



# **2019 Medicare Part D Prior Authorization Requirements**

**Effective: January 01, 2019**

## ACTEMRA

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### **Drugs**

#### **ACTEMRA**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

MAY NOT USE ACTEMRA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND/OR FUNCTIONAL ASSESSMENT AND TREATMENT GOALS, AND (3) FOR RHEUMATOID ARTHRITIS AND JUVENILE IDIOPATHIC ARTHRITIS ONLY, DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH ENBREL AND HUMIRA. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY RHEUMATOLOGY

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **ACTIMMUNE**

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### **Drugs**

**ACTIMMUNE**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A MAXIMUM DOSE OF 50 MCG PER SQUARE METER 3 TIMES WEEKLY.

## AIMOVIG

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### **Drugs**

**AIMOVIG AUTOINJECTOR, AIMOVIG AUTOINJECTOR (2 PACK)**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) PATIENT HAS GREATER THAN OR EQUAL TO 4 MIGRAINE DAYS PER MONTH, AND (3) PATIENT HAS A DOCUMENTED INADQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO AT LEAST TWO STANDARD PROPHYLACTIC PHARMACOLOGIC THERAPIES, AT LEAST ONE DRUG EACH FROM A DIFFERENT PHARMACOLOGIC CLASS SUCH AS ANTICONVULSANT, BETA-BLOCKER, ANTIDEPRESSANT. RENEWAL CRITERIA: DOCUMENTATION OF A POSITIVE RESPONSE.

### **Age Restriction**

RESERVED FOR PATIENTS AGE 18 AND OLDER.

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGY.

### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## ANDROGEN THERAPY

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### **Drugs**

*testosterone cypionate, testosterone enanthate, testosterone transdermal gel in metered-dose pump, testosterone transdermal gel in packet*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTED TESTOSTERONE DEFICIENCY IN MALES OF LESS THAN 300 NG/DL.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## ANTICONVULSANTS - SELECT AGENTS

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### **Drugs**

APTIOM, BANZEL ORAL SUSPENSION, BANZEL ORAL TABLET 200 MG, 400 MG, FYCOMPA ORAL SUSPENSION, FYCOMPA ORAL TABLET

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **ANTIDEPRESSANTS - NON-PREFERRED AGENTS**

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### **Drugs**

**FETZIMA, TRINTELLIX, VIIBRYD ORAL TABLET, VIIBRYD ORAL TABLETS, DOSE PACK 10 MG (7)- 20 MG (23)**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO TWO PREFERRED ALTERNATIVE ANTIDEPRESSANTS, SUCH AS: CITALOPRAM, ESCITALOPRAM, FLUOXETINE, PAROXETINE, SERTRALINE, VENLAFAXINE, OR DULOXETINE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## ANTINEOPLASTIC INJECTABLES

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### Drugs

**ABRAXANE**, **ALIMTA**, **ALIQOPA**, *amifostine crystalline*, **ARRANON**, **ARZERRA**, **AVASTIN**, *azacitidine*, **BAVENCIO**, **BELEODAQ**, **BENDEKA**, **BESPONS**, **BICNU**, **BLINCYTO INTRAVENOUS KIT**, **BORTEZOMIB**, *busulfan*, **CAMPTOSAR INTRAVENOUS SOLUTION 300 MG/15 ML**, *carboplatin intravenous solution*, *cisplatin*, *clofarabine*, **CYRAMZA**, *dacarbazine*, *dactinomycin*, **DARZALEX**, *daunorubicin*, *decitabine*, *docetaxel intravenous solution 160 mg/8 ml (20 mg/ml)*, *20 mg/2 ml (10 mg/ml)*, *20 mg/ml*, *20 mg/ml (1 ml)*, *80 mg/4 ml (20 mg/ml)*, *80 mg/8 ml (10 mg/ml)*, **EMPLICITI**, *epirubicin intravenous recon soln 50 mg*, *epirubicin intravenous solution*, **ERBITUX**, **ERWINAZE**, **FASLODEX**, *fludarabine*, **FOLOTYN**, **GAZYVA**, *gemcitabine*, **HALAVEN**, **HERCEPTIN**, *idarubicin*, *ifosfamide*, **IMFINZI**, *irinotecan*, **IXEMPRA**, **JEVTANA**, **KADCYLA**, **KEYTRUDA INTRAVENOUS SOLUTION**, **KYPROLIS**, **LARTRUVO**, **LUPRON DEPOT**, **LUPRON DEPOT (3 MONTH)**, **LUPRON DEPOT (4 MONTH)**, **LUPRON DEPOT (6 MONTH)**, *melphalan hcl*, *mitomycin intravenous*, *mitoxantrone*, **MUSTARGEN**, *mutamycin*, **MYLOTARG**, **ONCASPAR**, **ONIVYDE**, **OPDIVO**, *oxaliplatin*, *paclitaxel*, **PERJETA**, **PORTRAZZA**, **POTELIGEO**, **PROLEUKIN**, **RITUXAN HYCELA**, *romidepsin*, **SYLVANT**, **TECENTRIQ**, **TEMODAR INTRAVENOUS**, *temsirolimus*, *thiotepa*, **TORISEL**, **TREANDA INTRAVENOUS RECON SOLN**, **TRELSTAR INTRAMUSCULAR SYRINGE**, **TRISENOX INTRAVENOUS SOLUTION 2 MG/ML**, **UNITUXIN**, **UVADEX**, **VECTIBIX**, **VELCADE**, *vincasar pfs*, *vincristine*, *vinorelbine*, **VYXEOS**, **YERVOY**, **ZANOSAR**

### Covered Uses

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### Exclusion Criteria

### Required Medical Information

INITIAL: FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, OR (2) DOCUMENTATION THAT A PATIENT IS CURRENTLY RECEIVING OR HAS PREVIOUSLY RECEIVED AND BENEFITED FROM THE USE OF THIS MEDICATION FOR THE TREATMENT OF CANCER. RENEWAL: DOCUMENTATION OF A BENEFICIAL RESPONSE.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### Other Criteria



## ANTINEOPLASTIC INJECTABLES WITH BVD

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### **Drugs**

*bleomycin, cladribine, cytarabine, cytarabine (pf) injection solution 100 mg/5 ml (20 mg/ml), 2 gram/20 ml (100 mg/ml), doxorubicin intravenous solution, doxorubicin, peg-liposomal, fluorouracil intravenous solution 1 gram/20 ml, 5 gram/100 ml, 500 mg/10 ml, IMLYGIC, vinblastine intravenous solution, YONDELIS*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL: FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, OR (2) DOCUMENTATION THAT A PATIENT IS CURRENTLY RECEIVING OR HAS PREVIOUSLY RECEIVED AND BENEFITED FROM THE USE OF THIS MEDICATION FOR THE TREATMENT OF CANCER. RENEWAL: DOCUMENTATION OF A BENEFICIAL RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## ANTIPARKINSON AGENTS

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### **Drugs**

#### **NEUPRO**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF SIGNIFICANT SIDE EFFECTS, LOSS OF EFFICACY, OR COMPLIANCE CONCERNS WITH REGULAR RELEASE PRAMIPEXOLE OR ROPINIROLE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## ATYPICAL ANTIPSYCHOTIC AGENTS

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### **Drugs**

**FANAPT**, *paliperidone*, **REXULTI**, **SAPHRIS (BLACK CHERRY)**, **SAPHRIS SUBLINGUAL TABLET 2.5 MG**, **VRAYLAR**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO TWO OF THE FOLLOWING ALTERNATIVES: RISPERIDONE, ZIPRASIDONE, OLANZAPINE, QUETIAPINE REGULAR RELEASE, QUETIAPINE EXTENDED RELEASE OR ARIPIPRAZOLE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## AUSTEDO

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### **Drugs**

**AUSTEDO**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGY OR PSYCHIATRY.

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF POSITIVE RESPONSE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **BETASERON**

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### **Drugs**

#### **BETASERON SUBCUTANEOUS KIT**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO EXTAVIA.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGY

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **BRIVIACT**

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### **Drugs**

#### **BRIVIACT**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO LEVETIRACETAM AND ONE ADDITIONAL PREFERRED SEIZURE MEDICATION, SUCH AS LAMOTRIGINE, CARBAMAZEPINE, DIVALPROEX, PHENYTOIN, TOPIRAMATE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

**Drugs**

**CIMZIA, CIMZIA POWDER FOR RECONST**

**Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

**Exclusion Criteria**

MAY NOT USE CIMZIA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

**Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND/OR FUNCTIONAL ASSESSMENT AND TREATMENT GOALS, (3) FOR RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, ANKYLOSING SPONDYLITIS, AND PLAQUE PSORIASIS: DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH ENBREL AND HUMIRA, OR FOR CROHN'S DISEASE: DOCUMENTATION OF MEDICAL CONTRAINDICATION OR INADEQUATE RESPONSE TO HUMIRA. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

**Age Restriction**

**Prescriber Restriction**

RESERVED FOR PRESCRIBING BY RHEUMATOLOGY, DERMATOLOGY, OR GASTROENTEROLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

**Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

**Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## CLOMIPRAMINE

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### **Drugs**

*clomipramine*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: DIAGNOSIS OF OBSESSIVE-COMPULSIVE DISORDER, OR DOCUMENTATION THAT THE PATIENT IS MONITORED FOR ADVERSE DRUG EVENTS.

### **Age Restriction**

RESTRICTIONS APPLY TO PATIENTS GREATER THAN 64 YEARS OF AGE.

