ulcerative Colitis (UC): Trial of or contraindication to two of the following preferred agents: Humira, Stelara, Xeljanz, Rinvoq. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

# 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, and (2) Patient has been assessed using the modified Friedreich's Ataxia Rating Scale and has a score between 20 and 80.

## 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



# SKYRIZI

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

SKYRIZI 150 MG/ML SYRINGE, 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, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. Renewal: 1 year.

## OTHER CRITERIA

Initial- For Psoriatic Arthritis (PSA): previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. For PSO: trial of or contraindication to one conventional therapy such as phototherapy ultraviolet light A (PUVA), ultraviolet light B (UVB), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine. For Crohns Disease (CD): trial of or contraindication to one conventional therapy such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine. COC- PSA/PSO: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

## **SNRI**

---

### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

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

# SOHONOS

---

## 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

# SOLOSEC

---

## 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

# **SORIATANE**

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

ACITRETIN

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Renewal: Physician attestation that the patient continues to benefit from the medication. New requests for plaque psoriasis: Psoriasis involving greater than or equal to 5% of body surface area or psoriatic lesions affecting the hands, feet, face, or genital area.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a dermatologist.

## **COVERAGE DURATION**

Initial: 6 months. Renewal: 1 year.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **SOTYKTU**

---

## **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, or genital area.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Psoriasis: prescribed by or in consultation with a dermatologist.

## **COVERAGE DURATION**

Initial: 6 months. Renewal: 1 year.

## **OTHER CRITERIA**

Initial- For PSO: (1) Trial of or contraindication to two of the following preferred agents: Humira, Cosentyx, Stelara, Enbrel, Skyrizi, Tremfya. COC- For PSO: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

# SOVALDI

---

## 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

# STELARA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

STELARA 45 MG/0.5 ML SYRINGE, STELARA 45 MG/0.5 ML VIAL, STELARA 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, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. Renewal: 1 year.

## OTHER CRITERIA

Initial- For Psoriatic Arthritis (PSA): previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. For PSO: trial of or contraindication to one conventional therapy such as phototherapy ultraviolet light A (PUVA), ultraviolet light B (UVB), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine. For Crohns Disease (CD) / Ulcerative Colitis (UC): trial of or contraindication to one conventional therapy such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine. COC- PSA/PSO: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A



# **SYMDEKO**

---

## **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**

3 months

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# SYMLIN

---

## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

SYMLINPEN 120, SYMLINPEN 60

## 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 patients receiving concomitant metoclopramide, acarbose or glyset, patients with an A1c over 9%, patients not receiving concomitant insulin, patients with a diagnosis of gastroparesis.

## PART B PREREQUISITE

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

# TADALAFIL

---

## **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

# TAKHZYRO

---

## 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

PENDING CMS APPROVAL

## 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

# TALTZ

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

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, or genital area.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Initial: 6 months. Renewal: 1 year.

## **OTHER CRITERIA**

Initial- For PSO: Trial of or contraindication to two of the following preferred agents (where ages align): Humira, Cosentyx, Stelara, Enbrel, Skyrizi, Tremfya. For Psoriatic Arthritis (PSA): Trial of or contraindication to two of the following preferred agents: Humira, Cosentyx, Stelara, Enbrel, Xeljanz, Tremfya, Rinvoq, Skyrizi. For Ankylosing Spondylitis (AS): Trial of or contraindication to two of the following preferred agents: Enbrel, Humira, Cosentyx, Xeljanz, Rinvoq. For NR-AXSPA: Trial of or contraindication to two of the following preferred agents: Cosentyx, Rinvoq. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

# TARPEYO

---

## 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), (3) Confirmation of proteinuria as evidenced by equal to or greater than 1 g/day or a UPCR equal to equal to or greater than 0.8 g/g, (4) Patient has an eGFR of 35 L/min or greater, (5) History of failure, contraindication, or reason(s) for intolerance to an alternative oral corticosteroid (methylprednisolone, prednisolone, prednisone).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Nephrology or Immunology

