Pharmacy Management Drug Policy

SUBJECT: Clinical Review Prior Authorizations (CRPA) Rx
POLICY NUMBER: PHARMACY-09
EFFECTIVE DATE: 12/2004
LAST REVIEW DATE: 12/10/2024

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

POLICY:

The drug Clinical Review Prior-Authorization (CRPA) process is designed to ensure that newly approved (FDA) prescription drugs are used appropriately in cases where a drug poses potential efficacy, quality, toxicity, or utilization concerns for the members and the Health Plan. In addition, this policy may be used for medications that have significant concerns about safety or inappropriate use, but do not warrant a stand-alone policy. The Pharmacy Management clinical team reviews the drugs falling into these categories under the process of Clinical Review Prior Authorization (CRPA).
A Letter of Medical Necessity (LOMN), Exception Form, or Prior Authorization Form completion is required for consideration of drug coverage under this policy.

In addition, certain medications that are used primarily for cosmetic purposes and prescription homeopathic products are maintained on the CRPA list.

Abilify Mycite – aripiprazole tablets with sensor
1. Must have a diagnosis of Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder. 2. Must have attempted to use generic aripiprazole tablets with non-compliance documented in prescriber notes. Prescriber notes must also document the prescriber's attempted medication adherence counseling. 3. Must have had serious side effects or drug failure with long-acting injectable Abilify Maintena or have a medical reason why a long-acting injectable would not be appropriate 4. The prescriber must attest other atypical antipsychotics (such as risperidone, olanzapine, ziprasidone, quetiapine, and paliperidone ER) would not be as effective as aripiprazole or would be expected to cause similar compliance issues experienced with standard aripiprazole tablets. 5. Approval will be for 3 months. Recertification will require prescriber notes to confirm the patient has had an improvement in compliance and response to treatment. 6. Quantity limit: 30 per 30 days 7. Please note: FDA labeling states the ability of Abilify Mycite to improve patient compliance or modify aripiprazole dosage has not been established.
Absorica and isotretinoin 25 mg and 35 mg capsules and Absorica LD,
1. Must have a diagnosis of severe acne 2. Must have had serious side effects or drug failure with at least two different generic isotretinoin products (such as isotretinoin 10 mg, 20 mg, 30 mg, or 40 mg capsules, Amnesteem, Claravis, Myorisan, or Zenatane). 3. Requests for 25 mg or 35 mg strengths of isotretinoin or Absorica or Absorica LD will require a trial of the closest higher strength generic isotretinoin product (available as 10 mg, 20 mg, 30 mg, and 40 mg) that was effective but resulted in side effects.
Accrufer - ferric maltol capsules
1. Must be 18 years of age or older **AND** 2. Must have diagnosis of iron deficiency a. Must have a hemoglobin <12.0 g/dL for women and <13.0 g/dL for men **OR** b. Must have serum ferritin < 30 ug/L **AND** 3. Must have serious side effect or drug failure with at least two oral iron products that contain different salt formulations (i.e., ferrous sulfate, ferrous fumarate, ferrous gluconate). 4. Quantity Limit: 60 capsules/30 days
Aciphex Sprinkle - rabeprazole sprinkle capsules
1. Must be prescribed for a diagnosis of GERD 2. Must be between the ages of 1 and 11 3. Must have had a trial of both generic lansoprazole and omeprazole capsules (both of which can be opened and sprinkled) 4. Will not be authorized for individuals aged 12 or older. 5. Quantity limit of 60 per 30 days.

Acticlate and generic doxycycline hyclate tablets
1. Must have a diagnosis of severe acne that requires oral therapy 2. Must be prescribed by a dermatologist 3. Must have experienced failure or intolerance to at least one topical retinoid (tretinoin, adapalene, tazarotene) 4. Must have experienced failure or intolerance to generic minocycline 5. Must have an inability to swallow other forms of generic doxycycline (such as doxycycline monohydrate and doxycycline hyclate capsules) 6. Must be used in combination with topical therapy (benzoyl peroxide and/or retinoid) 7. Quantity limit of 30 tablets per 30 days 8. Initial approval will be for 12 weeks Recertification criteria: To limit antibiotic resistance, patients should not use oral antibiotics chronically. The following criteria are based on guidelines set forth by the Global Alliance to Improve Outcomes in Acne and the American Academy of Dermatology. 1. Patients should continue the use of a topical therapy to maintain remission of new acne lesions when antibiotic therapy is discontinued. 2. Patient progress notes documenting a flare in symptoms will need to be submitted for review by the clinical staff. 3. If patients have a flare of inflammatory lesions after the initial 12-week course, then they will be allowed to retreat as long as they have been using a topical maintenance therapy. Retinoids are the preferred maintenance agent or as an alternative, a combination of benzoyl peroxide and a topical antibiotic is acceptable. 4. Recertification will be approved for one year.
Addyi – flibanserin tablets
1. Must be prescribed by a gynecologist, psychiatrist, or psychiatric nurse practitioner 2. Must be a premenopausal Woman 3. Must have a diagnosis of Hypoactive Sexual Desire Disorder (HSDD) confirmed by Decreased Sexual Desire Screener (DSDS) by answering YES to **ALL** the following questions: a. In the past, was their level of sexual desire or interest good and satisfying? b. Has there been a decrease in their level of sexual desire or interest? c. Are they bothered by the decreased level of sexual desire or interest? d. Would they like their level of sexual desire or interest to increase? e. Have they been assessed for other factors that may be contributing to their current decrease in sexual desire or interest (including an operation, depression, injuries, other medical condition, medication, current drug or alcohol use, pregnancy, recent childbirth, menopausal symptoms, other sexual issues, partner's sexual problems, dissatisfaction with relationship or partner, stress, or fatigue)? 4. Must not have a history of alcohol abuse or overuse. 5. Must not be on any concurrent strong or moderate CYP3A4 inhibitors 6. Must not have hepatic impairment 7. Progress notes provided from the specialists required above are required for all Addyi requests. Cases received without progress notes cannot be approved 8. Initial approval will be for 8 weeks. Continuation of therapy will require the following: a. Provider must acknowledge that the patient has been evaluated for serious side effects b. Provider must acknowledge that the patient reports increased sexual desire and satisfying events as a result of drug therapy c. Recertification approval will be for 1 year at a time. 9. Quantity limit of 30 tablets per 30 days

Airsupra – albuterol/budesonide inhaler

1. Based on comparable indications, efficacy, and safety profile, the member will be required to use a budesonide/formoterol formulation (such as Breyna) unless there is adequate justification as to why a budesonide/formoterol formulation cannot be used
2. Please see the Quantity Limit Policy (Pharmacy-43) for specific quantity limitations for this product.

Aklief – trifarotene cream

1. Must be used for a diagnosis of acne vulgaris
2. Must have had serious side effects or drug failure with 2 generic topical retinoids (such as tretinoin and adapalene)
3. Will not be covered for any non-FDA approved indication or diagnosis
4. Quantity Limit of 45 grams per 30 days

Alkindi Sprinkle – hydrocortisone oral granule

1. Must be used as replacement therapy in pediatric patients with adrenocortical insufficiency
2. There must be documentation of serious side effects or drug failure to TWO of the following preferred alternatives: hydrocortisone tablets, cortisone acetate, prednisone, methylprednisolone, prednisolone, and dexamethasone
3. Alkindi Sprinkle is only FDA approved for pediatric patients with adrenocortical insufficiency and will not be covered for any non-FDA approved indication or diagnosis
4. Quantity limit is 30 granules per 30 days. Approval for increased quantity will be based on FDA approved dosing recommendations.

Allopurinol 200 mg tablets

1. The health plan has determined that allopurinol 200 mg is not medically necessary due to availability of lower costing allopurinol products strengths that allow for equivalent dosing and are likely to produce equal therapeutic results
2. Quantity limit: 30 tablets per 30 days
    a. Additional quantities will be approved for FDA-approved dosing

Alvaiz - eltrombopag tablets

1. Must be prescribed by a hematologist **AND**
2. Must have a diagnosis of immune (idiopathic) thrombocytopenia purpura (ITP) **AND**
    a. Must have a current platelet count less than 30 x 10^9/L **AND**
    b. Must have had an insufficient response (defined as a platelet count of less than 30 x 10^9/L, or greater but with bleeding symptoms) to corticosteroids OR immunoglobulins (IVIG)
        i. Patients who are dependent on corticosteroids (i.e., the need for continuous use or the need for frequent courses) to maintain a platelet count of ≥ 30 x 10^9/L will not require documentation of an insufficient response to corticosteroids as defined above **OR**
3. Must have a diagnosis of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy **OR**
4. Must have a diagnosis of severe aplastic anemia **AND**
    a. Diagnosis of severe aplastic anemia must be documented by:
        i. A marrow biopsy showing <25 percent of normal cellularity **OR**
        ii. A marrow biopsy showing <50 percent normally cellularity in which <30 percent of the cells are hematopoietic and at least two of the following are present: absolute reticulocyte count <40,000/microL, absolute neutrophil count (ANC) <500/microL, or platelet count <20,000/microL **AND**
    b. Must have had an insufficient response to immunosuppressive therapy
5. Alvaiz should not be used to normalize platelet counts
6. Quantity limit is 30 tablets per 30 days
    a. Approved requests for FDA approved indications that require 108 mg dosing will be approved with a quantity authorization to allow two 54 mg tablets per day
    b. Requests above the quantity limit will be reviewed for medical necessity **AND** reviewed to require

the most cost-efficient dose available for the quantity requested
Amrix, Fexmid and equivalent generic cyclobenzaprine
1. Member must have had severe intolerance or therapeutic failure of generic cyclobenzaprine 5 or 10mg three times a day 2. Member must have had severe intolerance or therapeutic failure of two other muscle relaxants (such as carisoprodol, baclofen, tizanadine, methocarbamol, orphenadrine and Skelaxin) 3. Amrix and Fexmid should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available and because muscle spasm associated with acute, painful musculoskeletal conditions is generally of short duration and specific therapy for longer periods is seldom warranted. Based on this a quantity limit of 21 pills per 90 days will be imposed on Amrix and 189 pills per 90 days will be imposed on Fexmid.
Antara, fenofibrate 30 mg, 40 mg, 50 mg, 90 mg, 120 mg, 130 mg, 150 mg, fenofibric acid 35 mg, 105 mg, Fibricor, Fenoglide and Lipofen
1. The health plan has determined that Antara, fenofibrate 30 mg, 40 mg, 50 mg, 90 mg, 120 mg, 130 mg, 150 mg, fenofibric acid 35 mg, 105 mg, Fibricor, Fenoglide and Lipofen are not medically necessary due to availability of lower costing fenofibrate containing products that are likely to produce equal therapeutic results.
Aplenzin – bupropion hydrobromide ER tablets
1. Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use the lower cost generic alternatives such as bupropion HCl SR, bupropion HCl XL 150 mg, bupropion HCl XL 300 mg, escitalopram, fluoxetine, citalopram, sertraline, paroxetine, mirtazapine, and venlafaxine unless the patient has tried and failed or had severe intolerance to all lower cost alternatives. 2. Quantity limit of 30 tablets per 30 days.
Apokyn and apomorphine hydrochloride injection
1. Must be prescribed by a neurologist 2. Must have a diagnosis of Parkinson's disease 3. Must be experiencing "off" episodes ("wearing off symptoms") 4. Must be currently taking oral carbidopa/levodopa 5. Must have attempted increasing the dose and dosing frequency of oral carbidopa/levodopa 6. Must have attempted two other treatments used for "off" episodes from two different medication classes: a. Catechol-O-methyl transferase (COMT) inhibitors (such as entacapone and tolcapone) b. Oral dopamine agonists (such as pramipexole and ropinirole) c. Monoamine oxidase type B (MAO B) inhibitors (such as rasagiline and selegiline) 7. Requests for brand name Apokyn will require documentation of use of generic apomorphine injection that led to serious side effects or drug failure 8. Quantity Limit: 30 mL/30 days (1 mL [10 mg] per day) a. The recommended starting dose is 0.2 mL (2 mg) per dose with a max of 0.6 mL (6 mg) per dose b. Due to limited experience, dosing of Apokyn more than 5 times per day and with total daily doses greater than 2 mL (20 mg) is not recommended. c. Based on the maximum recommended dosing, patients who need more than 10 mg per day will be considered for approval up to 20 mg per day (60 mL/30 days) when clinically justified
Arazlo (tazarotene lotion), Fabior (tazarotene foam), and generic tazarotene foam
1. Must be used for a diagnosis of acne 2. Must be prescribed by a dermatologist 3. Must have had previous trial and failure or intolerance to tretinoin and adapalene 4. Quantity limit for Arazlo lotion is 45 grams per 30 days. 5. Quantity limit for Fabior and tazarotene foam is 100 grams per 30 days.

Arikayce – liposomal amikacin for inhalation

1. Must be 18 years of age or older
2. Must be prescribed by an infectious disease specialist or pulmonologist
3. Must have a diagnosis of Mycobacterium avium complex (MAC) lung disease as confirmed by a MAC-positive sputum culture
4. Must have a positive sputum culture obtained after at least 6 months of compliant use of a multi-drug regimen for MAC lung disease such as clarithromycin (or azithromycin), rifampin, and ethambutol
5. Arikayce must be used as part of a multi-drug regimen and will not be approved for use as a single agent
6. Initial approval will be for 6 months. Recertification will require a negative sputum culture obtained within the last 30 days of recertification. Recertification will be approved for 1 year
7. The ATS/IDSA guidelines state that patients should continue to be treated until they have negative cultures for 1 year. Treatment beyond the first recertification approval (after 18 months) will require documentation of a positive sputum culture to demonstrate the need for continued treatment. Patients that have had negative cultures for 1 year will not be approved for continued treatment.
8. Quantity limit: 236 mL per 28 days

Aspruzyo sprinkle – ranolazine granule

1. Must be 18 years of age or older
2. Must have a diagnosis of chronic angina
3. Must have an inability to swallow whole tablets (such as using an NG/G tube, or a swallowing disorder) with documentation of inability to swallow provided
4. Quantity limit of 60 sachets per 30 days

Astagraf XL – tacrolimus ER24H capsules

1. Must be prescribed for post kidney transplant for organ rejection prophylaxis **AND**
2. Must have documentation of treatment failure (defined as severe and unmanageable side effects or previous graft rejection) while on generic tacrolimus.
3. Astagraf XL has not been studied in heart, liver, or other organ transplant and therefore will not be covered.
4. Quantity limit of 90 capsules per 30 days for 0.5mg capsules, 120 capsules per 30 days for 1mg capsules, and 180 capsules per 30 days for 5 mg capsules

Austedo and Austedo XR– deutetrabenazine and deutetrabenazine extended-release tablets

1. Patient must have a diagnosis of chorea associated with Huntington's Disease
   a. Must be 18 years of age or older
   b. Must be prescribed by a neurologist
   c. Diagnosis of Huntington's disease is confirmed by genetic testing (i.e., expanded *HTT* CAG repeat sequence ≥ 36) **OR**
2. Must have a diagnosis of tardive dyskinesia
   a. Must be 18 years of age and old
   b. Must have a diagnosis of tardive dyskinesia defined as a history of ≥ 3 months (or ≥ 1 month in patients over 60 years of age) total cumulative neuroleptic exposure (continuous or discontinuous), presence abnormal involuntary movements in one or more body areas, and absence of other conditions that might produce abnormal involuntary movements.
   c. Must be prescribed by or in consultation with a neurologist, psychiatrist, or psychiatric nurse practitioner.
   d. Must have attempted an alternative method to manage the condition (such as dose reduction or discontinuation of the offending medication).
3. Austedo will not be covered in combination with Xenazine or generic tetrabenazine
4. Austedo will not be covered for any non-FDA approved indications
5. Initial approval will be for 6 months. Recertification will be for 12 months and require documentation of the following:

a. For Huntington's Disease: symptom improvement and/or stabilization of disease
b. For tardive dyskinesia: symptom improvement

6. Quantity limit as follows:
   a. Austedo 6 mg tablets: 60 tablets per 30 days, Austedo 9 mg tablets: 120 tablets per 30 days, Austedo 12 mg tablets: 120 tablets per 30 days
   b. Austedo XR 6 mg tablets: 30 tablets per 30 days, Austedo XR 12 mg tablets: 30 tablets per 30 days, Austedo XR 18 mg tablets: 30 tablets per 30 days, Austedo XR 24 mg tablets: 60 tablets per 30 days, Austedo XR 30 mg tablets: 30 tablets per 30 days, Austedo XR 36 mg tablets: 30 tablets per 30 days, Austedo XR 42 mg: 30 tablets per 30 days, Austedo XR 48 mg: 30 tablets per 30 days
   c. Austedo XR titration kit: 28 tablets per 28 days

Auvelity - dextromethorphan hydrobromide/bupropion hydrochloride tablets

1. Must be 18 years of age or older **AND**
2. Must be prescribed by or in consultation with a neurologist, psychiatrist, or psychiatric nurse practitioner
3. Must have a diagnosis of major depressive disorder (MDD) **AND**
4. Must have drug failure with bupropion without any serious side effects **AND**
5. Must have serious side effects or drug failure with at least TWO other antidepressants from different drug classes **AND**
6. All medications must be taken compliantly based on pharmacy fill history and each trial must last a sufficient period of time (usually 4-6 weeks) and must be tried at the maximum dose or the maximumly tolerated dose
7. Auvelity will not be covered for any other non-FDA approved indication
8. Quantity limit: 60 tablets per 30 days

Azasan and azathioprine 75 mg and 100 mg tablets

1. Based on comparable indications, efficacy, safety profiles, and available strength that allows for equivalent dosing, the patient will be required to use generic azathioprine 50 mg tablets unless there is adequate justification as to why this formulation is not appropriate.
2. Quantity limit: 30 tablets/30 days. Additional quantities will be granted based on FDA-approved dosing.