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**



## **CLONIDINE EXTENDED RELEASE**

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### **Drugs**

*clonidine hcl oral tablet extended release 12 hr*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTED FAILURE WITH STANDARD GENERIC ADHD MEDICATIONS SUCH AS METHYLPHENIDATE OR DEXTROAMPHETAMINE-AMPHETAMINE COMBINATION.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **COPAXONE 20MG**

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### **Drugs**

**COPAXONE SUBCUTANEOUS SYRINGE 20 MG/ML**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO GLATOPA 20MG OR GLATIRAMER 20MG.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGY

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **COPAXONE 40MG**

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### **Drugs**

**COPAXONE SUBCUTANEOUS SYRINGE 40 MG/ML**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO GLATIRAMER 40MG.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGY

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## COSENTYX

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### **Drugs**

**COSENTYX (2 SYRINGES), COSENTYX PEN (2 PENS)**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

MAY NOT USE COSENTYX CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

### **Required Medical Information**

INITIAL: (1) MEDICAL CHART DOCUMENTATION OF TREATMENT GOALS AND BASELINE DISEASE ACTIVITY/FUNCTIONAL ASSESSMENT, AND (2) DIAGNOSIS OF: (A) MODERATE TO SEVERE PLAQUE PSORIASIS (AT LEAST 5% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, PUSTULAR PSORIASIS), OR (B) ANKYLOSING SPONDYLITIS, OR (C) PSORIATIC ARTHRITIS, AND (3) MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE TO BOTH ENBREL AND HUMIRA. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY DERMATOLOGY AND RHEUMATOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## CYSTARAN

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### **Drugs**

#### **CYSTARAN**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA: DIAGNOSIS OF CYSTINOSIS. RENEWAL CRITERIA: DOCUMENTATION OF CLINICAL TREATMENT EFFECT (SUCH AS DOCUMENTATION OF SLIT LAMP EXAM RESULTS)

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, OR FOR OPHTHALMOLOGY SPECIALISTS.

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

## DAKLINZA

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### **Drugs** **DAKLINZA**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT, AND (3) DOCUMENTED CLINICAL INAPPROPRIATENESS OF OR INABILITY TO TOLERATE HARVONI, EPCLUSA, OR MAVYRET REGIMENS.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, OR HEPATOLOGY, OR INFECTIOUS DISEASE SPECIALISTS.

#### **Coverage Duration**

DURATION PER GENOTYPE AND DIAGNOSIS. 12-24 WEEKS PER FDA APPROVED LABELING OR CLINICAL GUIDELINES.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **DALFAMPRIDINE ER**

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### **Drugs**

*dalfampridine*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, (2) DOCUMENTATION THAT THE PATIENT IS CURRENTLY ABLE TO WALK 25 FEET, AND (3) PHYSICIAN ATTESTATION THAT PATIENT HAS DIFFICULTY WALKING. RENEWAL CRITERIA: DOCUMENTATION OF A POSITIVE RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF POSITIVE RESPONSE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **DALIRESP**

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### **Drugs**

#### **DALIRESP**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF SEVERE COPD CONFIRMED WITH AN FEV-1 LESS THAN 50 PERCENT OF PREDICTED, AND (2) ASSOCIATED CHRONIC BRONCHITIS AS DEFINED BY THE PRESENCE OF COUGH AND SPUTUM PRODUCTION FOR AT LEAST 3 MONTHS IN EACH OF TWO CONSECUTIVE YEARS, AND (3) DOCUMENTATION OF INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATIONS TO TWO OF THE FOLLOWING: LONG-ACTING BETA-AGONIST (SUCH AS FORMOTEROL OR SALMETEROL), ANTICHOLINERGIC (SUCH AS IPRATROPIUM) OR ORAL INHALED STEROID (SUCH AS BECLOMETHASONE, BUDESONIDE, FLUTICASONE OR MOMETASONE).

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**



## **DESVENLAFAXINE**

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### **Drugs**

*desvenlafaxine succinate*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE TO VENLAFAXINE ER AND DULOXETINE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **DIFICID**

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### **Drugs DIFICID**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

(1) DIAGNOSIS OF CLOSTRIDIUM DIFFICILE INFECTION, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO METRONIDAZOLE AND VANCOMYCIN.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

## DIGOXIN

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### **Drugs**

*digitek oral tablet 250 mcg, digox oral tablet 250 mcg, digoxin oral tablet 250 mcg*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) THE PATIENT IS CURRENTLY STABLE ON DIGOXIN 0.25 MG AND IS MONITORED FOR ADVERSE DRUG EVENTS, OR (2) FOR PATIENTS WITH ATRIAL FIBRILLATION AND CONTRAINDICATIONS OR INADEQUATE RESPONSE TO COMBINATION THERAPY WITH A LOWER DOSE OF DIGOXIN AND EITHER A BETA BLOCKER OR A NON DIHYDROPYRIDINE CALCIUM CHANNEL BLOCKER (SUCH AS DILTIAZEM OR VERAPAMIL), OR (3) FOR PATIENTS WITH HEART FAILURE AND CONTRAINDICATIONS OR INADEQUATE RESPONSE TO COMBINATION THERAPY WITH A LOWER DOSE OF DIGOXIN AND A BETA BLOCKER.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## DIHYDROERGOTAMINE

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### **Drugs**

*dihydroergotamine*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH TWO TRIPTAN MEDICATIONS SUCH AS SUMATRIPTAN, NARATRIPTAN OR RIZATRIPTAN.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **DULERA**

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### **Drugs**

#### **DULERA**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF FAILURE WITH ADVAIR.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **DUPIXENT**

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### **Drugs DUPIXENT**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

(1) MEDICAL CHART DOCUMENTATION OF MODERATE TO SEVERE ATOPIC DERMATITIS WITH AT LEAST 10% BODY SURFACE AREA (BSA) OR INVOLVEMENT WITH THE FACE, NECK, HANDS, FEET, OR GENITALS, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE PRESCRIPTION-STRENGTH TOPICAL CORTICOSTEROID.

#### **Age Restriction**

RESERVED FOR PATIENTS AGE 18 AND OLDER.

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY AN ALLERGIST, IMMUNOLOGIST, OR DERMATOLOGIST.

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **EMSAM**

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### **Drugs EMSAM**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO ONE PREFERRED DRUG FROM EACH OF THE FOLLOWING TWO ANTIDEPRESSANT SUB-CLASSES: (A) SSRI'S SUCH AS CITALOPRAM, ESCITALOPRAM, FLUOXETINE, PAROXETINE, SERTRALINE, AND (B) SNRI'S SUCH AS VENLAFAXINE OR DULOXETINE.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

**Drugs**

**ENBREL, ENBREL SURECLICK**

**Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

**Exclusion Criteria**

MAY NOT USE ENBREL CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

**Required Medical Information**

INITIAL: (1) DOCUMENTATION OF TREATMENT GOALS AND BASELINE DISEASE ACTIVITY/FUNCTIONAL ASSESSMENT, AND (2) DIAGNOSIS OF: (A) RHEUMATOID ARTHRITIS W/DOCUMENTATION OF CONTRAINDICATION/INTOLERANCE TO/FAILURE (C/I/F) W/CONCURRENT USE OF 2 OF THE FOLLOWING FOR 3 MOS: METHOTREXATE, HYDROXYCHLOROQUINE, LEFLUNOMIDE, OR SULFASALAZINE, OR (B) JUVENILE IDIOPATHIC ARTHRITIS OR PSORIATIC ARTHRITIS W/DOCUMENTATION OF C/I/F TO BOTH OF THE FOLLOWING FOR 1 MONTH: CONTINUOUS TREATMENT WITH ONE NSAID AND METHOTREXATE, OR (C) ANKYLOSING SPONDYLITIS WITH DOCUMENTATION OF C/I/F TO CONTINUOUS TREATMENT WITH ONE NSAID FOR 1 MONTH, AND FOR PERIPHERAL DISEASE ONLY, DOCUMENTATION OF C/I/F W/ONE OF THE FOLLOWING: CONTINUOUS LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), METHOTREXATE, OR SULFASALAZINE, OR (D) PLAQUE PSORIASIS W/AT LEAST 5% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS, W/DOCUMENTATION OF C/I/F TO 2 OF THE FOLLOWING FOR 3 MOS: TOPICAL CORTICOSTEROID THERAPY, PHOTOTHERAPY, METHOTREXATE, CYCLOSPORINE, ACITRETIN. RENEWAL: DOCUMENTATION TREATMENT GOALS HAVE BEEN MET.

**Age Restriction**

**Prescriber Restriction**

RESERVED FOR PRESCRIBING BY DERMATOLOGY AND RHEUMATOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

**Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

**Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.



## ENZYME REPLACEMENT

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### **Drugs**

ADAGEN, ALDURAZYME, CERDELGA, CHOLBAM, ELAPRASE, ELELYSO, ELITEK, FABRAZYME, ILARIS (PF) SUBCUTANEOUS SOLUTION, LUMIZYME, NAGLAZYME, ORFADIN, VPRIV

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, GASTROENTEROLOGY, HEMATOLOGY, AND NEPHROLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## EPCLUSA

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### **Drugs** **EPCLUSA**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT.

#### **Age Restriction**

RESERVED FOR PATIENTS AGE 18 AND OLDER.

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

#### **Coverage Duration**

DURATION PER GENOTYPE AND DIAGNOSIS. 12 WEEKS PER FDA APPROVED LABELING OR CLINICAL GUIDELINES.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **ERYTHROPOIESIS STIMULATING AGENTS**

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### **Drugs**

**ARANESP (IN POLYSORBATE), PROCRIT, RETACRIT**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR CANCER DIAGNOSIS: DOCUMENTED CHEMOTHERAPY-ASSOCIATED ANEMIA (HEMOGLOBIN LESS THAN 10G/DL OR HEMATOCRIT LESS THAN 30%).