## COVERAGE DURATION

10 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# TAVALISSE

---

## 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. Renewal: 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



# TAVNEOS

---

## 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

# **TEDUGLUTIDE**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

GATTEX 5 MG INJECTION

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

3 months

## **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

# TEGSEDI

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

TEGSEDI

## EXCLUSION CRITERIA

Platelet count less than  $100 \times 10^9/L$  or UPCR of 1000 mg/g or higher or previous hypersensitivity reaction with use of Tegsedi

## REQUIRED MEDICAL INFORMATION

Labs for platelet count, serum creatinine, eGFR, AST, ALT, urine protein to creatinine ratio (UPCR), total bilirubin and urinalysis within the past 2 weeks.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Neurology

## COVERAGE DURATION

3 months

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **THALOMID**

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### **COVERED USES**

All Medically-Accepted Indications

### **MEDICATION(S)**

THALOMID

### **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

# TIGLUTIK

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

TEGLUTIK, TIGLUTIK

## **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

# **TIOPRONIN**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

TIOPRONIN

## **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**

3 months

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **TOPICAL ANTIHERPETIC**

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### **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

# **TRANSMUCOSAL IMMEDIATE RELEASE FENTANYL**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

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

## **EXCLUSION CRITERIA**

Any of the following: 1. Management of acute or post-operative pain. 2. Opioid non-tolerant patients. 3. Pain not associated with cancer. 4. Opioid naive.

## **REQUIRED MEDICAL INFORMATION**

N/A

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

3 months

## **OTHER CRITERIA**

Concurrent chemotherapy or documentation or record of a diagnosis of cancer is required. Patients must be opioid tolerant, as demonstrated by one week or longer of around-the-clock therapy with a total daily dose of 60 mg of oral morphine (or equivalent dose of another opioid).

## **PART B PREREQUISITE**

N/A



# TREMFYA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

TREMFYA 100 MG/ML INJECTOR, TREMFYA 100 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, or genital area.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

Initial: 6 months. Renewal: 1 year.

## OTHER CRITERIA

Initial- For Psoriatic Arthritis (PSA): previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. For PSO: trial of or contraindication to one conventional therapy such as phototherapy ultraviolet light A (PUVA), ultraviolet light B (UVB), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine. COC- All indications: Physician attestation that the patient continues to benefit from the medication.

## PART B PREREQUISITE

N/A

# TRIKAFTA

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## 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. Renewal: 1 year.

## OTHER CRITERIA

Must have a history of failure, contraindication, or reason(s) for intolerance to Orkambi or Symdeko.

## PART B PREREQUISITE

N/A

# **TYRVAYA**

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## **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

# **TYVASO DPI**

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

TYVASO DPI 16 MCG CARTRIDGE, TYVASO DPI 16-32-48 MCG TITRAT, TYVASO DPI 32 MCG CARTRIDGE, TYVASO DPI 32-48 MCG MAINT KIT, TYVASO DPI 48 MCG CARTRIDGE, TYVASO DPI 64 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 (2) 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: Confirmation of PAH based on right heart catheterization with results showing (1) mean pulmonary arterial pressure (mPAP) of greater than 20 mmHg and (2) pulmonary vascular resistance (PVR) of 3 Wood units or more and (3) pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less and (4) 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

# UBRELVY

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## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

UBRELVY

## 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) 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

# UCERIS

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## 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

## **UREA SPLITTING URINARY INFECTION**

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### **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



# VALTOCO

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

VALTOCO

## **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

# VELSIPITY

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## **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 Ulcerative Colitis (UC)- Trial of or contraindication to two of the following preferred agents: Humira, Stelara, Xeljanz, Rinvoq. COC: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

# **VENLAFAXINE BESYLATE**

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## **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

# VEOZAH

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## **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

# VERQUVO

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## 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/renewal: not concurrently taking long-acting nitrates, Adempas, or PDE-5 inhibitors.