Baclofen 15 mg tablets

1. The health plan has determined that baclofen 15 mg tablet is not medically necessary due to the availability of lower costing options that are likely to produce equal therapeutic results.

Bonjesta, Diclegis, and generic doxylamine/pyridoxine tablets

1. Must be used for pregnancy-induced nausea and vomiting.
2. Must have had trial and failure of an OTC antihistamine (doxylamine, diphenhydramine, meclizine), or pyridoxine.
3. Requests for brand name Bonjesta or Diclegis will require documentation of use of generic doxylamine/pyridoxine tablets that led to serious side effects or drug failure.
4. Bonjesta quantity limit is 60/30. Diclegis quantity limit is 120/30. Approval will be for 120 days.

Brexafemme – ibrexafungerp tablets

The following criteria applies to the following formulary IDs: 2950, 3295, 5574, 5578, 5576

1. Prior to initiation of treatment the provider must attest that the patient is not currently pregnant and will use effective contraception or be unable to get pregnant while on therapy **AND**
2. For treatment of vulvovaginal candidiasis (VVC), must have serious side effects or drug failure to oral fluconazole **AND**
   a. Approval will be granted for 2 years **OR**
      i. For use in reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) the following criteria must be met:
   b. Must have had at least three episodes of vulvovaginal candidiasis (VVC) within the past 12 months **AND**

c. Current VVC episode must have a positive potassium hydroxide (KOH) test **AND**
d. Must have clinical signs and symptoms associated with VVC (redness, swelling, itching, burning, etc.) **AND**
e. Must have experienced a recurrence during or following 6 months of oral fluconazole maintenance treatment, or patient has a contraindication to fluconazole (e.g., hypersensitivity or drug-drug interaction) **AND**
f. Approval will be for 6 months to allow for a single course of treatment. Recertification will not be granted due to lack of long-term safety and efficacy data

3. Quantity Limit: 4 tablets per 30 days

Bronchitol – mannitol inhalation powder

1. Must be 18 years of age or older
2. Quantity limit of 560 capsules per 28 days.

Cabtreo - clindamycin phosphate 1.2%, adapalene 0.15% and benzoyl peroxide 3.1%

1. Must have a diagnosis of moderate to severe acne
2. Must be 12 years of age or older
3. Must be prescribed by a dermatologist
4. Based on comparable indications, efficacy, safety profiles, and similar strengths of generic adapalene, clindamycin, and benzoyl peroxide, the member will be required to use generic adapalene, clindamycin and benzoyl peroxide as separate products or as generic combination products (such as benzoyl peroxide/clindamycin) unless they have tried generic adapalene, clindamycin and benzoyl peroxide as separate products in combination and have a valid medical reason for requiring combination therapy
5. Initial approval will be for 3 months. Recertification will require documentation of improvement in symptoms while on Cabtreo therapy
6. Quantity limit of 50 grams per 30 days.

Carac and generic fluorouracil 0.5% cream

1. The member must have a diagnosis of actinic keratosis
2. Must be 18 years of age or older
3. Must have had serious side effects or drug failure with imiquimod **AND** at least one of the following: fluorouracil 5% cream, fluorouracil 2% topical solution or fluorouracil 5% topical solution
4. Approval will be for 4 weeks

Carbinoxamine 6 mg and Ryvent tablets

1. The member must have had drug failure or serious side effects or drug failure with carbinoxamine 4 mg, clemastine, and diphenhydramine
2. Quantity limit of 120 tablets per 30 days

Cardizem CD 360 mg and diltiazem CD 360 mg capsules

1. Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use the lower cost generic alternatives such as diltiazem LA and diltiazem ER unless there is adequate justification as to why these formulations are not appropriate. In addition, there must be documentation of serious side effects or drug failure of diltiazem CD 180 mg (daily dose of 360 mg diltiazem CD may be obtained by ordering diltiazem CD 180 mg capsules, taken as 2 capsules once daily)

Chlorzoxazone 250 mg tablets

1. Must have had a trial of generic chlorzoxazone 500mg which resulted in clinical effectiveness but also significant drowsiness causing impairment of activities of daily living
2. Patient must have had severe intolerance or therapeutic failure of at least two other muscle relaxants in addition to chlorzoxazone (such as cyclobenzaprine, baclofen, tizanidine, methocarbamol, orphenadrine)
3. Quantity limit of 120/30

Citalopram 30 mg capsules
1. Based on comparable indications, efficacy, safety profiles, and available strengths that allow for equivalent dosing, the patient will be required to use generic citalopram tablets or solution unless there is adequate justification as to why these formulations are not appropriate **AND** 2. If the member is unable to use generic citalopram tablets or solution, the member must try and fail or have severe intolerance to all lower cost generic alternatives such as escitalopram, fluoxetine, paroxetine, sertraline, and venlafaxine **AND** 3. Citalopram 30 mg capsules will not be authorized as initial citalopram treatment as the package labeling notes that another citalopram product must be used for initial dosage and titration 4. Quantity limit of 30 capsules per 30 days
Clemastine fumarate syrup
1. Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use other antihistamine alternatives (such as clemastine tablets, diphenhydramine, carbinoxamine, cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine) 2. If unable to use the above alternatives, the following criteria must be met: a. Clemastine fumarate syrup is being requested to treat allergic rhinitis or mild uncomplicated allergic skin manifestations of urticaria or angioedema **AND** b. Evidence of a swallowing disorder is provided documenting an inability to take clemastine tablets **AND** c. There is a clinically valid medical reason why **ALL** the following cannot be used: diphenhydramine, carbinoxamine, cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine 3. Quantity limit is 120 mL/30 days a. Additional quantities will be granted based on FDA-approved dosing
Clomipramine capsules
1. Must have a diagnosis of obsessive-compulsive disorder (OCD) 2. Must have experienced an inadequate treatment response, intolerance, or contraindication to **TWO** of the following: escitalopram, fluoxetine, fluvoxamine citalopram, sertraline, paroxetine, mirtazapine, and venlafaxine. 3. Any Non-FDA approved indications will be evaluated using our off-label criteria.
Cobenfy - xanomeline and trospium chloride
1. Must be 18 years of age or older **AND** 2. Must be prescribed by, or in consultation with, a mental health provider **AND** 3. Must have a confirmed diagnosis of schizophrenia **AND** 4. Must have documentation of serious side effects or drug failure with **TWO** generic atypical antipsychotics at maximally tolerated doses for at least 4 weeks 5. Quantity Limit: 60 capsules per 30 days for the 50mg/20mg, 100mg/20mg and 125mg/30mg capsules. 56 capsules per 28 days for the Starter Pack
Conjupri and levamlodipine tablets
1. Must be used alone or in combination with other antihypertensives to treat hypertension 2. Must be at least 6 years of age or older 3. Must have had peripheral edema with amlodipine use **AND** 4. Must have had drug failure to at least one other antihypertensive medication from a different drug class (beta-blocker, ACE-inhibitor, etc.) **AND** 5. Requests for brand name Conjupri will require documentation of use of generic levamlodipine tablets that led to serious side effects or drug failure 6. Quantity limit of 30 tablets per 30 days

Consensi – amlodipine/celecoxib tablets
1. The member must have a diagnosis of hypertension **AND** osteoarthritis 2. Must be 18 years of age or older 3. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic amlodipine and celecoxib, the member will be required to use generic amlodipine and celecoxib (as separate pills) unless there is adequate justification as to why these are not appropriate. 4. Quantity limit of 30 tablets per 30 days.
Cosmetic drugs **Including, but not limited to Avage, bimatoprost 0.03%, Brimonidine 0.33% gel, finasteride 1 mg, Latisse, lidocaine-tetracaine cream, Litfulo, Mirvaso, Pliaglis, Propecia, Refissa, Renova, Rhofade, tretinoin emollient cream 0.05%, Tri- Luma, Vaniqa**
1. Cosmetic drugs are drugs that are used to improve a patient's appearance and/or self-esteem. Cosmetic drugs are considered not medically necessary. 2. Examples of diagnoses considered cosmetic include (but not limited to): vitiligo, hirsutism, hypotrichosis, hyperpigmentation, alopecia, melasma, solar lentigines 3. A drug can be considered cosmetic either based on its FDA approved indication, compendia reference or off-label use support.
Cuvposa and glycopyrrolate oral solution
1. Must have a neurological disorder associated with drooling (such as cerebral palsy or intellectual disability) 2. Must be unable to swallow glycopyrrolate tablets 3. Requests for brand name Cuvposa will require documentation of use of generic glycopyrrolate oral solution that led to serious side effects or drug failure 4. Quantity limit of 1350 mL per 30 days
Cystaran and Cystadrops – cysteamine ophthalmic drops
1. Must be prescribed by an ophthalmologist **AND** 2. Member must have a diagnosis of corneal cysteine crystal accumulation due to cystinosis 3. Recommended dosage is one drop of Cystaran in each eye, every waking hour **OR** one drop of Cystadrops in each eye, 4 times a day during waking hours 4. Cystaran should be stored in the freezer and thawed for approximately 24 hours before use. Thawed bottle will last up to 7 days. Discard after 7 days and do not refreeze. 5. Cystadrops should be stored in the refrigerator until opened. Once opened, store at room temperature and discard 7 days after opening 6. Quantity limit is 4 bottles per month a. Cystadrops: 20 mL per 28 days b. Cystaran: 60 mL per 30 days
Daraprim and pyrimethamine tablets
1. Must be prescribed by an infectious disease specialist 2. Must be prescribed for the treatment of toxoplasmosis and used in combination with sulfadiazine a. If sulfadiazine is unable to be taken, Daraprim/pyrimethamine may be used in combination with Atovaquone or clindamycin 3. Requests for brand name Daraprim must have had serious side effects to generic pyrimethamine
Dartisla ODT, Glycate and glycopyrrolate 1.5 mg tablets
1. Must have a diagnosis of peptic ulcer disease **AND** 2. Must be 18 years of age or older **AND** 3. Must not be used as initial treatment **AND** a. Patients should be initiated on 1 mg tablets and titrated based on response 4. Must have a previous trial and failure or intolerance to generic glycopyrrolate 1 mg AND 2 mg tablets in addition to two other generic medications used to treat peptic ulcer disease (including but not limited to: lansoprazole, omeprazole, pantoprazole, famotidine, and ranitidine) **AND**

5. Must be used in combination with a medication that treats peptic ulcer disease **AND**
6. Patients stable on a lower dosage strength of another oral glycopyrrolate product will be excluded from coverage **AND**
7. Glycate, glycopyrrolate 1.5 mg tablets, and Dartisla ODT will not be covered for any other non-FDA approved indication, including sialorrhea (excessive drooling) and hyperhidrosis (excessive sweating)
8. Quantity Limit
    a. Glycate and glycopyrrolate 1.5 mg tablets: 150 tablets/30 days
    b. Dartisla ODT: 120 tablets/30 days

Desvenlafaxine ER tablets (generic Khedezla)

1. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic desvenlafaxine succinate extended-release tablets (generic Pristiq) the patient will be required to use generic desvenlafaxine succinate extended-release tablets (generic Pristiq) unless there is adequate justification as to why this formulation is not appropriate **AND**
2. If unable to use generic desvenlafaxine succinate extended-release tablets (generic Pristiq), patient must have tried and failed or have severe intolerance to all lower cost generic alternatives such as escitalopram, fluoxetine, citalopram, sertraline, and venlafaxine

Diacomit – stiripentol capsules and powder

1. Must be prescribed by a neurologist
2. Must be 6 months of age or older and weigh 7 kg or more
3. Must have a diagnosis of seizures associated with Dravet syndrome
4. Must be taken in conjunction with clobazam
5. Quantity Limit: 180 capsules/powder packets per 30 days

Doptelet – avatrombopag tablets

1. Member must be at least 18 years old
2. Must have a diagnosis of chronic liver disease and be scheduled to undergo a procedure with date of the procedure provided
    a. Must also have a diagnosis of thrombocytopenia defined as a platelet count of less than 50 x 10^9/L within 6 weeks prior to procedure
    b. Must be prescribed by a hepatologist, gastroenterologist, or hematologist
    c. Must be prescribed for the appropriate dose based on platelet count prior to the scheduled procedure:
        i. For patients with a platelet count between 40 and 50 x 10^9/L, Doptelet can be approved at a dose of 2 tablets per day for 5 days
        ii. For patients with a platelet count less than 40 x 10^9/L, Doptelet can be approved at a dose of 3 tablets per day for 5 days
    d. Patients should begin dosing 10-13 days prior to their procedure and undergo their procedure within 5-8 days after their last dose
    e. Approval will be for 14 days **OR**
3. Member must have a diagnosis of immune (idiopathic) thrombocytopenia purpura (ITP) **AND**
    a. Must have a current platelet count less than 30 x 10^9/L **AND**
    b. Must have had an insufficient response (defined as a platelet count of less than 30 x 10^9/L, or greater but with bleeding symptoms) to corticosteroids **OR** immunoglobulins (IVIG)
        i. Patients who are dependent on corticosteroids (i.e., the need for continuous use or the need for frequent courses) to maintain a platelet count of ≥ 30 x 10^9/L will not require documentation of an insufficient response to corticosteroids as defined above
4. Doptelet should not be used to normalize platelet counts
5. Quantity limit of 15 tablets per 30 days. For a diagnosis of ITP, a quantity of 60 tablets per 30 days will be allowed

Duloxetine 40 mg capsules
1. All requests for duloxetine 40 mg capsules will be required to use duloxetine 20 mg capsules to obtain the same requested dose.
Duobrii – halobetasol and tazarotene lotion
1. Must be prescribed by a dermatologist 2. The member must have a diagnosis of plaque psoriasis 3. Must be 18 years of age or older 4. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic tazarotene and halobetasol, the member will be required to use generic tazarotene and halobetasol unless there is adequate justification as to why these are not appropriate. 5. Quantity limit of 200 mL.per 28 days
Dymista and generic azelastine/fluticasone combination spray
1. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic azelastine and fluticasone, the member will be required to use azelastine and fluticasone as separate products unless they have tried azelastine and fluticasone as separate products and have a valid medical reason for requiring combination therapy 2. Quantity limit of 23 grams per 30 days
Egrifta SV – tesamorelin injection
1. Individuals between 18-65 with a diagnosis of HIV-positive lipodystrophy 2. Currently receiving anti-retroviral therapy 3. Waist circumference ≥ 95 cm (37.4 inches) and a waist-to-hip ratio ≥ 0.94 for men **OR** Waist circumference ≥ 94 cm (37.0 inches) and a waist-to-hip ratio ≥ 0.88 for women 4. Current FBG <150 mg/dL 5. Individuals with the following will be excluded from coverage a. BMI ≤20 kg/m^2 b. Previously treated with insulin or with PO hypoglycemic or insulin-sensitizing agents c. History of malignancy d. Hypopituitarism e. Pregnancy 6. Approvals will be for 6 months at a time. a. Recertification following initial 6 months of therapy will require a minimum of 3cm reduction in waist circumference from baseline. b. Further recertification will require maintenance of 3cm reduction of waist circumference. 7. Quantity limit of 30 vials per 30 days.
Emrosi – minocycline ER capsules
1. Must have a diagnosis of inflammatory lesions (papules and pustules) of rosacea a. All other non-FDA approved indications will not be covered 2. Must have had serious side effects or drug failure to minocycline IR AND doxycycline IR
Emverm – mebendazole tablet
1. Must be 2 years of age or older **AND** 2. Must have a diagnosis of Enterobius vermicularis (pinworm) a. Must have had a trial and failure or intolerance to pyrantel pamoate and albendazole **OR** 3. Must have a diagnosis of Trichuris trichiura (whipworm) a. Must have had a trial and failure or intolerance to albendazole **OR** 4. Must have a diagnosis of Ascaris lumbricoides (common roundworm) a. Must have a trial and failure or intolerance to two of the following: albendazole, pyrantel pamoate, and ivermectin **OR** 5. Must have a diagnosis of Ancylostoma duodenale (common hookworm) or Necator americanus (American hookworm) a. Must have had a trial and failure or intolerance to pyrantel pamoate and albendazole

6. Quantity limit of 6 tablets per 30 days

Enstilar – calcipotriene/betamethasone topical foam

1. Must be prescribed by a dermatologist
2. Must have a diagnosis of plaque psoriasis
3. Must be at least 12 years of age or older
4. Must have had serious side effects or drug failure with a minimum 4-week trial of calcipotriene/ betamethasone suspension
5. Initial approval will be limited to 4 weeks. Approval for future treatment courses will require documentation of improved symptoms after 4 weeks.
6. Quantity Limit of 60 grams per 30 days

Envarsus XR – tacrolimus ER tablet

1. Must be prescribed for post kidney transplant for organ rejection prophylaxis **AND**
2. Must have documentation of treatment failure (defined as severe and unmanageable side effects or previous graft rejection) while on generic tacrolimus.
3. Envarsus XR has not been studied in heart, liver, or another organ transplant and therefore will not be covered.
4. Quantity limit of 90/30 days for 0.75mg and 1mg tablets, 210/30 days for 4mg tablets

Eohilia - budesonide suspension

1. Must be prescribed by a Gastroenterologist or Allergist/Immunologist; **AND**
2. Must be at least 11 years of age or older; **AND**
3. Must have a diagnosis of Eosinophilic Esophagitis with **ALL** the following:
   a. An upper endoscopy with an esophageal biopsy showing ≥ 15 eosinophils per high-power field (eso/hpf) (or 60 eosinophils per mm^2) **AND**
   b. The provider must attest other causes of symptoms/esophageal eosinophilia have been ruled out (including, but not limited to: GERD, hypereosinophilic syndrome, eosinophilic granulomatosis with polyangiitis); **AND**
4. The provider must attest that a dietary management strategy (such as empiric elimination diet, a targeted allergen elimination diet, or an elemental diet) has been discussed and implemented, when appropriate; **AND**
5. Must have had serious side effect or drug failure with a high dose Proton Pump Inhibitor for at least 8 weeks; **AND**
6. Must have had serious side effects or drug failure with oral fluticasone propionate (administered using a metered dose inhaler without a spacer) or oral budesonide inhalation suspension (administered as a viscous slurry) for at least 8 weeks; **AND**
7. Authorization will be provided for 12 weeks of treatment. Recertification will not be granted due to lack of efficacy data beyond 12 weeks of treatment.
8. Quantity limit of 600 mL per 30 days.