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## **EUCRISA**

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### **Drugs**

#### **EUCRISA**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ONE PRESCRIPTION-STRENGTH TOPICAL CORTICOSTEROID.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## FAMOTIDINE INJECTION

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### **Drugs**

*famotidine (pf), famotidine intravenous solution*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF: (A) FAILURE WITH ORAL FORMULARY HISTAMINE 2 RECEPTOR ANTAGONISTS FAMOTIDINE AND RANITIDINE, OR (B) MEDICAL CONTRAINDICATIONS TO ORAL HISTAMINE 2 RECEPTOR ANTAGONISTS.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## FDA-APPROVED INDICATIONS

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### Drugs

**ABILIFY MAINTENA**, *amikacin injection solution 1,000 mg/4 ml, 500 mg/2 ml*, **ANADROL-50**, **APOKYN**, **ARALAST NP INTRAVENOUS RECON SOLN 1,000 MG**, **ARISTADA**, **ARISTADA INITIO**, **ATGAM**, **BENLYSTA**, **BERINERT INTRAVENOUS KIT**, **CAPASTAT**, *casprofungin*, **CAYSTON**, *chloramphenicol sod succinate*, **CHORIONIC GONADOTROPIN, HUMAN**, **CINRYZE**, **CORLANOR**, *cycloserine, daptomycin*, **DEMSER**, *dexrazoxane hcl*, **ERAXIS(WATER DILUENT)**, **FIRAZYR**, *fomepizole*, **GLASSIA**, **HAEGARDA**, **HETLIOZ**, **INVEGA SUSTENNA**, **INVEGA TRINZA**, **KALBITOR**, **KEPIVANCE**, **KORLYM**, **KRYSTEXXA**, **LEVOLEUCOVORIN INTRAVENOUS RECON SOLN 175 MG**, *levoleucovorin intravenous recon soln 50 mg, levoleucovorin intravenous solution*, **LUPRON DEPOT-PED (3 MONTH) INTRAMUSCULAR SYRINGE KIT 30 MG**, **LUPRON DEPOT-PED INTRAMUSCULAR KIT 11.25 MG, 15 MG**, *mesna*, **MOVANTIK**, **MOZOBIL**, **NUPLAZID**, *oxandrolone oral tablet 10 mg, 2.5 mg*, **PROLASTIN-C INTRAVENOUS RECON SOLN**, *quinine sulfate*, **RANEXA**, *rifampin intravenous*, **RUCONEST**, **SIRTURO**, *sodium phenylbutyrate oral tablet*, **SOLIRIS**, **SOMATULINE DEPOT SUBCUTANEOUS SYRINGE 120 MG/0.5 ML, 60 MG/0.2 ML, 90 MG/0.3 ML**, **SOMAVERT SUBCUTANEOUS RECON SOLN 15 MG, 20 MG, 25 MG, 30 MG**, **SYMPROIC**, **SYNAGIS**, **SYNAREL**, **TARGRETIN TOPICAL**, **TOBI PODHALER INHALATION CAPSULE, W/INHALATION DEVICE**, *tobramycin sulfate injection solution, tranexamic acid intravenous*, **VISTOGARD**, **XYREM**, **ZEMAIRA**, **ZORBTIVE**, **ZYPREXA RELPREVV**

### Covered Uses

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### Exclusion Criteria

### Required Medical Information

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### Other Criteria

## **FDA-APPROVED INDICATIONS - DOSE LIMIT**

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### **Drugs**

#### **STRENSIQ**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## FDA-APPROVED INDICATIONS WITH BVD

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### Drugs

ABELCET, AMBISOME, *amphotericin b*, BIVIGAM, CARIMUNE NF NANOFILTERED INTRAVENOUS RECON SOLN 12 GRAM, 6 GRAM, CUVITRU, FLEBOGAMMA DIF, *foscarnet*, GAMASTAN S/D, GAMMAGARD LIQUID, GAMMAGARD S-D (IGA < 1 MCG/ML), GAMMAKED, GAMMAPLEX, GAMMAPLEX (WITH SORBITOL), GAMUNEX-C, HIZENTRA, HYQVIA, OCTAGAM, PRIVIGEN, PULMOZYME, *tobramycin in 0.225 % nacl*, ZORTRESS

### Covered Uses

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### Exclusion Criteria

### Required Medical Information

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### Other Criteria

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.



## FONDAPARINUX

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### **Drugs**

*fondaparinux*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D, DIAGNOSIS OF HEPARIN-INDUCED THROMBOCYTOPENIA, AND DIAGNOSIS OF MALIGNANCY WITH HYPERCOAGULABLE STATE.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND DOCUMENTATION OF FAILURE OR MEDICAL CONTRAINDICATIONS WITH ENOXAPARIN, OR (2) DIAGNOSIS OF HEPARIN-INDUCED THROMBOCYTOPENIA, OR (3) DIAGNOSIS OF MALIGNANCY WITH HYPERCOAGULABLE STATE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **FORTEO**

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### **Drugs**

#### **FORTEO**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

#### **Required Medical Information**

(1) DIAGNOSIS OF: (A) FRAGILITY FRACTURE OF THE SPINE OR HIP WITHIN THE LAST FIVE YEARS, OR (B) SEVERE OSTEOPOROSIS WITH A T-SCORE OF SPINE, HIP OR FEMORAL NECK OF MINUS 3.5 OR LOWER, OR (C) OSTEOPOROSIS WITH A T-SCORE OF MINUS 2.5 OR LOWER AND (I) INTOLERANCE OR CONTRAINDICATION TO BISPHOSPHONATE THERAPY, OR (II) PROGRESSIVE BONE LOSS DEFINED AS BONE LOSS OF THREE PERCENT OR HIGHER DESPITE THERAPY WITH BISPHOSPHONATES, ADEQUATE CALCIUM INTAKE AND VITAMIN D INTAKE WITH VITAMIN D SERUM LEVELS OF 30 NG/ML OR HIGHER, AND (2) DOCUMENTED FAILURE OF, INTOLERANCE TO, OR CONTRAINDICATIONS TO TYMLOS.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

## **FULYZAQ**

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### **Drugs**

**MYTESI**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND CONTRAINDICATIONS OR INADEQUATE RESPONSE TO LOPERAMIDE AND DIPHENOXYLATE/ATROPINE. RENEWAL CRITERIA: DOCUMENTATION OF BENEFICIAL RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

## GATTEX

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### **Drugs**

#### **GATTEX 30-VIAL**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA: (1) TREATMENT OF ADULT PATIENTS WITH SHORT BOWEL SYNDROME, AND (2) WHO HAVE BEEN DEPENDENT ON PARENTERAL (OR A COMBINATION OF PARENTERAL AND ENTERAL) NUTRITION FOR ALL NUTRITIONAL REQUIREMENTS FOR AT LEAST ONE YEAR, AND (3) IN WHOM A TAPER FROM PARENTERAL REQUIREMENTS HAS NOT BEEN POSSIBLE OR PLANNED. RENEWAL CRITERIA: MEDICAL RECORD DOCUMENTATION OF POSITIVE RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

DOSE IS LIMITED TO THE FDA-APPROVED DOSE OF 0.05 MG/KG PER DAY.

## HARVONI

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### **Drugs** **HARVONI**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT.

#### **Age Restriction**

RESERVED FOR PATIENTS AGE 12 AND OLDER.

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

#### **Coverage Duration**

12-24 WKS PER DIAGNOSIS, FDA LABELING OR CLINICAL GUIDELINES. 8 WK APPROVALS PER PROVIDER REQUEST.

#### **Other Criteria**

DOSE IS LIMITED TO THE FDA-APPROVED REGIMEN OF ONE TABLET DAILY.

## **HIGH-STRENGTH OPIOID AGENTS**

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### **Drugs**

*buprenorphine, fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, methadone oral concentrate, methadone oral solution, methadone oral tablet, morphine oral tablet extended release 15 mg, 30 mg, 60 mg*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) PROVIDER ATTESTATION OF INTENT TO MONITOR FOR SIDE EFFECTS AND APPROPRIATE USE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA AGENTS**

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### **Drugs**

**JUXTAPID, KYNAMRO**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL: (1) CONFIRMED DIAGNOSIS OF HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA, AND (2) THERAPEUTIC FAILURE, INTOLERANCE, OR CONTRAINDICATION TO ONE HIGH-INTENSITY STATIN THERAPY AND TO ONE PCSK9-INHIBITOR (SUCH AS REPATHA). RENEWAL: DOCUMENTATION OF BENEFICIAL RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY CARDIOLOGY AND ENDOCRINOLOGY.

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

## HUMIRA

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### **Drugs**

**HUMIRA, HUMIRA PEDIATRIC CROHN'S START, HUMIRA PEN, HUMIRA PEN CROHN'S-UC-HS START, HUMIRA PEN PSORIASIS-UVEITIS**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

MAY NOT USE HUMIRA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

### **Required Medical Information**

INITIAL: (1) DOCUMENTATION OF TREATMENT GOALS AND BASELINE DISEASE ACTIVITY/FUNCTIONAL ASSESSMENT, AND (2) DIAGNOSIS OF: (A) RHEUMATOID ARTHRITIS W/DOCUMENTATION OF CONTRAINDICATION/INTOLERANCE TO/FAILURE (C/I/F) W/CONCURRENT USE OF 2 OF THE FOLLOWING FOR 3 MOS: METHOTREXATE, HYDROXYCHLOROQUINE, LEFLUNOMIDE, OR SULFASALAZINE, OR (B) JUVENILE IDIOPATHIC ARTHRITIS OR PSORIATIC ARTHRITIS W/DOCUMENTATION OF C/I/F TO BOTH OF THE FOLLOWING FOR 1 MONTH: CONTINUOUS TREATMENT WITH ONE NSAID AND METHOTREXATE, OR (C) ANKYLOSING SPONDYLITIS W/DOCUMENTATION OF C/I/F TO CONTINUOUS TREATMENT WITH ONE NSAID FOR 1 MONTH, AND FOR PERIPHERAL DISEASE ONLY, DOCUMENTATION OF C/I/F W/ONE OF THE FOLLOWING: CONTINUOUS LOCAL CORTICOSTEROID INJECTION THERAPY (WHEN DISEASE PROCESS PERMITS), METHOTREXATE, OR SULFASALAZINE, OR (D) PLAQUE PSORIASIS W/AT LEAST 5% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS, W/DOCUMENTATION OF C/I/F TO 2 OF THE FOLLOWING FOR 3 MOS: TOPICAL CORTICOSTEROID THERAPY, PHOTOTHERAPY, METHOTREXATE, CYCLOSPORINE, ACITRETIN, OR (E) MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE W/: (I) FISTULIZING DISEASE, OR (II) DOCUMENTATION OF C/I/F TO 1 OF THE FOLLOWING: PREDNISONE OR BUDESONIDE FOR 14 DAYS, OR AZATHIOPRINE, 6-MERCAPTOPYRINE, OR METHOTREXATE FOR 3 MOS, OR (F) MODERATE TO SEVERELY ACTIVE ULCERATIVE COLITIS W/DOCUMENTATION OF C/I/F TO 2 OF THE FOLLOWING FOR 3 MOS: SULFASALAZINE, MESALAMINE, BALSALAZIDE, PREDNISONE, BUDESONIDE, AZATHIOPRINE, 6-MERCAPTOPYRINE, OR (G) HIDRADENITIS SUPPURATIVA, OR (H) NON-INFECTIOUS INTERMEDIATE, POSTERIOR AND PANUVEITIS. RENEWAL: DOCUMENTATION TREATMENT GOALS HAVE BEEN MET.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY DERMATOLOGY, GASTROENTEROLOGY, OPHTHALMOLOGY, AND RHEUMATOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.