## PART B PREREQUISITE

N/A

# VIBERZI

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## 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

# **VIJOICE**

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## **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

# 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**

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

## **PART B PREREQUISITE**

N/A



# 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

# VOWST

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## **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

# VRAYLAR

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## COVERED USES

All Medically-Accepted Indications

## MEDICATION(S)

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

# VTAMA

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## **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**

12 weeks

## **OTHER CRITERIA**

Medical justification specifying why tazarotene and calcipotriene could not be used.

## **PART B PREREQUISITE**

N/A

# VUITY

---

## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

VUITY

## **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**

PENDING CMS APPROVAL

## **PRESCRIBER RESTRICTION**

Optometrist or Ophthalmologist

## **COVERAGE DURATION**

1 year

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# VYNDAQEL

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## **COVERED USES**

All FDA-Approved Indications

## **MEDICATION(S)**

VYNDAMAX, VYNDAQEL

## **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

# WAINUA

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## COVERED USES

All FDA-Approved Indications

## MEDICATION(S)

WAINUA

## 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

## **WASTING**

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### **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**

3 months

### **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 7.5% 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



## **WEGOVY**

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### **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

# **XCOPRI**

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## **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

# **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**

PENDING CMS APPROVAL

## **PART B PREREQUISITE**

N/A

# **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. Renewal: 1 year.

## **OTHER CRITERIA**

Initial- For Rheumatoid Arthritis (RA) / Psoriatic Arthritis (PSA) / Polyarticular Course Juvenile Idiopathic Arthritis (PCJIA): previous trial of or contraindication to one DMARD (disease modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. For Ankylosing Spondylitis (AS): trial of or contraindication to an NSAID. For Ulcerative Colitis (UC): trial of or contraindication to one conventional therapy such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine. COC- All indications: Physician attestation that the patient continues to benefit from the medication.

## **PART B PREREQUISITE**

N/A

# **XERMELO**

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## **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

# **XIFAXAN**

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## **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**

3 days for travelers diarrhea, 1 year for hepatic encephalopathy, or 3 months for IBS.

## **OTHER CRITERIA**

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

## **PART B PREREQUISITE**

N/A

# **XOLAIR**

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## **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**

3 months

## **OTHER CRITERIA**

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

## **PART B PREREQUISITE**

N/A

# ZAVZPRET

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## 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



## **ZEPATIER**

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### **COVERED USES**

All FDA-Approved Indications

### **MEDICATION(S)**

ZEPATIER

### **EXCLUSION CRITERIA**

Moderate or severe liver impairment (Child-Pugh B or C)

### **REQUIRED MEDICAL INFORMATION**

HCV RNA level within past 6 months. For genotype 1A: testing for NS5A resistance-associated polymorphisms. 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. 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: phenytoin, carbamazepine, rifampin, efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir, atorvastatin at doses above 20mg per day or rosuvastatin at doses greater than 10mg per day.

### **PART B PREREQUISITE**

N/A

# **ZEPOSIA**

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## **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- MS: Trial of one sphingosine-1 phosphate receptor modulator (e.g., Gilenya, Mayzent) and any one agent indicated for the treatment of MS. UC: Trial of or contraindication to two of the following preferred agents: Humira, Stelara, Xeljanz, Rinvoq.

## **PART B PREREQUISITE**

N/A

## **ZILBRYSQ**

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### **MEDICATION(S)**

ZILBRYSQ

**PENDING CMS APPROVAL**

## ZORYVE

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### **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**

Medical justification specifying why tazarotene and calcipotriene could not be used.

### **PART B PREREQUISITE**

N/A

## **ZORYVE-AD**

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### **MEDICATION(S)**

ZORYVE 0.15% CREAM

**PENDING CMS APPROVAL**

## ZTALMY

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### **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

# 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