Epaned and enalapril 1mg/1mL solution

1. Coverage will be granted for children aged 7 years and under
2. Children aged 8-17 years old will require documentation of an attempt and inability to swallow an oral pill (whole or crushed)
3. Adults 18 years and older will require documentation of a swallowing disorder which prevents use of all oral pills
4. Approval for children aged 7 years and under will be until the child turns 8. Approval for children aged 8-17 years old will be until the child turns 18.
5. In addition to above, Epaned solution will require serious side effects or drug failure to enalapril solution (generic Epaned)
6. Quantity Limit 1200mL/30 days

Epidiolex – cannabidiol solution
1. Must be prescribed by a neurologist 2. Member must be 1 years of age or older 3. Must have a diagnosis of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or Tuberous Sclerosis Complex 4. Will not be covered for any other non-FDA approved indication or diagnosis 5. Quantity limit is one 10 gram/100 ml bottle per month. Requests in excess of this amount can be approved if the patient is using an FDA-approved dose for one of the above diagnoses 6. FDA approved starting dose is 5 mg/kg/day. After one week, the dose can be increased to 10 mg/kg/day. The maximum FDA approved dose is 20 mg/kg/day for Lennox-Gastaut syndrome or Dravet syndrome and 25 mg/kg/day for Tuberous Sclerosis Complex.
Epsolay – benzoyl peroxide 5% cream
1. Must have a diagnosis of inflammatory lesions of rosacea in adults 2. Must have had serious side effects or drug failure with topical metronidazole and one additional topical antibiotic (such as clindamycin, erythromycin, azelaic acid) 3. Quantity limit of 30 grams per 30 days
Esbriet, pirfenidone tablets, and pirfenidone capsules
1. Must be prescribed by a pulmonologist 2. Must have a diagnosis of idiopathic pulmonary fibrosis based on the following criteria a. Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic, and occupational environmental exposures, connective tissue disease and drug toxicity). b. The presence of a UIP (usual interstitial pneumonia) pattern on high-resolution computed tomography (HRCT) in patients not subjected to surgical lung biopsy i. UIP must be determined to be “definite” or “probable” from the CT scan, and may include terminology such as honeycombing, traction bronchiectasis, bronchiolectasis and/or ground glass opacities c. Specific combinations of HRCT and surgical lung biopsy pattern in patients subjected to surgical lung biopsy 3. The individual must be a non-smoker (defined as someone who has not smoked in the past month) 4. Esbriet, pirfenidone tablets, and pirfenidone capsules will not be authorized in combination with Ofev 5. Requests for brand name Esbriet and generic pirfenidone tablets will require documentation of serious side effects, drug failure or a medical reason why generic pirfenidone 267 mg capsules cannot be used (3 of the 267 mg pirfenidone capsules can be utilized to get 801 mg dosing) 6. The health plan has determined that pirfenidone 534 mg tablets are not medically necessary due to the availability of lower costing pirfenidone strengths that allow for equivalent dosing and are likely to produce equal therapeutic results. 7. Quantity Limits: a. 267 mg: 270 tablets or capsules/30 days b. 801 mg: 90 tablets/30 days
Ezetimibe/Atorvastatin
1. The health plan has determined that ezetimibe-atorvastatin is not medically necessary due to availability of lower costing equivalent strengths of generic ezetimibe and atorvastatin as separate products that are likely to produce equal therapeutic results.
Fintepla – fenfluramine oral solution
1. Must be prescribed by a neurologist 2. Member must be 2 years of age or older 3. Must have a diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome 4. Fintepla will not be covered for any other non-FDA approved indication or diagnosis 5. Quantity limit is one 360 mL (792 mg) bottle per month as the maximum FDA approved dosing is 26 mg per day

Fleqsuvy and baclofen 5 mg/1mL oral suspension, Ozobax and baclofen 5 mg/5 mL oral solution, Ozobax DS, and baclofen 10 mg/5 mL oral solution, and Lyvispah (baclofen oral granules)
1. Must be 12 years of age or older 2. Must have documentation of a swallowing disorder which prevents the use of all oral pills (a speech and swallow evaluation is required) 3. The following criterion applies to requests for Ozobax, Ozobax DS, Fleqsuvy, baclofen 10 mg/5 mL oral solution and baclofen 5 mg/5 mL oral solution: a. Based on comparable indications, efficacy, safety profiles, and available strengths that allows for equivalent dosing, the patient will be required to use Lyvispah unless there is adequate justification as to why this formulation is not appropriate 4. Requests for brand Fleqsuvy will also require serious side effects or drug failure to baclofen 5 mg/1 mL oral suspension (generic Fleqsuvy) 5. Quantity limits are as follows: a. Ozobax and baclofen 5 mg/5 mL oral solution quantity limit is 2,400 mL per 30 days b. Fleqsuvy and baclofen 5 mg/1 mL quantity limit is 480 mL per 30 days c. Ozobax DS and baclofen 10 mg/5 mL quantity limit is 1,200 mL per 30 days d. Lyvispah quantity limit is 30 packets per 30 days i) Additional quantities will be granted based on FDA approved dosing
Furoscix – furosemide injection
1. The health plan has determined that Furoscix is not medically necessary due to the availability of lower costing options that are likely to produce equal therapeutic results.
Gattex – teduglutide solution
1. Must be used for the treatment of Short Bowel Syndrome 2. Must be dependent on parenteral support for initial approval 3. Must be no history of malignancy within the last 5 years. 4. Initial approval of Gattex will be for six months. Further approval for another 6 months will require evidence of at least a 20% reduction in baseline IV/PN volume by week 24. 5. Approval beyond initial 1 year of treatment will require maintenance of at least a 20% reduction in IV/PN volume or titration off parenteral support **AND** submission of colonoscopy results demonstrating no presence of intestinal malignancy 6. Recommended daily dose is 0.05mg/kg 7. Quantity limit of 60 vials per 30 days
Gimoti – metoclopramide hydrochloride nasal spray
1. Must be 18 years of age or older 2. Must have a diagnosis of gastroparesis due to diabetes mellitus 3. Must have had serious side effects or drug failure of metoclopramide and erythromycin or azithromycin 4. The recommended dose is 1 spray (15 mg) in one nostril, 30 minutes before each meal and at bedtime (maximum of four times daily) for 2 to 8 weeks 5. Coverage will be limited to 8 weeks of treatment per recurrence. Recertification will require documentation that the patient had a response to previous/most recent therapy and had a return of symptoms after discontinuing treatment (taking a "drug holiday") with Gimoti. 6. Quantity Limit: 9.8 mL (112 metered doses) per 28 days
Glimepiride 3 mg tablet
1. The health plan has determined that glimepiride 3 mg tablet is not medically necessary due to the availability of lower costing glimepiride products that are likely to produce equal therapeutic results.
Gocovri – amantadine ER capsules
1. Must be prescribed by a neurologist 2. Must be prescribed for dyskinesia associated with a diagnosis of Parkinson's disease **AND** a. Member must be currently receiving levodopa-based therapy **AND** b. Must have had serious side effects or drug failure with generic amantadine at a total dose of at

least 200 mg per day **OR**
3. Must have a diagnosis of Parkinson's disease with "wearing off symptoms" **AND**
   a. Must be currently taking oral carbidopa/levodopa **AND**
   b. Must have attempted increasing the dose and dosing frequency of oral carbidopa/levodopa **AND**
   c. Must have had serious side effects or drug failure with **TWO** of the following: pramipexole, ropinirole, entacapone, tolcapone, selegiline, or rasagiline
4. Quantity Limit of 60 capsules/30 days

Gralise and gabapentin ER tablet

1. Must have a diagnosis of post herpetic neuralgia
2. Must be 18 years of age or older
3. Must have documented trial and failure or intolerance to generic immediate-release oral gabapentin at a minimum dose of 1800 mg per day for post herpetic neuralgia
4. Gralise/gabapentin ER tablets should be titrated to an 1800 mg dose taken orally, once daily, with the evening meal
5. Gralise/gabapentin ER tablets will not be approved for any other non-FDA approved indications
6. Requests for brand name Gralise will require documentation of serious side effects or drug failure to generic gabapentin ER tablets
7. Quantity limit as follows:
   b. Gralise 450 mg: 30 tablets per 30 days
   c. Gralise 750 mg and 900 mg: 60 tablets per 30 days
   d. Gralise 300 mg and 600 mg: 90 tablets per 30 days

Hetlioz, Hetlioz LQ (tasimelteon suspension), and tasimelteon capsules

1. Must be prescribed by a sleep specialist
2. For a diagnosis of Non-24 Hour Sleep-Wake Disorder:
   a. Progress notes should be submitted demonstrating that the diagnosis was confirmed by:
      i. The patient's sleep log suggesting a circadian rhythm sleep disorder
      ii. The measurement of biomarkers (such as urinary melatonin and/or cortisol levels) to confirm a non-24-hour circadian period
   b. Based on the patient population used in clinical studies evaluating the efficacy of Hetlioz and generic tasimelteon capsules for Non-24 Hour Sleep-Wake Disorder, Hetlioz and generic tasimelteon capsules will only be approved in patient's that are totally blind
   c. Hetlioz capsules and generic tasimelteon capsules for Non-24 Hour Sleep-Wake Disorder will only be approved for adult patients as this diagnosis has not been studied in pediatric patients
   d. Hetlioz LQ suspension will not be approved for this diagnosis
3. For a diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS):
   a. Diagnosis must be confirmed by deletion of chromosome 17p11.2 or RAI1 gene mutation
   b. Must have had serious side effects or drug failure to melatonin, with the trial confirmed in progress notes
   c. Hetlioz LQ suspension will only be approved in patients 3-15 years old
      i. Patients 28 kg and less will be approved at a dose of 0.7 mg/kg per day
      ii. Patients >28 kg will be approved at a dose of 20 mg per day
   d. Hetlioz capsules and generic tasimelteon capsules will be required for patients 16 years of age and older
4. Requests for Brand Hetlioz capsules will require documentation of use of generic tasimelteon capsules that led to serious side effects or drug failure
5. Hetlioz, Hetlioz LQ and tasimelteon capsules will not be covered for any non-FDA approved indications
6. Quantity limits are as follows:
   a. 30 capsules per 30 days for Hetlioz capsules and generic tasimelteon capsules
   b. 48 mL per 30 days for Hetlioz LQ suspension

i. Requests in excess of this amount will be reviewed in accordance with FDA-approved weight-based dosing (see 3c) and, as such, will be limited to minimum number of bottles required to obtain the appropriate daily dose/day supply

7. Quantity approvals will be added to allow for dispensing of the whole bottle size needed (48 mL or 158 mL)

Horizant - gabapentin enacarbil ER tablet

1. Must be prescribed for a diagnosis of Restless Legs Syndrome (RLS) in adults
   a. Must have had previous trial and severe intolerance/failure to either ropinirole or pramipexole AND generic gabapentin **OR**
2. Must be prescribed for a diagnosis of Postherpetic Neuralgia (PHN) in adults
   a. Must have had previous trial and severe intolerance/failure to generic gabapentin at a minimum dose of 1,800 mg per day.
3. All other non-FDA approved indications will be excluded
4. Quantity Limit of 90/30 days for 300mg tablet and 60/30 days for 600mg tablet.

Impavido – miltefosine capsules

1. Must be prescribed by or recommended by an infectious disease specialist
2. Patient must be at least 12 years of age and weigh at least 30kg (66lbs)
3. Patient must have a diagnosis of visceral (due to *Leishmania donovani)*, cutaneous (due to *Leishmania braziliensis, Leishmania guyanesis, or Leishmania panamensis),* or mucosal (*due to Leishmania braziliensis*) Leishmaniasis
4. Quantity limit of 84/28.

Inbrija – levodopa inhalation

1. Must be prescribed by a neurologist
2. Must have a diagnosis of Parkinson's disease with "wearing off symptoms"
3. Must be currently taking oral carbidopa/levodopa at a minimum dosage of 100 mg of carbidopa
4. Must have attempted increasing the dose and dosing frequency of oral carbidopa/levodopa
5. Must have had serious side effects or drug failure with **TWO** of the following: pramipexole, ropinirole, entacapone, tolcapone, selegiline, or rasagiline
6. The Quantity Limit is 120 capsules for inhalation per 30 days. Based on the maximum recommended dosing, requests for up to 300 capsules per 30 days will be considered when clinically justified

Ingrezza and Ingrezza Sprinkle – valbenazine capsules

1. Patient must have a diagnosis of chorea associated with Huntington's Disease
   a. Must be 18 years of age or older
   b. Must be prescribed by a neurologist
   c. Diagnosis of Huntington's disease is confirmed by genetic testing (i.e., expanded *HTT* CAG repeat sequence ≥ 36) **OR**
2. Must have a diagnosis of tardive dyskinesia
   a. Must be 18 years of age and old
   b. Must have a diagnosis of tardive dyskinesia defined as a history of ≥ 3 months (or ≥ 1 month in patients over 60 years of age) total cumulative neuroleptic exposure (continuous or discontinuous), presence abnormal involuntary movements in one or more body areas, and absence of other conditions that might produce abnormal involuntary movements
   c. Must be prescribed by or in consultation with a neurologist, psychiatrist, or psychiatric nurse practitioner
   d. Must have attempted an alternative method to manage the condition (such as dose reduction or discontinuation of the offending medication).
3. Ingrezza will not be covered for any non-FDA approved indications
4. Initial approval will be for 6 months. Recertification will be for 12 months and require documentation of the following:
   a. For Huntington's Disease: symptom improvement and/or stabilization of disease

b. For tardive dyskinesia: symptom improvement

5. Quantity limit of 30 capsules per 30 days

For members initiated on Ingrezza at 40 mg per day and increasing to 80 mg per day after 1 week, a quantity override for 60 capsules for 30 days will be authorized for the first month of therapy only. 80 mg capsules should be used thereafter

InnoPran XL and Inderal XL – propranolol ER capsule

1. Must be used for the treatment of hypertension
2. Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use other beta blocker alternatives (such as propranolol ER capsules, Inderal LA capsules, propranolol tablets, metoprolol succinate, metoprolol tartrate, or atenolol) unless there is a clinically valid medical reason why ALL other oral beta blockers are unable to be used
3. Quantity limit is 1 capsule per day
   a. An exception to this quantity limit will not be granted as doses above 120 mg per day were shown to have no additional effects on lowering blood pressure

Inpefa – sotagliflozin tablets

1. Must be 18 years of age or older **AND**
2. Must have a diagnosis of (a or b)
   a. Heart failure (HF) **AND**
      i. Must have serious side effects or drug failure with Farxiga and Jardiance **OR**
   b. Must have a diagnosis of type 2 diabetes mellitus, chronic kidney disease, and cardiovascular risk factors (i.e., obesity, dyslipidemia, hypertension, elevated cardiac and inflammatory biomarkers)
      i. Note: patients with heart failure should be reviewed using the criteria for heart failure above
3. Inpefa is not approved for glycemic control, including use to treat type 1 diabetes
   a. Requests for type 1 diabetes and heart failure should be reviewed using the heart failure criteria above
4. Quantity limit 30 tablets per 30 days

Iqirvo - elafibranor

1. Must be prescribed by a gastroenterologist, hepatologist, or liver transplant specialist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a diagnosis of primary biliary cholangitis (PBC)
   a. Must have at least 2 of the following:
      i. Positive antimitochondrial antibodies (AMA) or other PBC specific auto-bodies, including sp100 or gp210, if AMA are negative
      ii. History of elevated ALP levels above the upper limit of normal (ULN) as defined by normal laboratory reference values
      iii. Liver biopsy consistent with PBC, according to the pathology report **AND**
4. Must meet for one of the following:
   a. Must have had an inadequate response to ursodiol for a period of at least 12 months
      i. Inadequate response is defined as:
         1. ALP that is ≥ 1.67 times the upper limit of normal (ULN = 118 U/L for females and 124 U/L for males) **OR**
         2. Total bilirubin level that is greater than 1-times ULN but less than 2-times ULN (ULN = 1.1 mg/dL for females and 1.5 mg/dL for males) **OR**
   b. Must be unable to tolerate ursodiol **AND**
5. Must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
6. The initial approval timeframe will be for 6 months. Continued 12-month approval will require documentation that the member has responded to therapy defines as:
   a. ALP ≤ 1.67 times the upper limit of normal (ULN= 118 U/L for females and 124 U/L for males) **AND**
   b. Decrease in ALP of at least 15% compared to baseline **AND**

c. Total bilirubin ≤ ULN (ULN = 1.1 mg/dL for females and 1.5 mg/dL for males) **AND**
d. Must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
7. Quantity limit : 30 tablets per 30 days

Jublia – efinaconazole solution

1. Must be 6 years of age or older **AND**
2. Must be prescribed by a podiatrist or dermatologist **AND**
3. Must have a diagnosis of onychomycosis of the toenail with pain that impairs activities of daily living **AND**
3. Must have a positive KOH stain or positive culture (on Sabouraud's medium or dermatophyte test medium (DTM)) **AND**
4. Must have had failure or intolerance to oral terbinafine or a contraindication to oral therapy
   a. Oral terbinafine use will not be required in pediatric patients **AND**
4. Requests for Jublia will require documentation of serious side effects or drug failure to tavaborole
5. Jublia will be covered for a maximum duration of 48 weeks of therapy.
6. Quantity Limit 4 mL per 30 days
   a. Additional quantities will be approved based on FDA-approved dosing

Jylamvo – methotrexate oral solution

1. Must be 18 years of age or older
2. Must have a diagnosis of acute lymphoblastic leukemia (ALL), mycosis fungoides, relapsed or refractory non-Hodgkin lymphoma, rheumatoid arthritis, or severe psoriasis
3. Requires a trial of BOTH methotrexate oral tablets and injectable methotrexate solution
   b. For members unable to swallow, a speech and swallow evaluation is required to confirm a swallowing disorder
   c. For members unable to use injectable methotrexate, the patient must have a documented physical inability to inject
4. Quantity limit of 1 bottle (60 mL) per 30 days
   a. Requests in excess of this amount will be reviewed in accordance with FDA-approved dosing and as such, will be limited to the minimum number of bottles required to obtain the appropriate daily dose/day supply.