## **IDIOPATHIC PULMONARY FIBROSIS AGENTS**

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### **Drugs**

**ESBRIET, OFEV**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PULMONOLOGY

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES

## **INFECTIOUS DISEASE SELECT AGENTS**

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### **Drugs**

**CRESEMBA ORAL**, *linezolid*, *linezolid in dextrose 5%*, **NOXAFIL ORAL**, **SIVEXTRO**, *voriconazole*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH AN INFECTIOUS DISEASE SPECIALIST.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **INGREZZA**

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### **Drugs INGREZZA**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) MEDICAL CHART DOCUMENTATION OF FUNCTIONAL IMPAIRMENT DUE TO MODERATE-TO-SEVERE TARDIVE DYSKINESIA SYMPTOMS. RENEWAL CRITERIA: (1) DOCUMENTATION THAT THE PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) DOCUMENTATION OF EFFECTIVENESS.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGY OR PSYCHIATRY.

#### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF POSITIVE RESPONSE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **ITRACONAZOLE**

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### **Drugs**

*itraconazole oral capsule*, **SPORANOX ORAL SOLUTION**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR COMPLEX FUNGAL NAIL INFECTIONS (ONYCHOMYCOSIS): DOCUMENTED FAILURE ON ORAL TERBINAFINE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **KALYDECO**

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### **Drugs**

**KALYDECO, ORKAMBI, SYMDEKO**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: (1) DOCUMENTATION THAT THE PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS, AND (2) DOCUMENTATION OF EFFECTIVENESS.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **KEVZARA**

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### **Drugs**

#### **KEVZARA**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

MAY NOT USE KEVZARA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

#### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH ACTEMRA. RENEWAL CRITERIA: DOCUMENTATION OF A POSITIVE RESPONSE.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY RHEUMATOLOGY.

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **KINERET**

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### **Drugs**

#### **KINERET**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

MAY NOT USE KINERET CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

#### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND/OR FUNCTIONAL ASSESSMENT AND TREATMENT GOALS (3) FOR RHEUMATOLOGY: MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE TO ENBREL AND HUMIRA. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY RHEUMATOLOGY, PEDIATRICIAN (FOR CHILDREN WITH CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES), AND GENETICS SPECIALISTS WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **LATUDA**

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### **Drugs**

#### **LATUDA**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO ONE OF THE FOLLOWING ALTERNATIVES: RISPERIDONE, ZIPRASIDONE, OLANZAPINE, QUETIAPINE REGULAR RELEASE, QUETIAPINE EXTENDED RELEASE OR ARIPIPRAZOLE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**



## **LIDOCAINE PATCH**

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### **Drugs**

*lidocaine topical adhesive patch,medicated*

### **Covered Uses**

ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF A MEDICALLY ACCEPTED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR DIAGNOSIS OF POSTHERPETIC NEURALGIA OR DIABETIC NEUROPATHY, DOCUMENTATION THAT THE PATIENT HAS TRIED AND FAILED GABAPENTIN.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.

## **LOTRONEX**

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### **Drugs**

*alosetron*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

8 WEEKS, THEN BALANCE OF CONTRACT YEAR ONLY IF SIGNIFICANT IMPROVEMENT IN DISABILITY.

### **Other Criteria**

## MARQIBO

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### **Drugs**

#### **MARQIBO**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION THAT DISEASE PROGRESSION HAS NOT OCCURRED.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## MAVYRET

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### **Drugs** **MAVYRET**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT.

#### **Age Restriction**

RESERVED FOR PATIENTS AGE 18 AND OLDER.

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

#### **Coverage Duration**

8-16 WKS PER DIAGNOSIS, FDA LABELING OR CLINICAL GUIDELINES. 8 WK APPROVALS PER PROVIDER REQUEST.

#### **Other Criteria**

DOSE IS LIMITED TO THE FDA-APPROVED REGIMEN OF THREE TABLETS DAILY.

## **MECASERMIN**

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### **Drugs**

#### **INCRELEX**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY ENDOCRINOLOGY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **MEDICALLY ACCEPTED INDICATIONS**

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### **Drugs**

*armodafinil oral tablet 150 mg, 200 mg, 250 mg, 50 mg, cyclobenzaprine oral tablet 10 mg, 5 mg, modafinil*

### **Covered Uses**

ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION OR CMS-APPROVED COMPENDIA ACCEPTED INDICATION FOR THE REQUESTED MEDICATION.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **MEDROXYPROGESTERONE 400 MG/ML IM INJECTION**

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### **Drugs**

**DEPO-PROVERA INTRAMUSCULAR SUSPENSION 400 MG/ML**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF CANCER FOR A NEW START PATIENT, OR (2) DOCUMENTATION THAT A PATIENT IS CURRENTLY RECEIVING OR HAS PREVIOUSLY RECEIVED AND BENEFITED FROM DEPO-PROVERA 400MG/ML INTRAMUSCULAR INJECTION FOR THE TREATMENT OF CANCER.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **METABOLIC DISORDER AGENTS**

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### **Drugs**

**ARCALYST, CARBAGLU, KUVAN, RAVICTI, SUCRAID**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

### **Required Medical Information**

INITIAL CRITERIA: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.



## METHOXSALEN

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### **Drugs**

*methoxsalen*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY DERMATOLOGY AND ONCOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **MIACALCIN INJECTION**

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### **Drugs**

#### **MIACALCIN INJECTION**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND DOCUMENTATION OF TRIAL AND FAILURE OR MEDICAL CONTRAINDICATIONS TO BISPHOSPHONATES.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## MULTAQ

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### **Drugs**

#### **MULTAQ**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTED FAILURE WITH OR MEDICAL CONTRAINDICATIONS TO FIRST-LINE MEDICATIONS SUCH AS AMIODARONE, FLECAINIDE, PROPAFENONE OR SOTALOL.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY CARDIOLOGY

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **NARCOTIC AGENTS**

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### **Drugs**

*fentanyl citrate buccal lozenge on a handle 200 mcg, 400 mcg, LAZANDA*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION THAT THE PATIENT HAS DIFFICULTY SWALLOWING OR HAS COMPLIANCE CONCERNS WITH ORAL NARCOTIC TABLETS, CAPSULES, OR LIQUID.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.

## NATPARA

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### **Drugs** **NATPARA**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

#### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) HISTORY OF HYPOPARATHYROIDISM FOR AT LEAST 18 MONTHS, AND (3) SERUM THYROID FUNCTION TESTS WITHIN LABORATORY NORMAL LIMITS (FOR PATIENTS NOT ON THYROID REPLACEMENT) OR THYROID REPLACEMENT THERAPY MUST BE STABLE FOR AT LEAST 3 MONTHS (FOR PATIENTS TAKING THYROID REPLACEMENT), AND (4) SERUM MAGNESIUM LEVEL WITHIN LABORATORY NORMAL LIMITS, AND (5) UPON INITIATION OF NATPARA THERAPY, NATPARA TO BE USED AS AN ADJUNCT TO CALCITRIOL AT LEAST 0.25 MCG/DAY. RENEWAL CRITERIA: SERUM CALCIUM CONCENTRATION MUST BE MAINTAINED IN THE LOWER HALF OF LABORATORY NORMAL REFERENCE RANGE.

#### **Age Restriction**

LIMITED TO ADULTS AGE 18 YEARS AND OLDER.

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY ENDOCRINOLOGY.

#### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

#### **Other Criteria**

ALL FDA-LABELED DOSAGE AND ADMINISTRATION GUIDELINES MUST BE MET.

## **NON-PREFERRED SOMATOSTATIN**

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### **Drugs**

#### **SIGNIFOR LAR**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF TRIAL AND FAILURE WITH ONE LONG-ACTING SOMATOSTATIN ANALOGUE (SUCH AS SANDOSTATIN LAR). RENEWAL: DOCUMENTATION OF POSITIVE RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## **NON-PREFERRED TOBRAMYCIN**

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### **Drugs**

#### **BETHKIS**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF TRIAL AND FAILURE WITH GENERIC TOBRAMYCIN NEBULIZED SOLUTION, AND (3) CARE MANAGED BY A CYSTIC FIBROSIS SPECIALIST. RENEWAL CRITERIA: DOCUMENTATION OF A POSITIVE RESPONSE AND THE PATIENT HAS BEEN SEEN WITHIN THE LAST 12 MONTHS FOR CYSTIC FIBROSIS.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## **NORTHERA**

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### **Drugs**

**NORTHERA ORAL CAPSULE 100 MG, 200 MG, 300 MG**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: MEDICAL RECORD DOCUMENTATION OF CONTINUED EFFECTIVENESS.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH A CARDIOLOGIST OR NEUROLOGIST

### **Coverage Duration**

ONE MONTH, WITH APPROVAL EVERY THREE MONTHS IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**



## **NUEDEXTA**

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### **Drugs**

**NUEDEXTA**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.

## OLYSIO

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### **Drugs OLYSIO**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT, AND (3) DOCUMENTED CLINICAL INAPPROPRIATENESS OF OR INABILITY TO TOLERATE HARVONI, EPCLUSA, OR MAVYRET. IF GENOTYPE 1A: DOCUMENTATION PATIENT IS NEGATIVE FOR NS3 Q80K POLYMORPHISM.