Jynarque – tolvaptan tablets

1. Must be prescribed by a nephrologist
2. Must be 18 years of age or older
3. Must have a diagnosis of autosomal dominant polycystic kidney disease (ADPKD)
4. Jynarque will not be covered for patients with GFR < 15 mL/min/1.73 m^2 or those receiving dialysis
5. Quantity limits as follows:
   a. 15 mg tablets: 60 tablets per 30 days
   b. 30 mg tablets: 30 tablets per 30 days
   c. Combination packs of 15mg-15mg, 30mg-15mg, 45mg-15mg, 60mg-30mg, and 90mg-30mg: 56 tablets per 28 days

Kalydeco – ivacaftor tablets and granules

1. Must have a diagnosis of cystic fibrosis
2. Must have at least one mutation in the CFTR gene that is responsive to Kalydeco based on clinical and/or in vitro data (package insert includes a full list of responsive CFTR gene mutations)
3. Must be at least 1 month of age
4. Coverage will be excluded in patients with CF who are homozygous for the F508 del mutation in the CFTR gene
5. Liver enzymes should be assessed prior to initiation of Kalydeco, every 3 months during the first year of treatment, and annually thereafter.
6. For adults and pediatric patients aged 6 years and older, quantity limit is 60 **tablets** per 30-day supply.
7. Oral **granule packets** are only approved for children less than 6 years old with a quantity limit of 56

packets per 28-day supply for a maximum of 150mg/day. Patients who require higher doses must use oral tablets
Katerzia (amlodipine benzoate oral suspension) and Norliqva (amlodipine besylate oral solution)
1. Coverage will be allowed for children less than 8 years old 2. Children aged 8-17 years old will require documentation of an attempt and inability to swallow an oral pill 3. Adults 18 years and older will require documentation of a swallowing disorder which prevents use of all oral pills 4. Approval for children under 8 years of age will be until the child turns 8. Approval for children aged 8-17 years old will be until the child turns 18. 5. Quantity limit of 300 mL per 30 days
Kerendia – finerenone tablets
1. Must have a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes 2. Quantity limit of 30 tablets per 30 days.
Kerydin and tavaborole solution
1. Must be 6 years of age or older **AND** 2. Must be prescribed by a podiatrist or dermatologist **AND** 3. Must have a diagnosis of onychomycosis a toenail with pain that impairs activities of daily living **AND** 4. Must have a positive KOH stain or positive culture (on Sabouraud's medium or dermatophyte test medium (DTM)) **AND** 5. Must have had failure or intolerance to oral terbinafine or a contraindication to oral therapy a. Oral terbinafine use will not be required in pediatric patients 6. Requests for brand Kerydin will require documentation of serious side effects or drug failure to tavaborole 7. Will be covered for a maximum duration of 48 weeks of therapy 8. Quantity Limit 4 ml per 30 days 1. Additional quantities will be approved based on FDA-approved dosing
Klisyri – tirbanibulin ointment
1. Must have a diagnosis of actinic keratosis 2. Must be 18 years of age or older 3. Must have had serious side effects or drug failure with imiquimod **AND** at least one of the following: fluorouracil 5% cream, fluorouracil 2% topical solution or fluorouracil 5% topical solution 4. Approval will be for 4 weeks
Kristalose and lactulose powder for solution packets
1. Must have a diagnosis of constipation or hepatic encephalopathy 2. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of lactulose formulations available in a solution, the member will be required to use a lactulose solution unless there is adequate justification as to why these are not appropriate a. To determine that lactulose solution is not appropriate, all formulations of lactulose solution (Constulose, Enulose, Generlac and lactulose solution) must be attempted with serious side effects or drug failure prior to the approval of Kristalose or lactulose packets. Documentation of each trial will be required in progress notes for review 3. If packets are determined to be required, Kristalose packets will be the product authorized. Lactulose packets will not be authorized
Lidocan II, Lidocan III , Lidocan IV, Lidocan V, Tridacaine II and Tridacaine XL– lidocaine 5% patch
1. The health plan has determined that Lidocan II, Lidocan III, Lidocan IV, Lidocan V, Tridacaine II and Tridacaine XL patches are not medically necessary due to the availability of lower costing options that are likely to produce equal therapeutic effects
Likmez – metronidazole oral suspension
1. Based on comparable indications, efficacy, and safety profile, the member will be required to use

metronidazole tablets unless there is adequate justification as to why metronidazole tablets cannot be used
   a. If tablets are unable to be used due to swallowing difficulties, documentation of a swallowing disorder which prevents the use of all oral pills is required (a speech and swallow evaluation is required to be submitted)

Livdelzi – seladelpar

1. Must be prescribed by a gastroenterologist, hepatologist, or liver transplant specialist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a diagnosis of primary biliary cholangitis (PBC)
   a. Must have at least 2 of the following:
      i. Positive antimitochondrial antibodies (AMA) or other PBC specific auto-bodies, including sp100 or gp210, if AMA are negative
      ii. History of elevated ALP levels above the upper limit of normal (ULN) as defined by normal laboratory reference values
      iii. Liver biopsy consistent with PBC, according to the pathology report **AND**
4. Must meet for one of the following:
   a. Must have had an inadequate response to ursodiol for a period of at least 12 months
      i. Inadequate response is defined as:
         1. ALP that is ≥ 1.67 time the upper limit of normal (ULN = 118 U/L for females and 124 U/L for males) **AND**
         2. Total bilirubin level that is greater than 1-times ULN but less than 2-times ULN (ULN=1.1 mg/dL for females and 1.5 mg/dL for males) **OR**
   b. Must be unable to tolerate ursodiol **AND**
5. Must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
6. The initial approval timeframe will be for 6 months. Continued 12-month approval will require documentation that the member has responded to therapy defined as:
   a. ALP ≤ 1.67 times the upper limit of normal (ULN= 118 U/L for females and 124 U/L for males) **AND**
   b. Decrease in ALP of at least 15% compared to baseline **AND**
   c. Total bilirubin ≤ ULN (ULN = 1.1 mg/dL for females and 1.5 mg/dL for males) **AND**
   d. Must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
7. Quantity limit: 30 tablets per 30 days.

Lodoco – colchicine 0.5 mg tablets

1. Must be prescribed by or in consultation with a cardiologist, endocrinologist, lipidologist, **OR** nephrologist
2. Must have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or have experienced a cardiovascular event
   a. For a diagnosis of ASCVD, must have a history of acute coronary syndrome, myocardial infarction (MI), stable or unstable angina, coronary/other arterial revascularization, stroke, TIA, peripheral arterial disease, or other documented atherosclerotic disease (such as coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, or carotid plaque with ≥ 50% stenosis)
3. Must be on lipid-lowering therapy with a maximally tolerated statin
   a. If statin intolerant, must be receiving other lipid-lowering therapy
4. Must have blood pressure <130/80 mmHg or be optimized on standard of care medications (such as beta-blockers, ACE-I, ARBs)
5. Must be on an antiplatelet agent (such as aspirin) or an anticoagulant therapy for secondary ASCVD prevention unless contraindicated or not tolerated
6. Must have a clinically valid medical reason why colchicine 0.6 mg tablets cannot be used

7. Lodoco will not be approved for any non-FDA approved indications, including indications that colchicine 0.6 mg tablet/capsule are indicated to treat (such as gout)
8. Quantity limit of 30 tablets per 30 days

Loreev XR – lorazepam extended-release capsules

1. Based on comparable indications, dosing, efficacy, and safety profiles the patient will be required to use generic lorazepam tablets, administered three times daily in evenly divided doses, unless there is adequate justification why this formulation is not appropriate **AND**
2. Patient must have tried and failed or had severe intolerance to lower cost generic alternatives such as alprazolam, clonazepam, diazepam, sertraline, escitalopram, fluoxetine, paroxetine, duloxetine, and venlafaxine extended- release
3. For patients unable to swallow whole tablets or capsules, there must be adequate justification as to why lorazepam concentrate cannot be used **AND** a speech and swallow evaluation is required to confirm a swallowing disorder
4. Loreev XR will only be approved for the treatment of anxiety disorders in adults who are receiving stable, evenly divided, three times daily dosing with lorazepam tablets. Loreev XR will not be approved for any non-FDA approved indications
5. Quantity limit: 30 capsules/30 days. Requests in excess of this amount will be reviewed in accordance with FDA-approved dosing and as such, will be limited to the minimum number of capsules required to obtain the appropriate daily dose/day supply

Lorzone and generic chlorzoxazone 375 mg and 750 mg tablets

1. Patient must have had a trial of generic chlorzoxazone 500mg **AND**
2. Patient must have had severe intolerance or therapeutic failure of at least two other muscle relaxants in addition to chlorzoxazone (such as cyclobenzaprine, baclofen, tizanidine, methocarbamol, orphenadrine)
3. Quantity limit of 120/30 or 136/34 DS

Lumryz - sodium oxybate for suspension, extended release

1. Must be followed by a neurologist or sleep specialist
2. Must be 7 years of age or older and have a diagnosis of cataplexy associated with narcolepsy **OR** excessive daytime sleepiness associated with narcolepsy
    a. Narcolepsy must be confirmed by a sleep study which must be provided
3. If the diagnosis is excessive daytime sleepiness associated with narcolepsy:
    a. For patients 18 years of age or older, must have had serious side effects, drug failure or contraindication to TWO the following:
        i. Modafinil or armodafinil
        ii. A stimulant medication indicated for narcolepsy (amphetamine, dextroamphetamine/amphetamine, dextroamphetamine ER, or methylphenidate)
        iii. Sunosi (also requires prior authorization)
    b. For patients 7 to 17 years of age, must have had serious side effects, drug failure, or contraindication to a stimulant indicated for narcolepsy (amphetamine, dextroamphetamine/amphetamine, dextroamphetamine ER, or methylphenidate)
4. Must have had serious side effects or drug failure to sodium oxybate
5. Use of Lumryz and Xyrem/sodium oxybate and/or Xywav in combination will not be authorized
6. Lumryz will not be covered for any non-FDA approved indication or diagnosis
7. Quantity limit of 30 packets per 30 days for the 4.5 g, 6g, 7.5 g and 9 g packets. Quantity limit of 28 packets per 28 days for the Lumryz Starter Pack.

Lupkynis – voclosporin capsules

1. Must be prescribed by a rheumatologist or nephrologist
2. Must have a diagnosis lupus nephritis confirmed by a kidney biopsy
    a. Biopsy must reveal lupus nephritis class III, IV, or V, alone or in combination

i. Class III or IV lupus nephritis (alone or in combination with class V) will also require a urine protein to creatinine ratio (UPCR) of ≥1.5 mg/mg
ii. Class V lupus nephritis alone will require a urine protein to creatinine ratio (UPCR) of ≥2 mg/mg

3. Must be used in combination with mycophenolate and corticosteroids as Lupkynis is not approved to be used as monotherapy
    a. Lupkynis has not been studied in combination with any other immunosuppressants (such as cyclophosphamide or azathioprine) and will not be approved for use with other immunosuppressants except hydroxychloroquine, which is permitted to be used in combination with mycophenolate, corticosteroids and Lupkynis
4. Must have a baseline eGFR ≥ 45 mL/min/1.73m^2
5. Must have had serious side effects or drug failure to Benlysta SQ or IV
    a. Use of Lupkynis in combination with Benlysta will not be approved as these medications have not been studied for use together
6. Initial approval will be for 6 months
7. Recertification after 6 months of therapy will require:
    a. Documentation of therapeutic benefit defined as a reduction in urine protein to creatinine ratio (UPCR) and/or increase in eGFR compared to baseline
    b. Continued compliance with mycophenolate and corticosteroids
    c. Approval will be for an additional 6 months of therapy
8. Recertification after 1 year of therapy will require documentation of:
    a. UPCR ≤0.5 mg/mg, and
    b. eGFR ≥60 mL/min/1.73 m^2 or no decrease ≥20% from baseline eGFR
    c. Approval will be granted for 1 year of additional therapy
9. Subsequent recertifications will require documentation of continued therapeutic benefit compared to baseline and continued compliance with mycophenolate and corticosteroids
10. Quantity limit: 180 capsules/30 days

Lybalvi - olanzapine/samidorphan tablets

1. Must be prescribed by or in consultation with a mental health provider
2. Must be 18 years of age or older
3. Must have a diagnosis of schizophrenia or bipolar 1 disorder
4. Must have previous trial of generic olanzapine for at least 4 weeks which demonstrated positive clinical response, but unacceptable weight gain as determined by provider attestation **OR**
5. Must have documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (i.e., risperidone, ziprasidone, quetiapine, aripiprazole, paliperidone ER) at maximally tolerated doses for at least 4 weeks **AND**
6. Provider must attest that the patient does not have a known opioid use disorder or is dependent on opioids for a chronic health condition
    a. Note: Lybalvi is contraindicated in patients who are using opioids and who are undergoing acute opioid withdrawal. Prior to initiating Lybalvi, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal
7. Quantity limit: 30 tablets/30 days

Mavenclad – cladribine tablets

1. Must be 18 years of age or older
2. Must have a diagnosis of a relapsing form of multiple sclerosis (including relapsing-remitting MS and secondary progressive disease but NOT Clinically Isolated Syndrome) diagnosed by a neurologist
3. Must have had serious side effects or drug failure with two of the following: Avonex, Copaxone (or glatiramer), Glatopa, fingolimod, Mayzent, Rebif, teriflunomide, dimethyl fumarate, Plegridy, Kesimpta or Zeposia.

4. Approval will be for 3 months to allow for the first 2 fills, which make up the first treatment course. Recertification for the second treatment course will require documentation supporting disease response to Mavenclad. This recertification will also be approved for 3 months to allow for 2 more fills.
5. Mavenclad will not be approved for use beyond 2 years (4 total fills) as the FDA states treatment beyond 2 years may further increase the risk of malignancy
6. Quantity Limit: 10 tablets per 28 days. Maximum 2 fills per 300 days.

Metaxalone 400 mg tablets

1. The health plan has determined that metaxalone 400 mg is not medically necessary due to the availability of lower costing metaxalone 800 mg strength that allows for equivalent dosing and is likely to produce equal therapeutic results.