#### **Age Restriction**

RESERVED FOR PATIENTS AGE 18 AND OLDER.

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

#### **Coverage Duration**

DURATION PER GENOTYPE AND DIAGNOSIS. 12-24 WEEKS PER FDA APPROVED LABELING OR CLINICAL GUIDELINES.

#### **Other Criteria**

DOSE IS LIMITED TO THE FDA-APPROVED DOSE OF 150MG DAILY. MUST BE USED IN A COMBINATION ANTIVIRAL TREATMENT REGIMEN SUPPORTED BY FDA APPROVED LABELING OR RELEVANT CLINICAL GUIDELINES.

## ORAL DISSOLVE TABLETS PROTECTED CLASS

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### **Drugs**

*aripiprazole oral tablet, disintegrating, clozapine oral tablet, disintegrating, olanzapine oral tablet, disintegrating, risperidone oral tablet, disintegrating, **SPRITAM***

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF FAILURE WITH OR CONTRAINDICATION TO ONE REGULAR TABLET DOSAGE FORM OF THE REQUESTED MEDICATION.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## ORAL LIQUID PROTECTED CLASS

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### **Drugs**

**VERSACLOZ**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION THAT THE PATIENT HAS DIFFICULTY SWALLOWING OR HAS COMPLIANCE CONCERNS WITH REGULAR TABLET OR CAPSULE DOSAGE FORMS.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## ORAL ONCOLOGY AGENTS

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### **Drugs**

ALECENSA, ALUNBRIG, BOSULIF, BRAFTOVI, CABOMETYX, CALQUENCE, COMETRIQ, COTELLIC, ERIVEDGE, ERLEADA, FARYDAK, GILOTRIF, IBRANCE, ICLUSIG, IDHIFA, IMBRUVICA, INLYTA, IRESSA, JAKAFI, KISQALI, KISQALI FEMARA CO-PACK, LENVIMA, LONSURF, LYNPARZA, MEKINIST, MEKTOVI, NERLYNX, NINLARO, ODOMZO, POMALYST, RUBRACA, RYDAPT, STIVARGA, TAFINLAR, TAGRISSO, TIBSOVO, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, XALKORI, YONSA, ZEJULA, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

### **Required Medical Information**

INITIAL CRITERIA FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION THAT DISEASE PROGRESSION HAS NOT OCCURRED.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## ORENCIA

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### **Drugs**

**ORENCIA, ORENCIA (WITH MALTOSE), ORENCIA CLICKJECT**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

MAY NOT USE ORENCIA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND/OR FUNCTIONAL ASSESSMENT AND TREATMENT GOALS, AND (3) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH ENBREL AND HUMIRA. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY RHEUMATOLOGY

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## ORENITRAM

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### **Drugs**

#### **ORENITRAM**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

#### **Required Medical Information**

(1) (A) DIAGNOSIS OF VASOREACTIVE PULMONARY ARTERIAL HYPERTENSION (PAH) AS CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION AND TRIAL AND FAILURE OF CALCIUM CHANNEL BLOCKER THERAPY, OR (B) DIAGNOSIS OF NON-VASOREACTIVE PAH AS CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION, AND (2) A PREVIOUS TRIAL OF ONE PREFERRED AGENT SUCH AS UPTRAVI, AND (3) DEMONSTRATED MEDICAL NECESSITY.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PULMONOLOGY OR CARDIOLOGY.

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## OTEZLA

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### **Drugs**

**OTEZLA, OTEZLA STARTER**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

#### **Required Medical Information**

PLAQUE PSORIASIS INITIAL CRITERIA: (1) DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS (AT LEAST 5% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS), AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND TREATMENT GOALS. PSORIATIC ARTHRITIS INITIAL CRITERIA: (1) DIAGNOSIS OF PSORIATIC ARTHRITIS, AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND/OR FUNCTIONAL ASSESSMENT AND TREATMENT GOALS. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY, OR THAT SIGNIFICANT PROGRESS TOWARD ACHIEVEMENT OF TREATMENT GOALS HAS OCCURRED.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY RHEUMATOLOGY OR DERMATOLOGY.

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.



## **PANTOPRAZOLE IV**

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### **Drugs**

*pantoprazole intravenous*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF: (A) FAILURE WITH ORAL FORMULARY PROTON PUMP INHIBITORS OMEPRAZOLE AND LANSOPRAZOLE, OR (B) MEDICAL CONTRAINDICATIONS TO ORAL PROTON PUMP INHIBITORS.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## PARICALCITOL

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### **Drugs**

*paricalcitol oral*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF FAILURE WITH CALCITRIOL.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## PART B DRUGS

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### Drugs

*acetylcysteine, acyclovir sodium intravenous recon soln 500 mg, acyclovir sodium intravenous solution, albuterol sulfate inhalation solution for nebulization 0.63 mg/3 ml, 1.25 mg/3 ml, 2.5 mg /3 ml (0.083 %), 5 mg/ml, AMINOSYN 8.5 %-ELECTROLYTES, AMINOSYN II 10 %, AMINOSYN II 15 %, AMINOSYN II 7 %, AMINOSYN II 8.5 %, AMINOSYN II 8.5 %-ELECTROLYTES, AMINOSYN M 3.5 %, AMINOSYN-HBC 7%, AMINOSYN-PF 10 %, AMINOSYN-PF 7 % (SULFITE-FREE), aprepitant, AZASAN, azathioprine, azathioprine sodium, BCG VACCINE, LIVE (PF), budesonide inhalation, cromolyn inhalation, cyclophosphamide oral capsule, cyclosporine intravenous, cyclosporine modified, cyclosporine oral capsule, deltasone oral tablet 20 mg, dexamethasone oral elixir, dexamethasone oral tablet, dexamethasone sodium phosphate injection solution 4 mg/ml, dexamethasone sodium phosphate injection syringe, dronabinol oral capsule 10 mg, 2.5 mg, 5 mg, **EMEND ORAL SUSPENSION FOR RECONSTITUTION, ENGERIX-B (PF), ENGERIX-B PEDIATRIC (PF) INTRAMUSCULAR SYRINGE**, ganciclovir sodium, gengraf, granisetron hcl oral, heparin (porcine) in 5 % dex intravenous parenteral solution 20,000 unit/500 ml (40 unit/ml), **IMOVAX RABIES VACCINE (PF), INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %**, ipratropium bromide inhalation, ipratropium-albuterol, methotrexate sodium, methotrexate sodium (pf) injection solution, methylprednisolone acetate, methylprednisolone oral tablet, methylprednisolone sodium succ injection recon soln 40 mg, methylprednisolone sodium succ intravenous, **MILLIPRED ORAL TABLET**, mycophenolate mofetil, mycophenolate mofetil hcl, **NEBUPENT, NULOJIX**, ondansetron, ondansetron hcl oral, prednisolone oral solution 15 mg/5 ml, prednisolone sodium phosphate oral solution 10 mg/5 ml, 20 mg/5 ml (4 mg/ml), 25 mg/5 ml (5 mg/ml), 5 mg base/5 ml (6.7 mg/5 ml), **PREDNISONE INTENSOL**, prednisone oral solution, prednisone oral tablet, **PROGRAF INTRAVENOUS, RABAVERT (PF), RAPAMUNE ORAL SOLUTION, RECOMBIVAX HB (PF), SIMULECT**, sirolimus, tacrolimus oral, **TICE BCG**, trimethobenzamide oral*

### Covered Uses

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### Exclusion Criteria

### Required Medical Information

### Age Restriction

### Prescriber Restriction

### Coverage Duration

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### Other Criteria

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## PEGASYS

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### **Drugs**

**PEGASYS, PEGASYS PROCLICK**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR TREATMENT OF HEPATITIS C, DOCUMENTATION OF HCV GENOTYPE, VIRAL LOAD AND LIVER FUNCTION TESTS, AND DOCUMENTATION OF INTOLERANCE TO OR ADVERSE EFFECTS FROM PRIOR USE OF PEGINTRON.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, OR HEPATOLOGY, OR INFECTIOUS DISEASE SPECIALISTS.

### **Coverage Duration**

12-48 WEEKS PER FDA APPROVED LABELING OR CLINICAL GUIDELINES FOR PATIENT DIAGNOSIS AND GENOTYPE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD-IDS A GUIDANCE.

## PEGINTRON

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### **Drugs**

#### **PEGINTRON SUBCUTANEOUS KIT 50 MCG/0.5 ML**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR TREATMENT OF HEPATITIS C, DOCUMENTATION OF HCV GENOTYPE, VIRAL LOAD AND LIVER FUNCTION TESTS.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, OR HEPATOLOGY, OR INFECTIOUS DISEASE SPECIALISTS.

### **Coverage Duration**

DURATION PER DIAGNOSIS. 12-48 WEEKS PER FDA APPROVED LABELING OR CLINICAL GUIDELINES.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. CRITERIA WILL BE APPLIED CONSISTENT WITH CURRENT AASLD-IDSA GUIDANCE.

## **PENICILLAMINE**

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### **Drugs**

#### **DEPEN TITRATABS**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR CYSTINURIA: DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO THIOLA. RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE TO THERAPY.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, GASTROENTEROLOGY, HEPATOLOGY, AND NEPHROLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## PHENOXYBENZAMINE

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### **Drugs**

*phenoxybenzamine*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF AN INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO ONE GENERIC ALPHA-BLOCKER, SUCH AS TERAZOSIN OR DOXAZOSIN.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **PRADAXA**

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### **Drugs**

**PRADAXA**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO XARELTO AND ELIQUIS.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**



## **PROCARBAZINE**

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### **Drugs**

**MATULANE**

### **Covered Uses**

ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) USE IN COMBINATION WITH OTHER ANTICANCER DRUGS FOR THE TREATMENT OF STAGE III AND IV HODGKIN'S DISEASE, OR (2) DIAGNOSIS OF A MEDICALLY-ACCEPTED INDICATION. RENEWAL: DOCUMENTATION OF POSITIVE RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

DOSE UP TO THE RECOMMENDED MAX OF 6 MG/KG/DAY FOR ADULTS OR 100 MG PER SQUARE METER PER DAY FOR PEDIATRICS.

## **PROMACTA**

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### **Drugs**

#### **PROMACTA**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY HEMATOLOGY AND HEPATOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF POSITIVE RESPONSE.

### **Other Criteria**

## **PULMONARY ARTERIAL HYPERTENSION - NON-ORAL**

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### **Drugs**

*epoprostenol (glycine)*, **REMODULIN**, *sildenafil (antihypertensive)*, **TYVASO**, **VELETRI**, **VENTAVIS**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

### **Required Medical Information**

(1) DIAGNOSIS OF VASOREACTIVE PULMONARY ARTERIAL HYPERTENSION (PAH) AS CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION AND TRIAL AND FAILURE OF CALCIUM CHANNEL BLOCKER THERAPY, OR (2) DIAGNOSIS OF NON-VASOREACTIVE PAH AS CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PULMONOLOGY OR CARDIOLOGY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## **PULMONARY ARTERIAL HYPERTENSION - ORAL PREFERRED**

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### **Drugs**

**ADEMPAS, LETAIRIS, OPSUMIT, TRACLEER, UPTRAVI**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR VASOREACTIVE PULMONARY ARTERIAL HYPERTENSION (PAH) ONLY, CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION AND TRIAL AND FAILURE OF CALCIUM CHANNEL BLOCKER THERAPY, AND (3) FOR NON-VASOREACTIVE PAH ONLY, CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PULMONOLOGY OR CARDIOLOGY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## QUETIAPINE ER

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### **Drugs**

*quetiapine oral tablet extended release 24 hr*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION THAT THE PATIENT HAS SIGNIFICANT COMPLIANCE CONCERNS WITH QUETIAPINE REGULAR RELEASE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

**Drugs**

**RASUVO (PF) SUBCUTANEOUS AUTO-INJECTOR 10 MG/0.2 ML, 12.5 MG/0.25 ML, 15 MG/0.3 ML, 17.5 MG/0.35 ML, 20 MG/0.4 ML, 22.5 MG/0.45 ML, 25 MG/0.5 ML, 30 MG/0.6 ML, 7.5 MG/0.15 ML**

**Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

**Exclusion Criteria**

**Required Medical Information**

RESERVED FOR PATIENTS WHO HAVE: (1) LACK OF RESPONSE TO GENERIC METHOTREXATE INJECTION, OR (2) INTOLERANCE OR SIGNIFICANT ADVERSE EFFECTS FROM GENERIC METHOTREXATE INJECTION, OR (3) DEXTERITY CONCERNS, OR (4) VISUAL ACUITY CONCERNS, OR (5) IMPAIRED COGNITION PREVENTING SAFE USE OF GENERIC METHOTREXATE INJECTION, OR (6) MEDICAL CHART DOCUMENTATION OF NEEDLE PHOBIA PREVENTING USE OF GENERIC METHOTREXATE INJECTION.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

**Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## REMICADE

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### **Drugs**

#### **REMICADE**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

MAY NOT USE REMICADE CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

#### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF ANKYLOSING SPONDYLITIS, RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, PLAQUE PSORIASIS, CROHN'S DISEASE OR ULCERATIVE COLITIS, AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND/OR FUNCTIONAL ASSESSMENT AND TREATMENT GOALS, AND (3) CONCURRENT USE WITH METHOTREXATE (FOR RHEUMATOLOGY INDICATIONS ONLY), AND (4) MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE TO: (A) ENBREL AND HUMIRA (FOR RHEUMATOLOGY AND DERMATOLOGICAL INDICATIONS), OR (B) HUMIRA (FOR GASTROENTEROLOGY INDICATIONS OTHER THAN FISTULIZING CROHNS DISEASE). RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY DERMATOLOGY, GASTROENTEROLOGY AND RHEUMATOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## REPATHA

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### Drugs

REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE

### Covered Uses

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### Exclusion Criteria

#### Required Medical Information

INITIAL CRITERIA: (1) DIAGNOSIS OF (A) HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA CONFIRMED WITH CLINICAL CRITERIA SUCH AS WHO CLINICAL CRITERIA SCORE GREATER THAN OR EQUAL TO 6, OR (B) ATHEROSCLEROTIC CARDIOVASCULAR DISEASE AS DEFINED BY THE 2013 ACC/AHA GUIDELINE ON THE TREATMENT OF BLOOD CHOLESTEROL TO REDUCE ARTEROSCLEROTIC CARDIOVASCULAR RISK IN ADULTS, OR (C) HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA, AND (2) DOCUMENTATION OF (A) INABILITY TO ACHIEVE AND MAINTAIN LDL LEVEL LESS THAN OR EQUAL TO 100 MG/DL WITH STANDARD THERAPY (DEFINED AS A HIGH INTENSITY STATIN SUCH AS ATORVASTATIN 40-80MG DAILY), OR (B) INTOLERANCE (DEFINED AS INTOLERABLE MYALGIA OR MYOPATHY, OR ALT GREATER THAN OR EQUAL TO 3 TIMES ULN) TO STATIN THERAPY PROVEN WITH TWO TRIALS, OR (C) CONTRAINDICATIONS (DEFINED AS MYOSITIS WITH CREATINE KINASE LEVEL GREATER THAN OR EQUAL TO 10 TIMES ULN OR RHABDOMYOLYSIS) TO STANDARD THERAPY, AND (3) DOCUMENTATION OF CURRENT CHOLESTEROL LAB VALUES AND CHOLESTEROL TREATMENT HISTORY. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY, OR THAT SIGNIFICANT PROGRESS TOWARD ACHIEVEMENT OF TREATMENT GOALS HAS OCCURRED.

#### Age Restriction

#### Prescriber Restriction

RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH CARDIOLOGY, ENDOCRINOLOGY, OR LIPIDOLOGY SPECIALISTS

#### Coverage Duration

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

#### Other Criteria

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.



## RITUXAN

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### Drugs

#### RITUXAN

#### Covered Uses

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D, DIAGNOSIS AUTOIMMUNE HEMOLYTIC ANEMIA, AND DIAGNOSIS OF IDIOPATHIC THROMBOCYTOPENIC PURPURA.

#### Exclusion Criteria

#### Required Medical Information

RHEUMATOLOGY: (1) DIAGNOSIS OF AN FDA-APPROVED RHEUMATOLOGY DISORDER, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR FAILURE WITH ENBREL AND HUMIRA. HEMATOLOGY: (1) DIAGNOSIS OF IDIOPATHIC THROMBOCYTOPENIC PURPURA OR AUTOIMMUNE HEMOLYTIC ANEMIA AND (2) PATIENTS WITH INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATIONS TO CORTICOSTEROIDS .

#### Age Restriction

#### Prescriber Restriction

RESERVED FOR PRESCRIBING BY ONCOLOGY , HEMATOLOGY AND RHEUMATOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

#### Coverage Duration

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### Other Criteria

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## SABRIL

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### **Drugs**

**SABRIL ORAL TABLET**, *vigabatrin*, *vigadrone*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTED FAILURE ON TWO OTHER FORMULARY SEIZURE MEDICATIONS SUCH AS CARBAMAZEPINE, DIVALPROEX, LEVETIRACETAM, GABAPENTIN, TOPIRAMATE, AND OTHERS.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGIST

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **SEROSTIM**

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### **Drugs**

**SEROSTIM SUBCUTANEOUS RECON SOLN 4 MG, 5 MG, 6 MG**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DOCUMENTATION THAT OTHER THERAPIES HAVE PROVEN INEFFECTIVE FOR HIV-INFECTED PATIENTS DIAGNOSED WITH SIGNIFICANT WASTING.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **SIGNIFOR**

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### **Drugs**

#### **SIGNIFOR**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL: DOCUMENTATION OF BENEFICIAL RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

## SILDENAFIL

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### **Drugs**

*sildenafil (antihypertensive)*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

### **Required Medical Information**

(1) DIAGNOSIS OF VASOREACTIVE PULMONARY ARTERIAL HYPERTENSION (PAH) AS CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION AND TRIAL AND FAILURE OF CALCIUM CHANNEL BLOCKER THERAPY, OR (2) DIAGNOSIS OF NON-VASOREACTIVE PAH AS CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PULMONOLOGY OR CARDIOLOGY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES. THIS DRUG ALSO REQUIRES PAYMENT DETERMINATION.

## **SILIQ**

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### **Drugs SILIQ**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

MAY NOT USE SILIQ CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

#### **Required Medical Information**

PLAQUE PSORIASIS INITIAL CRITERIA: (1) DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS (AT LEAST 5% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS), AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND TREATMENT GOALS, AND (3) MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH COSENTYX AND TALTZ. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY DERMATOLOGY

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **SIMPONI**

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### **Drugs SIMPONI**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

MAY NOT USE SIMPONI CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

#### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND/OR FUNCTIONAL ASSESSMENT AND TREATMENT GOALS, AND (3) FOR RHEUMATOLOGY: MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH ENBREL AND HUMIRA, OR FOR GASTROENTEROLOGY: DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO HUMIRA. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY RHEUMATOLOGY AND GASTROENTEROLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## SOMATROPIN