Methocarbamol 1000 mg tablets and Tanlor 1000 mg tablets

1. The health plan has determined that methocarbamol and Tanlor1000 mg tablets are not medically necessary due to the availability of lower costing methocarbamol strengths that allow for equivalent dosing and are likely to produce equal therapeutic results
2. Quantity Limit: 30 tablets per 30 days
    a. Additional quantities will be granted based on FDA-approved dosing

Miebo - perfluorohexyloctane ophthalmic solution

1. Must be prescribed by or in consultation with an ophthalmologist or optometrist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a diagnosis of dry eye disease (DED) confirmed by abnormal testing results (such as tear osmolarity, Schirmer test, tear break-up time, matrix metalloproteinase-9, etc.)
4. Must have had serious side effects or drug failure of artificial tears **AND**
5. Step Therapy Applies – Must have had serious side effects or drug failure to cyclosporine ophthalmic emulsion **AND** Xiidra
6. Miebo will not be covered for non-FDA approved uses (such as Sjogren syndrome, Thyroid Eye Disease [TED], Sarcoidosis, Ocular mucous membrane pemphigoid)
7. Quantity Limit: 3 mL (1-container) per 30 days

Minolira, Ximino, minocycline ER capsules (generic Ximino), and minocycline ER tablets (alternative to Minolira)

1. Must have a diagnosis of moderate to severe acne
2. Must be prescribed by a dermatologist
3. Must have had failure or intolerance with at least one topical retinoid (tretinoin, adapalene or tazarotene) AND doxycycline
4. Must have also had vestibular side effects with a trial of generic immediate release minocycline
5. Quantity limit of 30 tablets or capsules per 30 days
6. Initial approval will be for 12 weeks

Recertification criteria: To limit antibiotic resistance, patients should not use oral antibiotics chronically. The following criteria are based on guidelines set forth by the Global Alliance to Improve Outcomes in Acne and the American Academy of Dermatology.

1. Patients should continue the use of a topical therapy to maintain remission of new acne lesions when antibiotic therapy is discontinued.
2. Patient progress notes documenting a flare in symptoms will need to be submitted for review by the clinical staff.
3. If patients have a flare of inflammatory lesions after the initial 12-week course than patients will be allowed to retreat as long as they are using a topical maintenance therapy. Retinoids are the preferred agent or alternatively a combination of benzoyl peroxide and a topical antibiotic is acceptable.
4. Recertification will be approved for one year.

Mirapex ER and pramipexole ER

1. Must be 18 years of age or older

2. Must have a diagnosis of Parkinson's Disease
3. Must have had a trial and failure of immediate release pramipexole
4. Quantity limit:
    a. 30 tablets/30 days for 0.375 mg, 0.75 mg, 1.5 mg, 3 mg, 3.75 mg, and 4.5 mg strengths
    b. 60 tablets/30 days for 2.25 mg strength

Motpoly XR – lacosamide ER capsule

1. Must be 17 years of age or older **OR**
    a. Must be less than 17 years of age and weigh at least 50 kg
2. Must have a diagnosis of partial-onset seizures **OR**
3. Must have a diagnosis of primary generalized tonic-clonic seizures
    a. Must be used as adjunctive therapy **AND**
4. Motpoly XR coverage will only be granted for those who have had documented non-compliance with lacosamide dosed twice daily that resulted in breakthrough seizure and now require once daily dosing with Motpoly XR for successful seizure treatment
5. Quantity limit as follows:
    a. Motpoly XR 100 mg: 30 capsules per 30 days
    b. Motpoly XR 150 mg: 60 capsules per 30 days
    c. Motpoly XR 200 mg: 60 capsules per 30 days

Moxatag – amoxicillin trihydrate ER tablet

1. Prescribed by an infectious disease specialist **OR**
2. Diagnosis of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes* in adults and children 12 years of age and older
3. Quantity limit of 10 tablets / 30 days
4. Approval will be for 30 days

Mulpleta – lusutrombopag tablet

1. Must be prescribed by a hepatologist, gastroenterologist, or hematologist
2. Member must be at least 18 years old
3. Must have a diagnosis of thrombocytopenia defined as a platelet count of less than 50 x 10^9/L within 6 weeks prior to procedure
4. Must also have a diagnosis of chronic liver disease and be scheduled to undergo a procedure with date of the procedure provided
5. Patients should begin dosing 8-14 days prior to their procedure and undergo their procedure within 2-8 days after their last dose
6. Approval will be for 14 days

Myfembree - relugolix/estradiol/norethindrone tablets

1. Member must be at least 18 years of age
2. Must be premenopausal
3. Must be prescribed by a gynecologist
4. Must not be pregnant or actively trying to conceive
5. Must have a diagnosis of heavy menstrual bleeding associated with uterine fibroids
    a. Uterine fibroids must be documented by pelvic ultrasound **AND**
    b. Must have had serious side effects or drug failure with a contraceptive (such as estrogen-progesterone, progesterone alone, or progesterone-releasing intrauterine device contraceptives) AND tranexamic acid **OR**
6. Must have a diagnosis of pain associated with endometriosis
    a. Must have had serious side effects or drug failure with two different continuous hormonal contraceptives, unless contraindicated **AND**
7. Myfembree will not be approved if the patient has had previous treatment with the maximum duration of Orilissa, Oriahnn, or Synarel
8. Myfembree will not be approved for non-FDA approved indications (such as heavy menstrual bleeding

without uterine fibroids)
9. Initial approval will be for 12 months. Recertification for 12 months will require the prescriber to attest to improved symptoms
10. Treatment beyond 24 months total (two 12-month courses) will not be approved

Mytesi – crofelemer tablets

1. Indicated for the symptomatic relief of NON-INFECTIOUS diarrhea (one or more watery bowel movements per day) in patients with HIV/AIDS on anti-retroviral therapy
2. Drug therapy will not be authorized for individuals who have a history of ulcerative colitis, Crohn's disease, celiac sprue, chronic pancreatitis, malabsorption, or any other GI disease associated with diarrhea.
3. Patients must have had ADEQUATE TRIAL and failure or intolerance to **TWO** of anti-diarrheal medications (loperamide, diphenoxylate, and bismuth subsalicylate) unless contraindication is present.
4. Recommended daily dose is 125mg twice daily with, or without food
5. Quantity limit of 60 tablets/30 days.
6. Recertification will be required after initial 16-week approval to assess for improvement in symptoms. If no improvement in frequency of water bowel movements is noted, further therapy will not be authorized.

Namzaric ER – donepezil/memantine capsule

1. Must have a diagnosis of moderate to severe Alzheimer's disease **AND**
2. Must have documented stabilization on *both* Memantine (IR or ER) *and* Donepezil for the **3** months immediately preceding the request.
3. Quantity limit of 30 capsules per 30 days

Natpara – parathyroid hormone solution

1. Must be prescribed by an endocrinologist
2. Must be an adult patient with a diagnosis of hypoparathyroidism, defined as hypocalcemia (calcium concentration below the lower limit of normal) and documented parathyroid levels below the lower limit of normal range, both levels recorded on 2 separate occasions within the past 12 months
3. Must confirm that there is no evidence of Vitamin D deficiency. If 25 (OH) D levels are below lower limit of normal, treatment with Natpara will not be authorized until serum 24(OH) D level returns to normal
4. Must be experiencing symptoms of disease while currently receiving calcium and vitamin D supplementation which is causing intolerable side effects, and unable to achieve target serum calcium levels (8-9mg/dL)
5. Lab results with reference ranges must be submitted
6. The starting dose is 50 µg injected once daily in the thigh and then individualized to achieve albumin-corrected serum calcium between 8 to 9 mg/dL

Neupro – rotigotine patch

1. Must have FDA-approved diagnosis of Parkinson disease or moderate to severe restless legs syndrome
2. Must have had serious side effects or drug failure with both oral pramipexole **AND** ropinirole. This requirement is waived upon documentation of an inability to swallow.
3. Quantity limit of 1 patch per day

Nexiclon XR and clonidine extended-release tablet

1. The health plan has determined that Nexiclon XR and clonidine extended-release tablets are not medically necessary due to the availability of lower costing clonidine options that are likely to produce equal therapeutic results.

Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe) (Rx)

1. Must be prescribed by or in consultation with a cardiologist, endocrinologist, lipidologist, **OR** nephrologist
2. Member must be 18 years of age or older
3. Must have one of the following diagnoses:
    a. **Clinical atherosclerotic cardiovascular disease (ASCVD)**
        i. Must have a history of acute coronary syndrome, myocardial infarction (MI), stable or unstable angina, coronary/other arterial revascularization, stroke, TIA, peripheral arterial disease, or other documented atherosclerotic disease (such as coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, or carotid plaque with ≥ 50% stenosis) **OR**
    b. **Heterozygous Familial Hypercholesterolemia (HeFH)**
        i. Molecular genetic testing must demonstrate evidence of an LDL-R mutation, familial defective apo B_{100} **OR**
        ii. Diagnosis must be confirmed as “definite” according to the World Health Organization Criteria (Dutch Lipid Network) **OR** Simon-Broome Register Diagnostic Criteria. Documentation of the criteria which confirms this diagnosis much be submitted **OR**
    c. **Primary Hyperlipidemia without ASCVD or HeFH**
        i. Patient is at high risk for ASCVD as evidenced by one of the following (documentation must be submitted):
            1. Severe hypercholesterolemia with an untreated LDL-C ≥ 190 mg/dL and poorly controlled risk factors (i.e., age > 35, male sex, obesity, smoking, hypertension, lipoprotein (a) ≥ 50 mg/dL, low HDL-C < 35 mg/dL) **OR**
            2. American College of Cardiology/American Heart Association (ACC/AHA) pooled cohort risk assessment score ≥ 7.5% **OR**
            3. Framingham Risk Score ≥ 20%

4. **The patient has initiated all the following lifestyle modifications:**
    a. Must currently be a non-smoker (defined as someone who has not smoked in the past 6 months)
        i. Non-smoker is defined as someone who has not smoked in the past 6 months
    b. Patient must be initiated on a heart-healthy diet
    c. Patient must engage in physical activity (at their level of ability) for at least 30 minutes most days of the week
5. **Documentation of baseline LDL-C level must be provided -** measurement must occur within 60 days prior to treatment.
6. **The patient must have failed to reach target LDL-C while receiving treatment with high-intensity statin therapy (atorvastatin 80mg/day or rosuvastatin 40mg/day), or maximally tolerated statin therapy, in combination with ezetimibe (if not contraindicated) for at least 8 weeks:**
    a. LDL-C must be ≥ 70 mg/dL for patients with ASCVD or HeFH, LDL-C must be ≥ 100 mg/dL for patients with primary hyperlipidemia without ASCVD or HeFH
    b. Patient must be compliant with their previous statin and ezetimibe therapy. Prescription drug claims from the last 6 months will be assessed for medication adherence. If pharmacy refill history is not available, a recent pharmacy profile will be requested. Progress notes documenting usage of sample medication may also be requested. A threshold of 80% PDC (Percent Days Covered) is typically defined as being compliant with drug therapy.
    c. If patient is unable to tolerate statin therapy, documentation in progress notes must include:
        i. A contraindication to statin therapy according to FDA labeling **OR**
        ii. History of statin-related rhabdomyolysis
            1. Must have symptoms consistent with rhabdomyolysis (i.e., muscle pain, swelling, and weakness, dark urine) **AND**

2. Must have Creatine kinase (CK) level ≥ 10 times the upper limit of normal (ULN), Myoglobinuria, or acute renal failure (increase in serum creatinine >0.5 mg/dL) **AND**
3. Member was receiving a statin at the time of the event and symptoms resolved upon discontinuation of the statin **OR**

iii. History of statin intolerance. Documentation must include the following:
1. Inability to tolerate at least 2 different statins:
a. At least 1 statin must be hydrophilic (such as pravastatin, fluvastatin, or Crestor) starting at the lowest starting average daily dose **AND**
2. Intolerance associated with confirmed, intolerable statin-related adverse effects(s) (i.e., muscle related symptoms) or significant biomarker abnormalities (i.e., ALT/AST >3 times the upper limit of normal accompanied by increases in total bilirubin >2 times the upper limit of normal) **AND**
3. Symptom or biomarker change, resolution, or significant improvement on dose decrease or discontinuation **AND**
4. Non-statin causes of muscle symptoms or biomarker abnormalities have been ruled out (For example, hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders such as polymyalgia rheumatic, steroid myopathy, vitamin D deficiency, or primary muscle disease)

7. If the patient can tolerate statins, Nexletol and Nexlizet must be prescribed in combination with the maximum tolerated dose of a statin. Nexletol must also be prescribed with ezetimibe whether the patient can tolerate statins or not.
a. Simvastatin >20mg and pravastatin >40mg should be avoided with bempedoic acid due to increased risk of myopathy.
8. The patient must have had serious side effects or drug failure with either Repatha or Praluent, except for individuals at high risk for a CVD event (Framingham Risk score ≥ 20%) but without established CVD
9. Nexletol and Nexlizet will not be approved in combination with Repatha, Praluent or Leqvio as there are no data showing safety and efficacy with this combination.

Approval Timeframes

1. Approval will be for 12 weeks for initial requests and 12 months for recertification requests.
a. **Initial Recertification requires:**
i. Demonstrated adequate reduction in LDL cholesterol defined as:
(1) ≥18% reduction in LDL after 4-8 weeks of therapy as compared to baseline LDL level or reduction to LDL goal for patients with a diagnosis of ASCVD **OR**
(2) An adequate reduction in LDL level after 4-8 weeks of therapy as compared to baseline LDL level for patients with a diagnosis of HeFH or primary hyperlipidemia **AND**
ii. Continued adherence to a high intensity statin at maximum tolerated dose, or maximally tolerated statin, (and ezetimibe for Nexletol) **AND**
iii. Continued adherence to lifestyle modifications (non-smoker, diet, and exercise)
b. **Subsequent Recertifications require:**
i. Documentation that confirms the patient has maintained an adequate reduction in LDL cholesterol compared to baseline (The LDL level must have been measured within the past 12 months) **AND**
ii. Continued adherence to a high intensity statin at maximum tolerated dose, or maximally tolerated statin, (and ezetimibe for Nexletol) **AND**
iii. Continued adherence to lifestyle modifications (non-smoker, diet, and exercise)

Niacin 500 mg tablet

1. The health plan has determined that niacin 500 mg tablet is not medically necessary due to availability of lower costing niacin containing products that are likely to produce equal therapeutic results
2. Quantity limit of 30 tablets/30 days. Additional quantities will be granted based on FDA-approved dosing.

Northera and droxidopa capsules
1. Must be prescribed for a diagnosis of Neurogenic Orthostatic Hypotension (NOH) 2. Must have had previous trial and failure or intolerance to generic midodrine 5-10mg three daily 3. NOH is associated with disease states such as Parkinson's disease, multiple-system atrophy, and pure autonomic failure. Northera/droxidopa will not be approved for nonneurogenic causes of OH, which include hypovolemia, cardiac pump failure, venous pooling, and drugs. 4. Quantity limit of 180 capsules per 30 days
Nourianz – istradefylline tablets
1. Must be prescribed by a neurologist 2. Must have a diagnosis of Parkinson's disease with "wearing off symptoms" 3. Must be currently taking a regimen of oral carbidopa/levodopa 4. Must have attempted increasing the dose and dosing frequency of oral carbidopa/levodopa 5. Must have had serious side effects or drug failure with **TWO** of the following: pramipexole, ropinirole, entacapone, tolcapone, selegiline, or rasagiline 6. Quantity limit of 30 tablets per 30 days
Nuedexta – dextromethorphan/quinidine capsules
1. Diagnosis of Pseudobulbar Affect (PBA) diagnosed by a neurologist, psychiatrist, psychiatric nurse practitioner, or geriatrician 2. Symptoms of involuntary and inappropriate outbursts of laughter and/or crying 3. Quantity limit of 60 capsules per 30 days
Nuplazid – pimavanserin tablets and capsules
1. Member must have a diagnosis of Parkinson's disease psychosis (PDP) 2. Nuplazid will not be approved for any other non-FDA approved indication, including dementia related psychosis. 3. Medication must be prescribed by a neurologist, psychiatrist, psychiatric nurse practitioner or geriatrician 4. Nuplazid is not recommended in patients with hepatic impairment or severe renal impairment (CrCL< 30ml/min) 5. Quantity limit is 30 tablets or capsules per 30 days
Nuzyra – omadacycline tablet
1. Coverage will be granted for members who are being discharged from the hospital with a prescription for Nuzyra 2. If Nuzyra is being prescribed in an outpatient setting, the member must have had a consultation with an infectious disease specialist 3. Quantity limit is 30 tablets per 14 days a. Approval will be for 14 days b. Duration of treatment beyond 14 days of use will be considered on a case-by-case basis for patients without any other treatment options and will only be granted for the guideline recommended duration of treatment 4. Quantity limit and approval duration applies to all requests over 30 tablets per 14 days regardless of prescriber specialty or hospital discharge
Ocaliva – obeticholic acid tablet
On Friday September 12, 2024, the FDA 's Gastrointestinal Drug Advisory Committee held a meeting to assess whether Ocaliva met its postmarketing requirement following the 2016 accelerated approval of the drug. The panel voted 13 to 1 stating the manufacturer's data did not adequately prove Ocaliva's clinical benefit. In addition, 10 panelists felt the overall risk-benefit profile was not favorable, with one 1-member voting for the drug, while 3 abstained. The upcoming PDUFA data for full approval for Ocaliva is set for October 15, 2024. **Based on the above information, The Health Plan will not authorize coverage for Ocaliva for new patients (naïve to Ocaliva therapy) at this time.**