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### Drugs

#### **NORDITROPIN FLEXPRO**

#### **Covered Uses**

ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

CRITERIA FOR CHILDREN: EITHER 1 OR 2 OR 3: (1) SHORT STATURE INITIAL: A) CURRENT HEIGHT IS 2.25 OR MORE STANDARD DEVIATIONS BELOW NORMAL, OR B) TARGET ADULT HEIGHT OF 2 OR MORE STANDARD DEVIATIONS BELOW MIDPARENTAL HEIGHT, OR C) HEIGHT VELOCITY OF MINUS 2 OR MORE STANDARD DEVIATIONS FOR AGE AND TANNER STAGE, AND D) GROWTH HORMONE (GH) PROVOCATIVE TESTING (GH PEAK LESS THAN 10 MG/ML), OR E) SERUM IGF LEVELS (IGF-1 OR IGFBP-3) LESS THAN 1 STANDARD DEVIATION BELOW NORMAL, OR F) IGF GENERATION TEST (STIMULATE LEVEL 3 TIMES BASELINE OR GREATER THAN 250MG/ML). (1) SHORT STATURE RENEWAL: A) DOCUMENTATION OF POSITIVE RESPONSE, AND B) GROWTH VELOCITY IS GREATER THAN OR EQUAL TO 2 CM/YEAR, AND C) PATIENT HAS NOT ACHIEVED MATURE BONE AGE (17 OR GREATER FOR BOYS OR 15 OR GREATER FOR GIRLS), (2) PANHYPOPITUITARISM, (3) DIAGNOSIS OF PRADER-WILLI, TURNER SYNDROME, OR NOONAN SYNDROME AND EPIPHYSES ARE NOT CLOSED. CRITERIA FOR ADULTS: PATIENT HAS GROWTH HORMONE DEFICIENCY (GHD) WITH 1 OR 2 AND 3 AND 4 AND 5 LISTED BELOW: (1) HISTORY OF HYPOTHALAMIC OR PITUITARY DISEASE OR HISTORY OF CRANIAL IRRADIATION, OR (2) LOW IGF-1 LEVELS BASED ON AGE ADJUSTED VALUES AND SERUM GROWTH HORMONE CONCENTRATION OF LESS THAN 5NG/ML (PEAK LEVELS) FOLLOWING STIMULATION TESTING. ITT (INSULIN TOLERANCE TEST) IS THE DIAGNOSTIC TEST OF CHOICE UNLESS CONTRAINDICATED, AND (3) COMPLETE PITUITARY HORMONE FUNCTION HAS BEEN TESTED AND REPLACED WHEN APPROPRIATE, AND (4) THREE OF THE FOLLOWING: A) ALTERED BODY COMPOSITION WITH INCREASED BODY FAT MASS AND DECREASED LEAN BODY MASS, OR B) DECREASED MUSCLE STRENGTH AND EXERCISE CAPACITY, OR C) REDUCED BONE DENSITY OR PRESENCE OF A FRAGILITY FRACTURE, OR D) POOR SLEEP, OR E) IMPAIRED SENSE OF WELL BEING, AND (5) SECONDARY MEDICAL ILLNESSES THAT AFFECT GH HAVE BEEN RULED OUT.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY ENDOCRINOLOGY

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.



## STELARA

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### **Drugs** **STELARA**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

MAY NOT USE STELARA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

#### **Required Medical Information**

PLAQUE PSORIASIS INITIAL CRITERIA: (1) (A) DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS (AT LEAST 5% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP, AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS), OR (B) PSORIATIC ARTHRITIS, AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND TREATMENT GOALS, AND (3) MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH COSENTYX. MODERATELY TO SEVERELY ACTIVE CROHNS DISEASE INITIAL: (1) DOCUMENTATED CONTRAINDICATION, INTOLERANCE TO, OR FAILURE ON 1 OF THE FOLLOWING: PREDNISONE OR A CORTICOSTEROID EQUIVALENT FOR 2 WEEKS, OR AN IMMUNOMODULATORY MED FOR 3 OR MORE MOS, AND (2) MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE TO HUMIRA. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY, OR THAT SIGNIFICANT PROGRESS TOWARD ACHIEVEMENT OF TREATMENT GOALS HAS OCCURRED.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY DERMATOLOGY, RHEUMATOLOGY, AND GASTROENTEROLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **SUBLINGUAL IMMUNOTHERAPY**

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### **Drugs**

**GRASTEK, RAGWITEK**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF TRIAL AND FAILURE OF SUBCUTANEOUS IMMUNOTHERAPY.

### **Age Restriction**

LIMITED TO THOSE AGES SPECIFIED WITHIN THE FDA-APPROVED LABEL

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY OR IN CONSULTATION WITH AN ALLERGIST OR IMMUNOLOGIST

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **SYNRIBO**

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### **Drugs**

#### **SYNRIBO**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION THAT DISEASE PROGRESSION HAS NOT OCCURRED

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## TADALAFIL

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### **Drugs**

*tadalafil (antihypertensive)*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1)(A) DIAGNOSIS OF VASOREACTIVE PULMONARY ARTERIAL HYPERTENSION (PAH) AS CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION AND TRIAL AND FAILURE OF CALCIUM CHANNEL BLOCKER THERAPY, OR (B) DIAGNOSIS OF NON-VASOREACTIVE PAH AS CONFIRMED BY PRETREATMENT RIGHT HEART CATHETERIZATION, AND (2) TRIAL AND FAILURE OF SILDENAFIL ORAL.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PULMONOLOGY OR CARDIOLOGY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

**Drugs**

**TALTZ AUTOINJECTOR, TALTZ SYRINGE**

**Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

**Exclusion Criteria**

MAY NOT USE TALTZ CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

**Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF: (A) MODERATE TO SEVERE PLAQUE PSORIASIS (AT LEAST 5% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS), OR (B) PSORIATIC ARTHRITIS, AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND TREATMENT GOALS, AND (3) MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH COSENTYX. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

**Age Restriction**

**Prescriber Restriction**

RESERVED FOR PRESCRIBING BY DERMATOLOGY AND RHEUMATOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY

**Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

**Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## THALASSEMIA AGENTS

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### **Drugs**

**EXJADE, FERRIPROX, JADENU, JADENU SPRINKLE**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY HEMATOLOGY AND ONCOLOGY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **THIOLA**

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### **Drugs**

**THIOLA**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGY OR NEPHROLOGY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## TREMFYA

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### **Drugs**

#### **TREMFYA**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

MAY NOT USE TREMFYA CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

#### **Required Medical Information**

PLAQUE PSORIASIS INITIAL CRITERIA: (1) DIAGNOSIS OF MODERATE TO SEVERE PLAQUE PSORIASIS (AT LEAST 5% BODY SURFACE AREA, OR PRESENTATION IN PALMAR, PLANTAR, FACIAL, SCALP AND/OR GENITAL REGIONS, OR PUSTULAR PSORIASIS), AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND TREATMENT GOALS, AND (3) MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH COSENTYX. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY DERMATOLOGY

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.



## **TRICYCLIC ANTIDEPRESSANTS IN ELDERLY**

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### **Drugs**

*amitriptyline, doxepin oral, imipramine hcl, trimipramine*

### **Covered Uses**

ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: DIAGNOSIS OF A MEDICALLY ACCEPTED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND DOCUMENTATION THAT THE PATIENT IS MONITORED FOR ADVERSE DRUG EVENTS.

### **Age Restriction**

RESTRICTIONS APPLY TO PATIENTS GREATER THAN 64 YEARS OF AGE.

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## TRIENTINE

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### **Drugs**

*trientine*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF WILSON'S DISEASE AND (2) DEMONSTRATED INTOLERANCE TO PENICILLAMINE. RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY PROVIDERS SPECIALIZING IN GENETICS AND METABOLISM, GASTROENTEROLOGY, AND HEPATOLOGY WITHIN THE SCOPE OF THE APPLICABLE PRESCRIBER SPECIALTY.

### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF POSITIVE RESPONSE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **TYMLOS**

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### **Drugs**

#### **TYMLOS**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF POSTMENOPAUSAL OSTEOPOROSIS AT HIGH RISK FOR FRACTURE DEFINED AS A HISTORY OF OSTEOPOROTIC FRACTURE OR MULTIPLE RISK FACTORS FOR FRACTURE, OR (2) POSTMENOPAUSAL OSTEOPOROSIS AND (A) INTOLERANCE TO, FAILURE WITH, OR CONTRAINDICATION TO BISPHOSPHONATE THERAPY.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## **TYSABRI**

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### **Drugs**

#### **TYSABRI**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

#### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) FOR NEUROLOGY: DOCUMENTED FAILURE WITH ONE PREFERRED AGENT, SUCH AS AUBAGIO, AVONEX, GLATIRAMER 40MG, EXTAVIA, GILENYA, GLATOPA 20MG, GLATIRAMER 20MG, PLEGRIDY, REBIF, OR TECFIDERA, OR FOR GASTROENTEROLOGY: DOCUMENTATION OF AN INADEQUATE RESPONSE TO CONVENTIONAL THERAPY, SUCH AS MERCAPTOPURINE, AZATHIOPRINE OR METHOTREXATE, OR WITH MEDICAL NECESSITY FOR EARLIER USE OF TYSABRI.

#### **Age Restriction**

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGY AND GASTROENTEROLOGY

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## VALCHLOR

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### Drugs

#### VALCHLOR

### Covered Uses

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### Exclusion Criteria

### Required Medical Information

INITIAL CRITERIA FOR NEW START PATIENTS: (1) FOR THE TOPICAL TREATMENT OF STAGE 1A OR 1B MYCOSIS FUNGOIDES-TYPE CUTANEOUS T-CELL LYMPHOMA IN PATIENTS WHO HAVE RECEIVED PRIOR SKIN-DIRECTED THERAPY. RENEWAL CRITERIA: DOCUMENTATION OF BENEFICIAL RESPONSE

### Age Restriction

### Prescriber Restriction

### Coverage Duration

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### Other Criteria

APPROVALS ARE LIMITED TO A QUANTITY OF TWO 60 GRAM TUBES PER MONTH.

## VIEKIRA

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### **Drugs**

**TECHNIVIE, VIEKIRA PAK, VIEKIRA XR**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT, AND (3) DOCUMENTED CLINICAL INAPPROPRIATENESS OF OR INABILITY TO TOLERATE HARVONI, EPCLUSA, OR MAVYRET.

### **Age Restriction**

RESERVED FOR PATIENTS AGE 18 AND OLDER.