1. Must be prescribed by a gastroenterologist, hepatologist, or liver transplant specialist **AND**
2. Must be age 18 year or older **AND**
3. Must have a diagnosis of primary biliary cholangitis (PBC)
    a. Must have at least 2 of the following:
        i. Positive antimitochondrial antibodies (AMA) or other PBC specific auto-bodies, including sp100 or gp210, if AMA are negative
        ii. History of increased ALP levels above the upper limit of normal (ULN) as defined by normal laboratory reference values
        iii. Liver biopsy consistent with PBC, according to the pathology report **AND**
4. Must meet for one of the following:
    a. Must have had an inadequate response to ursodiol for a period of at least 12 months
        i. Inadequate response is defined as:
            (1) ALP that is ≥ 1.67 times the upper limit of normal (ULN = 118 U/L for females and 124 U/L for males) **OR**
            (2) Total bilirubin level that is greater than 1-times ULN but less than 2 times ULN (ULN=1.1 mg/dL for females and 1.5mg/dL for males) **OR**
        b. Must be unable to tolerate ursodiol:
5. The patient's Child-Pugh score must be submitted for review. Coverage will require:
    a. No evidence of decompensated cirrhosis (Child-Pugh Class B or C)
    b. Attestation of no prior decompensation event
    c. No evidence of compensated cirrhosis with evidence of portal hypertension
6. The initial approval timeframe will be for 6 months. Continued 12-month approval will require:
    a. Documentation that the member has responded to therapy defined as:
        i. ALP ≤ 1.67 times the upper limit of normal (ULN = 118 U/L for females and 124 U/L for males) **AND**
        ii. Decrease in ALP of at least 15% compared to baseline **AND**
        iii. Total bilirubin ≤ ULN (1.1 mg/dL for females and 1.5mg/dL for males) **AND**
    b. No contraindications to therapy:
        i. No evidence of decompensated cirrhosis (Child-Pugh Class B or C)
        ii. Attestation of no prior decompensation event
        iii. No evidence of compensated cirrhosis with evidence of portal hypertension
7. Quantity Limit 30 tablets per 30 days

Ofev – nintedanib capsule

1. The member must be a non-smoker (defined as someone who has not smoked in the past month)
2. For a diagnosis of idiopathic pulmonary fibrosis (IPF):
    a. Must be prescribed by a pulmonologist
    b. The diagnosis of IPF must be based on the following criteria:
        i. Exclusion of other known causes of interstitial lung disease (ILD) (e.g., environmental exposures, connective tissue disease and drug toxicity).
        ii. The presence of a UIP (usual interstitial pneumonia) pattern on computed tomography (CT) in patients not subjected to surgical lung biopsy
            1. UIP must be determined to be "definite" or "probable" from the CT scan, and may include terminology such as honeycombing, traction bronchiectasis, bronchiolectasis and/or ground glass opacities
        iii. Specific combinations of CT and surgical lung biopsy pattern in patients subjected to surgical lung biopsy
3. For a diagnosis of systemic sclerosis with declining pulmonary function:
    a. Must be prescribed by a pulmonologist or a rheumatologist
    b. Must have fibrosis affecting at least 10% of the lung based on a CT scan from within the last 12 months

c. Must have been treated with azathioprine, mycophenolate mofetil (MMF), or prednisone 4. For a diagnosis of chronic fibrosing interstitial lung disease with a progressive disease phenotype a. Must be prescribed by a pulmonologist or rheumatologist b. Must have had a HRCT scan showing fibrosing lung disease with a disease extent of at least 10% within the last 12 months c. Must have been treated with azathioprine, mycophenolate mofetil (MMF), prednisone, n-acetylcysteine (NAC), a rituximab-containing product, cyclophosphamide, cyclosporine, or tacrolimus and have had one of the following while on this treatment: i. A decline in forced vital capacity (FVC) predicted of at least 10% ii. A decline in forced vital capacity (FVC) predicted of at least 5% with worsening respiratory symptoms iii. A decline in forced vital capacity (FVC) predicted of at least 5% with increasing extent of fibrotic changes shown on chest imaging iv. Worsening of respiratory symptoms as well as increasing extent of fibrotic changes shown on chest imaging 5. Ofev will not be authorized in combination with Esbriet, pirfenidone tablets, or pirfenidone capsules 6. Quantity limit 60 capsules per 30 days
Omnipod kits and pods
1. Must have at least 90 days of insulin use prior to initiating use of Omnipod 2. Quantity limit of 15 pods per 30 days and 1 kit per 365 days
Ondansetron ODT 16 mg tablet
1. The health plan has determined ondansetron ODT 16 mg tablet is not medically necessary due to the availability of lower costing ondansetron products that are likely to produce equal therapeutic results.
Onexton and clindamycin phosphate/benzoyl peroxide 1.2%-3.75% gel
1. Must have a diagnosis of moderate to severe acne 2. Must be prescribed by a dermatologist 3. Must have had failure or intolerance to generic benzoyl peroxide/clindamycin gel (generic for Benzaclin) for a minimum of 3 months of therapy documented by progress notes or pharmacy fill history 4. Must have had failure or intolerance to a generic topical retinoid for a minimum of 3 months of therapy documented by progress notes or pharmacy fill history 5. Requests for brand name Onexton will require documentation of use of clindamycin phosphate/benzoyl peroxide 1.2%-3.75% gel (generic Onexton) that led to serious side effects or drug failure
Onmel - itraconazole tablet
1. Must be prescribed by a Podiatrist or Dermatologist 2. Must have a diagnosis of onychomycosis with pain that impairs activities of daily living. 3. Must have a positive KOH stain or positive culture (on Sabouraud's medium or dermatophyte test medium (DTM)) 4. Must have had failure or intolerance to itraconazole and terbinafine. 5. Quantity Limit of 84 tablets per 365 days.
Opipza – aripiprazole oral film
1. The health plan has determined that Opipza is not medically necessary due to the availability of lower costing options that are likely to produce equal therapeutic results.
Opzelura - ruxolitinib phosphate cream
1. The diagnosis of nonsegmental vitiligo is considered a cosmetic use and therefore, Opzelura will not be approved for treatment of vitiligo 2. For a diagnosis of atopic dermatitis, the following criteria must be met: a. Must be 12 years of age or older b. Must be prescribed by a dermatologist

c. Must have diagnosis of mild to moderate atopic dermatitis
   ii) Baseline BSA must be provided and be <20%
   iii) Baseline vIGA-AD (validated investigator global assessment for atopic dermatitis) score must be provided (see references for link to assessment tool)
d. Must have had serious side effects or drug failure with an adequate trial of ONE generic topical steroid
   i) Adequate trial is defined as ≥ 28 days or for the maximum duration recommended by the product prescribing information (i.e., 14 days for super-potent topical corticosteroids), whichever is shorter
e. Must have had serious side effects or drug failure with an adequate trial of ONE of the following: tacrolimus ointment or pimecrolimus cream
   i) Adequate trial is defined as ≥ 6 weeks based on prescribing information
f. Must have had serious side effects or drug failure with an adequate trial of Eucrisa
   i) Adequate trial is defined as ≥ 28 days based on prescribing

3. Approval will be granted for 8 weeks
   a. Recertification of the first approval after 8 weeks of use will require documentation of improvement in disease (decreased BSA and/or vIGA-AD score)
   b. Additional recertifications (2nd recertification and beyond) will require documentation that the patient maintained their improvement in BSA and/or vIGA-AD score from baseline, but continues to have signs/symptoms of disease requiring continued use with Opzelura
4. Opzelura will not be covered for any non-FDA approved indications
5. Opzelura will not be allowed in combination with therapeutic biologics (such as Dupixent and Adbry), other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine
6. Quantity limit: 60 grams per 30 days

Oracea and doxycycline IR-DR 40 mg capsules

1. Must have a diagnosis of inflammatory lesions (papules and pustules) of rosacea
   a. All other non-FDA approved indications will not be covered
2. Must have had serious side effects or drug failure to doxycycline IR 20 mg tablet dosed twice daily AND minocycline IR

Oravig - miconazole buccal tablet

1. Must be ≥ 18 years of age
2. Must be used for the treatment of oropharyngeal candidiasis
3. Must have had previous trial and failure or intolerance to oral Nystatin and clotrimazole.
4. Recommended dosage for Oravig is application of one 50mg buccal tablet to the gum region once daily for 14 consecutive days.
5. Quantity Limit 14 tablets per 30 days.

Oriahnn – elagolix/estradiol/norethindrone tablets

1. Member must be at least 18 years of age
2. Must have a diagnosis of heavy menstrual bleeding associated with uterine fibroids
   a. Uterine fibroids must be documented by pelvic ultrasound
3. Must be premenopausal
4. Must be prescribed by a gynecologist
5. Must have had serious side effects or drug failure with a contraceptive (such as estrogen-progesterone, progesterone alone, or progesterone-releasing intrauterine device contraceptives) AND tranexamic acid
6. Must not be pregnant or actively trying to conceive
7. Oriahnn will not be approved if the member has had previous treatment with the maximum duration of Myfembree or Orilissa
8. Oriahnn will not be covered for non-FDA approved indications (such as heavy menstrual bleeding without uterine fibroids)

9. Initial approval will be for 12 months. Recertification for 12 months will require the prescriber to attest to improved symptoms
10. Treatment beyond 24 months total (two 12-month courses) will not be approved

Orilissa – elagolix tablets

1. Must be at least 18 years of age
2. Must have a diagnosis of pain associated with endometriosis
3. Must be prescribed by a gynecologist
4. Must have had serious side effects or drug failure with two different continuous hormonal contraceptives, unless contraindicated
5. Patient must not be pregnant or actively trying to conceive
6. For patients with cirrhotic liver disease, a Child-Pugh score is required. Orilissa is contraindicated in patients who are Child-Pugh C and will not be covered.
7. Orilissa will not be approved if the member has had previous treatment with the maximum duration of Myfembree, Oriahnn, or Synarel
8. Orilissa will not be covered for non-FDA approved indications (such as heavy menstrual bleeding with uterine fibroids)
9. Dosing and lifetime approval duration will be limited based on the following coexisting conditions:
    a. Coexisting condition of dyspareunia: the prescriber may consider using 200 mg twice daily for a maximum of 6 months **OR** can use standard dosing of 150 mg once daily for a maximum of 24 months.
    b. Coexisting condition of moderate hepatic impairment (Child-Pugh B): 150 mg once daily for a maximum of 6 months
        1. Neither of the above coexisting conditions: 150 mg once daily for a MAXIMUM of 24 months
10. Initial approval will be for 6 months. Recertification for Orilissa 150 mg will be for 18 months for patients without moderate hepatic impairment (Child-Pugh B) to allow for 24 months of total therapy. Recertification will require the prescriber to attest to improved symptoms
11. Recertification will **NOT** be approved:
    a. For patients with moderate hepatic impairment as 6 months is the total lifetime treatment duration in these patients.
    b. For patients with dyspareunia who have received 6 months of treatment with the 200 mg strength as continued use of the 200 mg or 150 mg strength has not been studied in these patients.

Quantity Limits: 200 mg tablets: 56 tablets per 28 days, 150 mg tablets: 28 tablets per 28 days

Orkambi – lumacaftor/ivacaftor tablets and granules

1. Individual must have a diagnosis of Cystic Fibrosis **AND**
2. Must be 1 year of age or older **AND**
3. Must have 2 copies of the F508del mutation in the CFTR gene **AND**
4. Quantity limits as follows:
    a. Tablets:120 tablets per 30 days

Granules: 60 packets per 30 days

Ortikos – budesonide ER capsules

1. Must be prescribed by a gastroenterologist
2. Must have a diagnosis of Crohn's disease **AND** be in an active disease flare
3. Must have had serious side effects or drug failure to budesonide EC capsules
4. Initial approval will be for 8 weeks of therapy to treat active disease
    a. Subsequent approval will be for 12 weeks for maintenance therapy if symptoms are controlled after initial course **OR** another 8-week initial treatment if there is documentation of a new active disease flare after completion of therapy

Quantity limit of 30 capsules per 30 days

Osmolex – amantadine ER tablet
1. Must be prescribed by a neurologist 2. Must be prescribed for either: a. Parkinson's disease **OR** b. Drug-induced extrapyramidal reactions **AND** 3. Must have had serious side effects or drug failure with generic amantadine
Otrexup – methotrexate injection
1. Must have a diagnosis of severe, active rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), or severe, recalcitrant, disabling psoriasis **AND** 2. Must have an inability to self-inject generic methotrexate a. For pediatric patients, documentation must also include the inability of a caregiver to inject the child **AND** 3. Must have documented intolerance or failure to oral methotrexate
Oxervate – cenegermin-bkbj ophthalmic solution
1. Must have a diagnosis of stage 2 (persistent epithelial defect, PED) or stage 3 (corneal ulcer) neurotrophic keratitis (NK) 2. Must have failed treatment with one or more conventional treatments for NK such as preservative-free ophthalmic lubricants (artificial tears, gel, or ointment) 3. Approval will be for 8 weeks 4. Retreatment courses will not be approved as there have been no studies to document the efficacy of treatment beyond a single 8-week course 5. Quantity limit is 56 mL per 365 days to allow for 8 weeks of treatment in one eye If there is documentation of a need for treatment in both eyes, a quantity limit of 112 mL per 365 days will be granted
Pexeva – paroxetine mesylate tablets
1. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic paroxetine hydrochloride tablets the patient will be required to use generic paroxetine hydrochloride tablets unless there is adequate justification as to why this formulation is not appropriate **AND** 2. If unable to use generic paroxetine hydrochloride tablets, patient must have tried and failed or have severe intolerance to all lower cost generic alternatives such as escitalopram, fluoxetine, citalopram, sertraline, and venlafaxine
Pokonza – potassium chloride 10 mEq packets
1. Based on comparable indications, efficacy, safety profiles, and available strength that allows for equivalent dosing, the patient will be required to use generic potassium chloride tablets, potassium chloride capsules, potassium chloride 20 mEq packets, or potassium chloride solution unless there is adequate justification as to why all of these formulations are not appropriate 2. Quantity limit of 30 packets per 30 days a. Additional quantities can be granted if generic potassium chloride tablets, potassium chloride capsules, potassium chloride 20 mEq packets, and potassium chloride solution have been used to obtain the same daily dose or there is adequate justification as to why all of these formulations are not appropriate
Pradaxa packets - dabigatran etexilate oral pellets
1. Must be between 3-months and less than 12 years of age a. Patients between the ages of 8 and 12 will require documentation of a swallowing disorder (a speech and swallow evaluation will be required) **AND** 2. Must be used for **ONE** of the following: a. For the treatment of venous thromboembolic events (VTE) that has been treated with a parenteral anticoagulant for at least 5 days **OR** b. To reduce the risk of recurrence of VTE in pediatric patients who have been previously treated **AND**

3. Must have a medical reason why Xarelto (suspension or tablets) cannot be used **AND**

A sufficient quantity will be granted for the appropriate dose based on age and weight in accordance with the prescribing information

Promacta – eltrombopag tablet and powder for suspension

1. Promacta must be prescribed by a hematologist **AND**
2. Member must have a diagnosis of immune (idiopathic) thrombocytopenia purpura (ITP) **AND**
   a. Must have a current platelet count less than 30 x 10^9/L **AND**
   b. Must have had an insufficient response (defined as a platelet count of less than 30 x 10^9/L, or greater but with bleeding symptoms) to corticosteroids OR immunoglobulins (IVIG)
      i. Patients who are dependent on corticosteroids (i.e., the need for continuous use or the need for frequent courses) to maintain a platelet count of ≥ 30 x 10^9/L will not require documentation of an insufficient response to corticosteroids as defined above **OR**
3. Must have a diagnosis of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy **OR**
4. Must have a diagnosis of severe aplastic anemia
   a. Diagnosis of severe aplastic anemia must be documented by:
      i. A marrow biopsy showing <25 percent of normal cellularity **OR**
      ii. A marrow biopsy showing <50 percent normally cellularity in which <30 percent of the cells are hematopoietic and at least two of the following are present: absolute reticulocyte count <40,000/microL, absolute neutrophil count (ANC) <500/microL, or platelet count <20,000/microL
5. Promacta should not be used to normalize platelet counts
6. Quantity limit is 30 tablets or packets per 30 days
   a. Approved requests for FDA approved indications that require 150 mg dosing will be approved with a quantity authorization to allow two 75 mg tablets per day

Requests above the quantity limit will be reviewed for medical necessity **AND** reviewed to require the most cost-efficient dose available for the quantity requested

Qbrelis – lisinopril solution 1mg/ml

1. Qbrelis will be allowed for children 7 years of age and under.
2. Children aged 8-17 years old will require documentation of an attempt and inability to swallow an oral pill
3. Adults 18 years and older will require documentation of a swallowing disorder which prevents use of all oral pills.
4. Approval for children aged 7 years old and under will be until the child turns 8. Approval for children aged 8-17 years old will be until the child turns 18.
5. Quantity Limit 1200mL/30 days

Qualaquin and quinine sulfate capsules

1. Must have a diagnosis of Malaria

Rasuvo – methotrexate injection

1. Must have a diagnosis of severe, active rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), or severe, recalcitrant, disabling psoriasis
2. Must have an inability to self-inject generic methotrexate
   a. For pediatric patients, documentation must also include the inability of a caregiver to inject the child **AND**
3. Must also have documented intolerance or failure to oral methotrexate

Rayaldee – calcifediol ER capsules

1. Must be 18 years or older **AND**
2. Must have a diagnosis of secondary hyperparathyroidism with stage 3 or 4 chronic kidney disease **AND**
3. Must not have stage 5 chronic kidney disease or end-stage renal disease on dialysis **AND**
4. Must have tried and failed therapy with all the following: calcitriol capsules, doxercalciferol capsules and paricalcitol capsules

Rayos – prednisone tablet, gastro-resistant

1. Must have a diagnosis of rheumatoid arthritis
2. Must be prescribed by a rheumatologist
3. Must have received non-biologic DMARD therapy for at least 6 months prior to Rayos use and had an incomplete response to DMARD therapy alone
4. As Rayos is designed to reduce the duration of morning stiffness, the patient must have a trial of and failure to prednisone **AND** methylprednisolone that resulted in continued morning stiffness when used in combination with a DMARD
5. Rayos must be used in combination with a DMARD
6. Quantity limit is 30 tablets per 30 days
7. Based upon our criteria and review of the peer-review literature, Rayos tablets for the treatment of all other indications is considered not medically necessary and will be excluded. There has been no guideline/literature support to indicate that Rayos would be more effective or better tolerated than prednisone. The clinical evidence does not support the use of Rayos for other disease states including, but not limited to, the following: allergic conditions, dermatologic diseases, endocrine conditions, gastrointestinal diseases, hematologic diseases, neoplastic conditions, nervous system conditions, ophthalmic conditions, conditions related to oral transplantation, pulmonary diseases, renal conditions, infectious diseases, and rheumatologic conditions other than rheumatoid arthritis.

Reltone and generic ursodiol 200 mg and 400 mg capsules

1. Due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results, patients must use the closest equivalent dose of the lower cost generic alternatives (such as ursodiol 300 mg capsules, ursodiol 250 mg tablets, and ursodiol 500 mg tablets)
2. If unable to use the above alternatives, the following requirements must be met:
   a. Must be prescribed to treat gallbladder stones <20 mm in diameter
      i. Must be unable to undergo surgery due increased surgical risk due to systemic disease, advanced age, or idiosyncratic reaction to general anesthesia **OR**
   b. Must be prescribed for prevention of gallstone formation in obese patients experiencing rapid weight loss **AND**
   c. There is a clinically valid medical reason why ursodiol 300 mg capsules, ursodiol 250 mg tablets, and ursodiol 500 mg tablets cannot be used **AND**
3. If all the above are met, brand name Reltone will be required to be used
   a. Coverage of generic ursodiol 200 mg or 400 mg capsules will require serious side effects or drug failure to brand name Reltone
4. Requests will not be approved for any other non-FDA approved indications

Ryaltris – mometasone and olopatadine nasal spray

1. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic mometasone and olopatadine, the member will be required to use generic mometasone and olopatadine as separate products unless they have tried mometasone and olopatadine as separate products and have a valid medical reason for requiring combination therapy.
2. Quantity limit of 29 grams per 30 days

Rytary and Crexont- carbidopa/levodopa ER capsule

1. Must have a diagnosis of Parkinson's disease, post-encephalitic Parkinsonism, or Parkinsonism following carbon monoxide/manganese intoxication
2. Must have motor fluctuations despite carbidopa/levodopa with entacapone therapy
3. Quantity limit will vary by product and dosage strength:
   a. Rytary:
      i. 23.75mg/95 mg: 150 capsules/30 days
      ii. 36.25mg/145mg: 300 capsules/30 days
      iii. 48.75mg/195 mg: 300 capsules/30 days
      iv. 61.25 mg/245mg: 300 capsules/30 days

b. Crexont:
   i. 35mg/140mg: 60 capsules/30 days
   ii. 52.5mg/210mg: 180 capsules/30 days
   iii. 70mg/280mg: 180 capsules/30 days
   iv. 87.5mg/350mg: 180 capsules/30 days

Sabril, vigabatrin tablets, vigabatrin packets, Vigadrone, Vigafyde and Vigpoder

1. Must be prescribed by, or in consultation with, a neurologist
2. For Sabril, vigabatrin tablets, vigabatrin packets, Vigadrone and Vigpoder requests, patient must meet one of the following:
   a. Must have a diagnosis of infantile spasms and be between 1 month and 2 years of age **OR**
   b. Must have a diagnosis of refractory complex partial seizures **AND** must have had drug failure or serious side effects with at least 3 of the following: carbamazepine, sodium valproate, lamotrigine, or oxcarbazepine
3. For Vigafyde requests, patient must have a diagnosis of infantile spasms and be between 1 month and 2 years of age
4. Requests for brand Sabril packets and Vigpoder packets will require documentation of use of generic vigabatrin packets or Vigadrone packets that led to serious side effects or drug failure
5. Requests for brand Sabril tablets and Vigadrone tablets will require documentation of use of generic vigabatrin tablets that led to serious side effects or drug failure
6. Quantity limit for Sabril, vigabatrin tablets, vigabatrin packets, Vigadrone and Vigpoder is 180 tablets/packets per 30 days.
7. Quantity limit for Vigafyde is 300 mL per 30 days.
   a. Approval for increased quantity will be based on FDA approved dosing recommendations.

Semglee-yfgn

1. The health plan has determined that Semglee-yfgn is not medically necessary due to availability of lower costing options that are likely to produce equal therapeutic results.

Sertraline capsules

1. Based on comparable indications, efficacy, safety profiles, and available strengths that allow for equivalent dosing, the member will be required to use generic sertraline tablets unless there is adequate justification as to why this formulation is not appropriate **AND**
2. If unable to use generic sertraline tablets, the member must try and failed or have severe intolerance to all lower cost generic alternatives such as escitalopram, fluoxetine, citalopram, paroxetine, and venlafaxine.

Seysara – sarecycline tablets

1. Must have a diagnosis of moderate to severe acne that requires oral therapy
2. Must be prescribed by a dermatologist
3. Must have experienced serious side effects or drug failure with a topical retinoid (such as tretinoin, adapalene, tazarotene) **AND** generic minocycline **AND** generic doxycycline
4. Must be used in combination with topical therapy (benzoyl peroxide and/or retinoid)
5. Quantity Limit 30 per 30 days
6. Initial approval will be for 12 weeks

Recertification criteria: To limit antibiotic resistance, patients should not use oral antibiotics chronically. The following criteria are based on guidelines set forth by the Global Alliance to Improve Outcomes in Acne and the American Academy of Dermatology.

1. Patients should continue the use of a topical therapy to maintain remission of new acne lesions when antibiotic therapy is discontinued.
2. Patient progress notes documenting a flare in symptoms will need to be submitted for review by the clinical staff.
3. If patients have a flare of inflammatory lesions after the initial 12-week course, then they will be allowed

to retreat as long as they have been using a topical maintenance therapy. Retinoids are the preferred maintenance agent or as an alternative, a combination of benzoyl peroxide and a topical antibiotic is acceptable.

Recertification will be approved for one year.

Sitagliptin-Metformin, Zituvimet and Zituvimet XR tablets

1. The health plan has determined that sitagliptin-metformin, Zituvimet and Zituvimet XR tablets are not medically necessary due to the availability of lower costing options that are likely to produce equal therapeutic results.

Sitavig – acyclovir buccal tablet

1. Must have a diagnosis of herpes labialis **AND**
2. Must have had previous failure or intolerance to at least **TWO** of the following: acyclovir, famciclovir, and valacyclovir.
3. Quantity Limit 2 tablets per 30 days

Sivextro – tedizolid phosphate tablet

1. Sivextro will only be approved for patients 12 years of age and older
2. Infectious Disease specialists are exempt from prior authorization criteria (lines 3, 4 and 5 only)
3. All other prescribers must meet the following criteria:
   a. Infectious Disease consult recommending tedizolid therapy **OR**
   b. Laboratory data including culture site, organism identified (must include gram-positive organisms) and susceptibility must accompany prior-authorization request **AND**
   c. Documentation must support the trial and therapeutic failure of at least one first-line antibacterial agent that is clinically appropriate for the organism identified.
4. Tedizolid will only be approved for a diagnosis of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following gram-positive microogranisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), and *Enterococcus faecalis*.
5. Tedizolid will not be approved for infections caused by aerobic and facultative anaerobic gram-positive bacteria such as *Staphylococcus epidermidis* (including methicillin-susceptible and methicillin-resistant isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis, and Enterococcus* faecium as the safety and effectiveness of tedizolid in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled clinical trials.
6. The quantity limit is 6 tablets per 30 days and the authorization will be for a 6-day time-period.
   a. Quantity limit applies to all requests over 6 tablets per 30 days regardless of prescriber specialty

Coverage of Sivextro for prophylactic therapy is excluded as it is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Soaanz – torsemide tablet

1. The health plan has determined that Soaanz is not medically necessary due to availability of lower costing torsemide options that are likely to produce equal therapeutic results

Sofdra - sofpironium

1. Must be prescribed by or in consultation with a dermatologist **AND**
2. Must be 9 years of age or older **AND**
3. Must have a diagnosis of primary axillary hyperhidrosis (e.g., resulting in medical complications such as skin maceration and infection or significant disruption of professional/social life) **AND**
4. Must be experiencing symptoms of hyperhidrosis for at least 6 months **AND**
5. Provider must attest that secondary causes of hyperhidrosis have been ruled out (e.g., underlying medical condition, medications) **AND**
6. Must have experienced drug failure with a 4-week trial of topical aluminum chloride, unless contraindicated or serious side effects are experienced **AND**

7. Must have experienced drug failure with a 4-week trial of Qbrexza, unless contraindicated or serious side effects are experienced **AND**
8. Initial approval will be for 3 months. Continued approval will be for 12 months at a time and require documentation that the patient is experiencing clinical benefit.
9. Quantity limit: 1 bottle (50 mL) per 30 days
    a. Note: Each bottle is 50 mL and is capable of dispensing 60 pump actuations. Each pump actuation dispenses 0.67 mL of gel

Solaraze and generic diclofenac 3% gel

1. Must have a diagnosis of actinic keratosis
2. Must have had a previous trial of imiquimod that resulted in serious side effects or drug failure
3. Diclofenac 3% will not be authorized for any other diagnosis including osteoarthritis and other acute pain conditions such as minor strains, sprains, and contusions.
4. Approval will be for 90 days
5. Quantity limit of 100 grams/30 days.
    a. Please note: Solaraze gel and generic diclofenac 3% gel is applied to lesion areas twice daily. Normally 0.5 grams of gel is used on each 5 cm x 5 cm lesion site. An additional 100 gram per 30 days will be authorized if there is documentation of more than three 5 cm x 5 cm lesions.

Soma 250mg and carisoprodol 250mg tablet

1. Patient must have had a trial of generic carisoprodol 350mg resulting in clinical effectiveness but significant drowsiness causing impairment of activities of daily living
2. Patient must have had severe intolerance or therapeutic failure of at least two other muscle relaxants in addition to carisoprodol (such as cyclobenzaprine, baclofen, tizanidine, methocarbanol, orphenadrine and Skelaxin)
3. Quantity limit of 120/30 or 136/34

Sorilux and generic calcipotriene foam

1. Must have a diagnosis of plaque psoriasis
2. Must be written by a dermatologist
3. Must have had serious side effects or drug failure with minimum 4-week trial of calcipotriene cream, ointment or solution **AND**
4. Must have serious side effects or drug failure to a minimum 4-week trial of a high potency topical corticosteroid (such as augmented betamethasone, betamethasone, clobetasol, desoximetasone, diflorasone, fluocinonide, or halobetasol) or for the maximum duration recommended by the product prescribing information (i.e., 14 days for super-potent topical corticosteroids)
5. Quantity limit of 1 canister per 30 days

Sotylize – sotalol solution

1. Must be prescribed by a Cardiologist
2. Must have a diagnosis of life-threatening ventricular arrhythmias or maintenance of normal sinus rhythm in patients with highly symptomatic atrial fibrillation/flutter
3. Must have documentation of a swallowing or absorptive disorder which results in an inability to use all oral dosage forms such as sotalol tablets.
4. Quantity limit of 1920 mL per 30 days

Sovuna – hydroxychloroquine tablets

1. The health plan has determined that Sovuna is not medically necessary due to availability of lower costing hydroxychloroquine options that are likely to produce equal therapeutic results

Sunosi - solriamfetol tablet

1. Must be 18 years of age or older
2. Must be prescribed by a neurologist, sleep specialist, or pulmonologist
3. Must have a diagnosis of excessive daytime sleepiness associated with either narcolepsy, obstructive sleep apnea (OSA)**,** or hypersomnolence of central origin. The diagnosis must be confirmed by a sleep study which must be submitted for review

4. For a diagnosis of OSA, the prescriber must attest that the patient's underlying airway obstruction has been treated with continuous positive airway pressure for at least one month prior to initiating Sunosi
5. Must have had serious side effects or drug failure with modafinil or armodafinil or have a contraindication to these drugs
6. If the diagnosis is narcolepsy, must also have had serious side effects or drug failure with a stimulant medication indicated for narcolepsy (amphetamine, dextroamphetamine/amphetamine, dextroamphetamine ER, or methylphenidate)

Sunosi will not be covered for any other non-FDA approved conditions

Symdeko - tezacaftor/ivacaftor tablets

1. Must have a diagnosis of cystic fibrosis
2. Must be 6 years or older
3. Must have 2 copies of the F508del mutation in the CFTR gene (homozygous) **OR**
4. Must have at least one mutation in the CFTR gene that is responsive to Symdeko based on *in vitro* data and/or clinical evidence (package insert includes a full list of responsive CFTR gene mutations).
5. Recommended dosage one tablet containing tezacaftor 100mg/ivacaftor 150mg in the morning and one tablet containing ivacaftor 150 mg in the evening, approximately 12 hours apart. Symdeko should be taking with fat-containing food.
6. Liver enzymes should be assessed prior to initiation of Symdeko, every 3 months during the first year of treatment, and annually thereafter.
7. Quantity Limit 56 tablets per 28 days (available in 56 count tablet cartons containing 4 weekly wallets, each with 7 tezacaftor/ivacaftor and 7 ivacaftor tablets).

Synarel – nafarelin nasal spray

1. Must be used for a diagnosis of endometriosis
   a. Must be at least 18 years of age
   b. Must be prescribed by a gynecologist
   c. Must have had serious side effects or drug failure with two different continuous hormonal contraceptives (unless contraindicated)
   d. Synarel will not be approved if the patient has had previous treatment with the maximum duration of Myfembree or Orilissa
   e. Approval will be for a max of 6 months of therapy per prescribing information **OR**
2. Must be used for a diagnosis of central precocious puberty
   a. Must be prescribed by an endocrinologist or pediatrician
   b. Must use Lupron Depot-Ped unless there is adequate medical justification as to why Lupron Depot-Ped cannot be used
      i. Lupron Depot-Ped requirement applies to both new starts and existing users
3. Quantity limit: 8 mL per 30 days. Approval for increased quantity will be granted for the appropriate dose based on indication in accordance with the prescribing information.

Syndros – dronabinol oral solution

1. Covered for a diagnosis of anorexia associated with weight loss in patients with AIDS **OR**
2. Covered for a diagnosis of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments
3. For either diagnosis the member must have an inability to swallow oral pills

Synera – lidocaine/tetracaine patch

1. Must be used as local dermal analgesia on intact skin for superficial venous access or for superficial dermatological procedures
2. Quantity Limit of 30 patches / 30 days

Tascenso ODT – fingolimod tablets

1. Must have diagnosis of Multiple Sclerosis (MS) **AND**
2. Must be at least 10 years of age or older **AND**
3. There must be documentation of an inability to swallow whole tablets or capsules (such as using an

NG/G tube, or a swallowing disorder) with documentation of inability to swallow provided 4. Quantity limit of 30 tablets per 30 days
Tavalisse – fostamatinib tablet
1. Must be prescribed by a hematologist 2. Member must be at least 18 years old 3. Member must have a diagnosis of immune (idiopathic) thrombocytopenia purpura (ITP) **AND** a. Must have a current platelet count less than 30 x 10^9/L **AND** b. Must have had an insufficient response (defined as a platelet count of less than 30 x 10^9/L, or greater but with bleeding symptoms) to corticosteroids **OR** immunoglobulins (IVIG) i. Patients who are dependent on corticosteroids (i.e., the need for continuous use or the need for frequent courses) to maintain a platelet count of ≥ 30 x 10^9/L will not require documentation of an insufficient response to corticosteroids as defined above 4. Tavalisse should not be used to normalize platelet counts 5. The starting dose of Tavalisse is 100 mg twice daily. After 4 weeks, the dose can be increased to 150 mg twice daily to achieve a platelet count of at least 50 x 10^9/L to reduce the risk of bleeding 6. Quantity limit of 60 per 30 days
Tetracycline tablets
1. The health plan has determined that tetracycline tablet is not medically necessary due to the availability of lower costing options that are likely to produce equal therapeutic results
Tolsura – itraconazole tablets
1. Must be 18 years of age or older 2. Must have one of the following diagnoses: a. Histoplasmosis b. Pulmonary or extrapulmonary Blastomycosis c. Pulmonary or extrapulmonary Aspergillosis 3. Must have had serious side effects or drug failure with generic itraconazole 100 mg capsules for any of these three diagnoses 4. If the diagnosis is aspergillosis, must also have had serious side effects or drug failure with amphotericin B 5. Quantity Limit 120 tablets per 30 days
Trianex and triamcinolone 0.05% ointment (the generic equivalent of Trianex)
1. Must have a skin condition that effects at least 30% of the body surface area 2. Must have had drug failure with triamcinolone 0.025% ointment 3. Must have had serious side effects with triamcinolone 0.1% ointment 4. In addition, coverage of brand name Trianex will require serious side effects or drug failure to triamcinolone 0.05% ointment (the generic equivalent of Trianex) 5. Quantity limit of 430 grams per 30 days
Trikafta – elexacaftor/ivacaftor/tezacaftor
1. Member must have a diagnosis of cystic fibrosis 2. Must be 2 years of age or older 3. Must have at least one copy of the F508del mutation in the CFTR gene **OR** 4. Must have at least one mutation in the CFTR gene that is responsive to Trikafta (package insert includes a full list of responsive CFTR gene mutations) 5. Quantity limits as follows: a. 84 tablets per 28 days b. 56 packets per 28 days
Tryvio - aprocitentan
1. Must be 18 years of age or older **AND** 2. Must have a diagnosis of inadequately controlled hypertension, defined as above-goal elevated blood pressure (BP) in a patient despite adherence to the concurrent use of three antihypertensive drug

classes
   a. Inadequate control of hypertension must not be due to non-compliance with medication regimen
3. Patient must have been treated with quadruple antihypertensive therapy which included the addition of a mineralocorticoid receptor agonist (such as spironolactone or eplerenone) within the last six months
4. Must use Tryvio in combination with at least three other anti-hypertensive medications. Tryvio will not be authorized as monotherapy.
5. Initial approval will be for 3 months. Recertification for one year at a time will require documentation that patient is tolerating and responding adequately to treatment as documented by improvement in blood pressure.
6. Quantity limit of 30 tablets per 30 days.