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

### **Coverage Duration**

DURATION PER GENOTYPE AND DIAGNOSIS. 12-24 WEEKS PER FDA APPROVED LABELING OR CLINICAL GUIDELINES.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## VIRAZOLE

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### **Drugs**

*ribavirin inhalation*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, OR (2) FOR TREATMENT OF RESPIRATORY SYNCYTIAL VIRUS INFECTION FOLLOWING STEM CELL TRANSPLANT.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## VORAXAPAR

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### **Drugs**

#### **ZONTIVITY**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO CONCOMITANT ASPIRIN AND CLOPIDOGREL.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**



## VOSEVI

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### **Drugs** **VOSEVI**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF HEPATITIS C GENOTYPE AND BASELINE VIRAL LOAD, PROVIDER ATTESTATION OF READINESS TO TREAT, PATIENT ATTESTATION OF READINESS FOR TREATMENT, AND SUBMISSION OF VIROLOGIC RESPONSE UPON COMPLETION OF TREATMENT.

#### **Age Restriction**

RESERVED FOR PATIENTS AGE 18 AND OLDER.

#### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY, HEPATOLOGY, INFECTIOUS DISEASE SPECIALISTS, OR TRANSPLANT SPECIALIST.

#### **Coverage Duration**

12 WKS PER DIAGNOSIS, FDA LABELING OR CLINICAL GUIDELINES.

#### **Other Criteria**

DOSE IS LIMITED TO THE FDA-APPROVED REGIMEN OF ONE TABLET DAILY.

## **XATMEP**

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### **Drugs**

#### **XATMEP**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

FOR NEW START PATIENTS: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION THAT THE PATIENT HAS DIFFICULTY SWALLOWING OR HAS COMPLIANCE CONCERNS WITH METHOTREXATE TABLETS OR INJECTION.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

THIS DRUG MAY BE COVERED UNDER MEDICARE PART B OR PART D DEPENDING ON THE CIRCUMSTANCES. INFORMATION MAY NEED TO BE SUBMITTED DESCRIBING THE USE OF THE DRUG AND SETTING WHERE THE DRUG IS DISPENSED TO MAKE THE PART B OR PART D COVERAGE DETERMINATION.

## **XELJANZ**

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### **Drugs**

**XELJANZ, XELJANZ XR**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

MAY NOT USE XELJANZ CONCURRENTLY WITH OTHER BIOLOGIC THERAPIES.

### **Required Medical Information**

INITIAL CRITERIA: (1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) MEDICAL CHART DOCUMENTATION OF BASELINE DISEASE ACTIVITY AND/OR FUNCTIONAL ASSESSMENT AND TREATMENT GOALS, AND (3) FOR RHEUMATOID ARTHRITIS AND PSORIATIC ARTHRITIS: MEDICAL CHART DOCUMENTATION OF CONTRAINDICATIONS OR INADEQUATE RESPONSE WITH ENBREL AND HUMIRA, OR FOR ULCERATIVE COLITIS: DOCUMENTATION OF MEDICAL CONTRAINDICATIONS OR INADEQUATE RESPONSE TO HUMIRA. RENEWAL CRITERIA: MEDICAL CHART DOCUMENTATION THAT TREATMENT GOALS HAVE BEEN MET FOR THERAPY.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY RHEUMATOLOGY OR GASTROENTEROLOGY.

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **XENAZINE**

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### **Drugs**

*tetrabenazine*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D.

RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE TO THERAPY.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY NEUROLOGY.

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF POSITIVE RESPONSE.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## **XERMELO**

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### **Drugs**

**XERMELO**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION OF POSITIVE RESPONSE.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

## **XGEVA**

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### **Drugs XGEVA**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

(1) FOR PREVENTION OF SKELETAL-RELATED EVENTS IN PATIENTS WITH BONE METASTASES FROM SOLID TUMORS WITH INADEQUATE RESPONSE OR MEDICAL CONTRAINDICATION TO ZOLEDRONIC ACID, OR (2) FOR TREATMENT OF ADULTS AND SKELATALLY MATURE ADOLESCENTS WITH GIANT CELL TUMOR OF BONE THAT IS UNRESECTABLE OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY, OR (3) DIAGNOSIS OF HYPERCALCEMIA OF MALIGNANCY REFRACTORY TO BISPHOSPHONATE THERAPY.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

## **XIFAXAN**

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### **Drugs**

#### **XIFAXAN**

### **Covered Uses**

ALL MEDICALLY ACCEPTED INDICATIONS NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF HEPATIC ENCEPHALOPATHY AND DOCUMENTATION THAT SIDE EFFECTS HAVE LIMITED THE DOSE OF LACTULOSE, OR (2) DIAGNOSIS OF TRAVELER'S DIARRHEA AND DOCUMENTATION OF TRIAL AND FAILURE OF OR CONTRAINDICATIONS TO CIPROFLOXACIN, OR (3) DIAGNOSIS OF MODERATE TO SEVERE IRRITABLE BOWEL DISEASE, INCLUDING BLOATING, WITHOUT CONSTIPATION AND WITH (A) AN INADEQUATE RESPONSE TO FIRST LINE THERAPY INCLUDING AN ANTISPASMODIC AGENT SUCH AS DICYCLOMINE AND AN ANTIDIARRHEAL AGENT SUCH AS LOPERAMIDE OR DIPHENOXYLATE/ATROPINE.

### **Age Restriction**

### **Prescriber Restriction**

RESERVED FOR PRESCRIBING BY GASTROENTEROLOGY FOR TREATMENT OF IRRITABLE BOWEL DISEASE

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

IRRITABLE BOWEL DISEASE: DOSE IS LIMITED TO 550 MG THREE TIMES DAILY FOR 14 DAYS. RETREATMENT IS LIMITED TO PATIENTS WITH A POSITIVE RESPONSE AND LIMITED TO A MAXIMUM OF TWO, 14 DAY TREATMENTS.

## XOLAIR

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### **Drugs**

#### **XOLAIR**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

PATIENT MUST NOT HAVE AN FDA-LABELED LIMITATION OF USE OR CONTRAINDICATION TO THERAPY.

#### **Required Medical Information**

DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (1) FOR ASTHMA: DOCUMENTATION OF FAILURE WITH AT LEAST TWO OF THE FOLLOWING STANDARD THERAPIES: (A) REGULAR USE OF INHALED STEROIDS (SUCH AS FLOVENT), (B) REGULAR USE OF A LONG-ACTING BETA-AGONIST (SUCH AS SEREVENT), (C) REGULAR USE OR A TRIAL OF A LEUKOTRIENE ANTAGONIST (SUCH AS MONTELUKAST), AND (D) REGULAR OR PERIODIC USE OF ORAL STEROIDS (SUCH AS PREDNISONE), OR (2) FOR CHRONIC URTICARIA: SYMPTOMS FOR LONGER THAN 6 MONTHS, AND DOCUMENTATION OF FAILURE WITH AT LEAST TWO OF THE STANDARD THERAPIES: (A) AN H1 ANTIHISTAMINE (SUCH AS LEVOCETIRIZINE), (B) AN H2 ANTIHISTAMINE (SUCH AS FAMOTIDINE), (C) LEUKOTRIENE ANTAGONIST (SUCH AS MONTELUKAST), AND (D) MULTIPLE COURSES OF OR DEPENDENT ON AN ORAL STEROID (SUCH AS PREDNISONE).

#### **Age Restriction**

#### **Prescriber Restriction**

FOR CHRONIC URTICARIA: RESERVED FOR PRESCRIBING BY AN ALLERGIST, IMMUNOLOGIST, OR DERMATOLOGIST.

#### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.



## **XTANDI**

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### **Drugs**

#### **XTANDI**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

#### **Required Medical Information**

INITIAL CRITERIA FOR NEW START PATIENTS: (1) DIAGNOSIS OF METASTATIC CASTRATION-RESISTANT PROSTATE CANCER, AND (2) PRIOR TREATMENT WITH ABIRATERONE (ZYTIGA) WITH NEW DISEASE PROGRESSION OR IN CASES WHERE ABIRATERONE REGIMENS ARE CONTRAINDICATED OR NOT TOLERATED. RENEWAL CRITERIA: DOCUMENTATION OF NO DISEASE PROGRESSION AND NO NEW CHEMOTHERAPY REGIMENS. FAILURE IS DEFINED AS SYMPTOMS OF PROGRESSIVE DISEASE OR A SUSTAINED INCREASE IN PSA OF 25-30% OVER AT LEAST TWO MONTHS.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## ZALTRAP

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### **Drugs**

#### **ZALTRAP**

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

INITIAL CRITERIA FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION THAT DISEASE PROGRESSION HAS NOT OCCURRED.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

THREE MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.

## ZYFLO

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### **Drugs**

*zileuton*

### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

### **Exclusion Criteria**

### **Required Medical Information**

(1) DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D, AND (2) DOCUMENTATION OF FAILURE WITH MONTELUKAST.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

CONTRACT YEAR, BALANCE OF CONTRACT YEAR, OR FDA-APPROVED DURATION, WHICHEVER IS APPLICABLE FOR USE.

### **Other Criteria**

## ZYTIGA

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### **Drugs** **ZYTIGA**

#### **Covered Uses**

ALL FDA-APPROVED INDICATIONS, NOT OTHERWISE EXCLUDED FROM PART D.

#### **Exclusion Criteria**

#### **Required Medical Information**

INITIAL CRITERIA FOR NEW START PATIENTS: DIAGNOSIS OF AN FDA-APPROVED INDICATION, NOT OTHERWISE EXCLUDED FROM PART D. RENEWAL CRITERIA: DOCUMENTATION THAT (1) DISEASE PROGRESSION HAS NOT OCCURRED, AND (2) NO OTHER CHEMOTHERAPY REGIMENS HAVE BEEN INITIATED. FAILURE IS DEFINED AS SYMPTOMS OF PROGRESSIVE DISEASE OR A SUSTAINED INCREASE IN PSA OF 25-30% OVER AT LEAST TWO MONTHS.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

SIX MONTHS, THEN BALANCE OF CONTRACT YEAR IF RENEWAL CRITERIA ARE MET.

#### **Other Criteria**

LIMITED TO A DOSE WITHIN THE FDA LABELED DOSING GUIDELINES.



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