Twiist Starter Kit and Refill Kits

1. Must have a diagnosis of Type 1 diabetes **AND**
2. Must be 6 years of age or older **AND**
3. Must have at least 90 days of insulin use prior to initiating use of Twiist
4. Quantity limit of 1 refill kit per 30 days and 1 starter kit per 365 days

Uceris rectal foam and budesonide rectal foam

1. Must be prescribed by a gastroenterologist **AND**
2. Must have a diagnosis of active, mild to moderate ulcerative colitis. Uceris foam is only approved for UC and therefore, all other indications are excluded from coverage **AND**
3. Must have documentation of clinical failure or intolerance to both topical mesalamine (enema or suppository) and topical hydrocortisone (such as enemas) **AND**
4. Requests for brand Uceris will require documentation of use of generic budesonide rectal foam that led to serious side effects or drug failure
5. The recommended dosage is 1 metered dose administered twice daily for 2 weeks followed by 1 metered dose administered once daily for 4 weeks.
6. Quantity limit of 3 canisters per 30 days (maximum of 4 canisters for total treatment course).
7. Initial approval will be for 6 weeks. Approval for future treatment courses will require documentation that remission (UCDAI score ≤ 1) was achieved after the initial 6 weeks, and that the patient has failed to maintain remission while on an immunomodulator (azathioprine or mercaptopurine) or biologic. Topical budesonide has not been proven to be effective for maintaining remission therefore chronic therapy will not be authorized. Retreatment will be authorized for 6 weeks.

Undecatrex – testosterone undecanoate

1. Must be 18 years of age or older
2. Provider attestation patient has one of the following:
   a. Primary hypogonadism (congenital or acquired)
   b. Hypogonadotropic hypogonadism (congenital or acquired)
3. Quantity limit of 120 capsules per 30 days.

Valsartan oral solution

1. Coverage will be allowed for children less than 8 years old
2. Children aged 8-17 years old will require documentation of an attempt and inability to swallow an oral pill
3. Adults 18 years and older will require documentation of a swallowing disorder which prevents use of all oral pills
4. Approval for children under 8 years of age will be until the child turns 8. Approval for children aged 8-17 years old will be until the child turns 18.
5. Quantity limit of 120 mL per 30 days
   a. Approval for increased quantity will be based on FDA approved dosing recommendations

Veozah – fezolinetant tablets

1. Must have a diagnosis of vasomotor symptoms associated with menopause
2. Must have had serious side effects or drug failure to two other medications proven to be effective for

the treatment of vasomotor symptoms
   a. One treatment option must be a non-hormonal treatment option (such as paroxetine, gabapentin, clonidine, venlafaxine, desvenlafaxine and citalopram)
3. Quantity limit of 30 tablets per 30 days

Verquvo – vericiguat tablets

1. Must have chronic heart failure with an ejection fraction <45% **AND**
2. Must have been hospitalized due to heart failure in the previous 6 months **OR**
3. Must have had outpatient IV diuretics for heart failure in the previous 3 months **AND**
4. Must be currently on or have tried standard of care for heart failure (a beta-blocker in combination with an ACE inhibitor, ARB, or Entresto)

Verkazia – cyclosporine 0.1% ophthalmic emulsion

1. Must be 4 years of age or older
2. Must have a diagnosis of vernal keratoconjunctivitis (VKC)
   a. All other diagnoses will not be covered
3. Must be prescribed by an ophthalmologist
4. Must have had serious side effects or drug failure to an ophthalmic antihistamine with mast cell stabilizer properties (such as olopatadine, azelastine, epinastine or ketotifen) **OR** an antihistamine eye drops in combination with a mast cell stabilizer (such as cromolyn, Alocril or Alomide) **AND**
5. Must have had persistent symptoms despite treatment with an ophthalmic steroid or an inability to titrate off of ophthalmic steroids
6. Quantity limit of 120 vials per 30 days

Vesicare LS – solifenacin succinate suspension

1. Must have a diagnosis of neurogenic detrusor overactivity (NDO) **AND**
2. Patients 5 years of age and older must have had serious side effects or drug failure of oxybutynin tablets or syrup
   a. Patients with difficulty swallow oxybutynin tablets must try the syrup **AND**
3. Children weighing more than 60 kg will require documentation of an attempt and inability to swallow solifenacin oral tablets
4. VESIcare LS will not be covered for patients over the age of 17 as it is only approved in pediatric patients with NDO
5. Recommended Dose: Once daily weight-based dosing
   a. 9 kg - 15 kg: 2 mL - 4 mL (2 - 4 mg)
   b. > 15 kg - 30 kg: 3 mL - 5 mL (3 - 5 mg)
   c. > 30 kg - 45 kg: 3 mL - 6 mL (3 - 6 mg)
   d. > 45 kg - 60 kg: 4 mL - 8 mL (4 - 8 mg)
   e. > 60 kg: 5 mL - 10 mL (5 - 10 mg)
6. Quantity Limit: 300 mL/30 days

Vevye – cyclosporine 0.1% ophthalmic solution

1. The health plan has determined that Vevye is not medically necessary due to the availability of lower costing options that are likely to produce equal therapeutic results.

Vivjoa – oteseconazole capsule

1. Must NOT be of reproductive potential (defined as persons who are biological females who are postmenopausal or have another reason for permanent infertility [e.g., tubal ligation, hysterectomy, salpingo-oophorectomy]) **AND**
2. Must have had at least three episodes of vulvovaginal candidiasis (VVC) within the past 12 months **AND**
3. Current VVC episode must have a positive potassium hydroxide (KOH) test **AND**
4. Must have clinical signs and symptoms associated with VVC (redness, swelling, itching, burning, etc.) **AND**
5. Must have experienced a recurrence during or following 6 months of oral fluconazole maintenance treatment, or patient has a contraindication to fluconazole (e.g., hypersensitivity or drug-drug

interaction) **AND**
6. Vivjoa will not be approved for non-FDA approved diagnoses (such as acute VVC)
7. Approval will be for 12 weeks to allow for a single course of treatment. Recertification will not be granted due to lack of long-term safety and efficacy data

Voquezna – vonoprazan tablets

1. Must be 18 years of age or older **AND**
2. Must be prescribed by or in consultation with a gastroenterologist **AND**
3. Must have a diagnosis of *Helicobacter pylori (H. pylori)* infection and be used in combination with amoxicillin with or without clarithromycin **OR**
4. Must have a diagnosis of erosive esophagitis confirmed via upper endoscopy **AND**
    a. Must have had serious side effects or drug failure to two different proton pump inhibitors (PPIs)
        i. Each PPI trial must be at least 8 weeks in duration
        ii. One of the PPI trials must be twice daily dosing **OR**
5. Must have a diagnosis of non-erosive gastroesophageal reflux disease (GERD) **AND**
    a. Patient must be experiencing heartburn symptoms on at least 4 of the 7 days per week **AND**
    b. Must have had serious side effects or drug failure to two different proton pump inhibitors (PPIs)
        i. Each PPI trial must be at least 8 weeks in duration
        ii. One of the PPI trials must be twice daily dosing
6. Approval duration as follows:
    a. *H. Pylori* treatment: 14-day approval
    b. Erosive esophagitis:
        i. 6-month initial approval
        ii. Recertification will require documentation showing symptom improvement and can be approved for 1 year at a time
    c. Non-erosive GERD:
        i. 3-month initial approval
        ii. Recertification will require documentation showing symptom improvement and can be approved for 1 year at a time
7. Quantity limit is 30 tablets per 30 days
    a. If the request is for *H. Pylori* treatment, a quantity of 2 tablets per day will be granted for 14 days

Vowst - fecal microbiota spores, live-brpk

1. The patient must be at least 18 years of age **AND**
2. Must be used to prevent the recurrence of Clostridioides difficile infection (CDI) **AND**
3. The patient must have a diagnosis of **at least 2** recurrent episodes of Clostridioides difficile infection (CDI) **AND**
4. The patient must have had a positive stool test for the presence of toxigenic Clostridioides difficile within 30 days **AND**
5. The completion of an antibiotic course used for CDI treatment must have been completed 2 to 4 days before initiating treatment with Vowst **AND**
6. Must have had a trial of Rebyota **AND**
7. Patients with a high risk of recurrence must have had a trial of Zinplava (bezlotoxumab)
    a. High risk of recurrence is defined as:
        i. 65 years of age or older **OR**
        ii. Experiencing their second episode of CDI within the past 6 months **OR**
        iii. Severe CDI (defined as having a white blood cell (WBC) count of ≥15,000 cells/mm3 **OR** serum creatinine (SCr) >1.5 mg/dL at the time of diagnosis **OR** hospitalized due to CDI) **AND**
8. Patient must not be immune compromised
9. Retreatment with Vowst for the same CDI will not be covered
10. Vowst will not be covered for the treatment of Clostridioides difficile infection (CDI) or any other non-FDA approved indications

11. Approval will be for 1 month
12. Approved dosing: 4 capsules per day for 3 consecutive days
13. Quantity limit:
    a. 4 capsules per day
    b. 12 capsules per year to ensure Vowst is not used for re-treatment of the same CDI

Vtama – tapinarof 1% cream

1. Must be prescribed by a dermatologist **AND**
2. Must be at least 18 years of age **AND**
3. Must have a diagnosis of chronic plaque psoriasis **AND**
4. Must have a maximum body surface area (BSA) involvement of 20% **AND**
5. Must have had serious side effects or drug failure of a minimum 4-week trial of a medium/high potency topical steroid **AND** a minimum 4-week trial of a topical vitamin D analog
    a. Trial of topical therapies do not have to occur simultaneously (in combination), but consideration will be granted if the topical therapies were trialed together
6. Vtama will not be approved for any non-FDA approved indications
7. Quantity Limit: 60 grams per 30 days

Vyleesi – bremelanotide injection

1. Must be prescribed by a gynecologist psychiatrist, or psychiatric nurse practitioner
2. Must be a premenopausal woman
3. Must have a diagnosis of Hypoactive Sexual Desire Disorder (HSDD) confirmed by Decreased Sexual Desire Screener (DSDS) by answering YES to all the following questions:
    a. In the past, was their level of sexual desire or interest good and satisfying?
    b. Has there been a decrease in their level of sexual desire or interest?
    c. Are they bothered by the decreased level of sexual desire or interest?
    d. Would they like their level of sexual desire or interest to increase?
    e. Have they been assessed for other factors that may be contributing to their current decrease in sexual desire or interest (including an operation, depression, injuries, other medical condition, medication, current drug or alcohol use, pregnancy, recent childbirth, menopausal symptoms, other sexual issues, partner's sexual problems, dissatisfaction with relationship or partner, stress, or fatigue)?
4. Progress notes provided from the specialists required above are required for all Vyleesi requests. Cases received without progress notes cannot be approved
5. Initial approval will be for 8 weeks. Continuation of therapy will require the following:
    a. Provider must acknowledge that the patient has been evaluated for serious side effects
    b. Provider must acknowledge that the patient reports increased sexual desire and satisfying events as a result of drug therapy
    c. Recertification approval will be for 1 year at a time.
6. Quantity limit of 4 injections/30 days

Wakix – pitolisant tablet

1. Must be prescribed by a neurologist or sleep specialist
2. Must have a diagnosis of cataplexy associated with narcolepsy **AND**
    a. Must be 18 years of age or older; **OR**
3. Must have a diagnosis of excessive daytime sleepiness associated with narcolepsy **AND**
    a. Must be 6 years of age or older; **AND**
4. Narcolepsy must be confirmed by a sleep study which must be provided
5. For a diagnosis of excessive daytime sleepiness associated with narcolepsy:
    a. Pediatric patients ages 6 to 17 must have had serious side effects or drug failure with a stimulant medication indicated for narcolepsy (amphetamine, dextroamphetamine/amphetamine, dextroamphetamine ER, or methylphenidate)
    b. Adult patients 18 years of age or older must have had serious side effects or drug failure with

TWO of the following:
   i. Modafinil or armodafinil
   ii. A stimulant medication indicated for narcolepsy (amphetamine, dextroamphetamine/amphetamine, dextroamphetamine ER, or methylphenidate)
   iii. Sunosi (also requires prior authorization)
6. Wakix will only be approved for excessive daytime sleepiness or cataplexy associated with narcolepsy and will not be approved to treat any other non-FDA approved conditions
7. Quantity limit of 60 tablets per 30 days

Winlevi – clascoterone cream

1. Must be used for a diagnosis of acne vulgaris
2. Must be 12 years of age or older
3. Must be prescribed by a dermatologist
4. Must have documentation of serious side effects or drug failure of a generic topical retinoid (tretinoin or adapalene) and topical dapsone 5% gel
5. Winlevi will not be approved for any non-FDA approved indications
6. Quantity Limit: 60 grams per 30 days

Wynzora - calcipotriene/betamethasone topical cream

1. Must be prescribed by a dermatologist
2. Must have a diagnosis of plaque psoriasis
3. Must have had serious side effects or drug failure with a minimum 4-week trial of calcipotriene/betamethasone ointment (the generic for Taclonex ointment)
4. Initial approval will be limited to 4 weeks. Approval for future treatment courses will require documentation of improved symptoms after 4 weeks
5. Quantity limit of 60 grams per 30 days

Xatmep – methotrexate oral solution

1. Must have a diagnosis of acute lymphoblastic leukemia (ALL) or polyarticular juvenile idiopathic arthritis (pJIA)
2. Children 7 years of age and under will require a trial of methotrexate tablets
   a. An exception to this requirement can be made if the prescriber attests to an inability to swallow oral tablets
3. Children 8-17 years of age will require a trial of **BOTH** methotrexate oral tablets and injectable solution (administered either IM or orally).
   a. For members unable to swallow tablets, a speech and swallow evaluation is required to confirm a swallowing disorder.
   b. For members unable to use injectable methotrexate, the patient's caregiver must have a documented physical inability to inject.
4. For the diagnosis of JIA, the member must have had an adequate trial and failure of a full dose NSAID (minimum 12 weeks).
5. Coverage of Xatmep is excluded for patients 18 and older.

Xdemvy - lotilaner ophthalmic solution

1. Must be 18 years of age or older
2. Must be prescribed by an ophthalmologist
3. Must have a diagnosis of Demodex blepharitis confirmed by microscopic examination of the eyelashes to detect Demodex mites
4. Must have bothersome symptoms of Demodex blepharitis (such as itchy eyelids, excessive eye tearing, light sensitivity, gritty or burning eye sensation)
5. Approval will be granted for 6 weeks.
   a. Recertification will not be granted as Xdemvy has not been studied beyond 6 weeks of therapy or for retreatment.
6. Quantity limit of 10 mL per 365 days

Xenazine and tetrabenazine tablets
1. Must have a diagnosis of chorea associated with Huntington's Disease a. Must be 18 years of age or older b. Must be prescribed by a neurologist c. Diagnosis of Huntington's disease is confirmed by genetic testing (i.e., expanded *HTT* CAG repeat sequence ≥ 36) **OR** 2. Must have a diagnosis of Tardive dyskinesia a. Must be 18 years of age or older b. Must be prescribed by or in consultation with a neurologist, psychiatrist, or psychiatric nurse practitioner c. Must have a diagnosis of tardive dyskinesia defined as a history of ≥ 3 months (or ≥ 1 month in patients over 60 years of age) total cumulative neuroleptic exposure (continuous or discontinuous), presence abnormal involuntary movements in one or more body areas, and absence of other conditions that might produce abnormal involuntary movements d. Must have attempted an alternative method to manage the condition (such as dose reduction or discontinuation of the offending medication) **OR** 3. Must have a diagnosis of Tourette's syndrome a. Must be prescribed by a neurologist, psychiatrist, or psychiatric nurse practitioner b. Must have documentation of symptoms that affect activities of daily living which interfere with work, school, or social interactions c. Must have tried and failed behavioral therapy such as habit reversal training or Comprehensive Behavioral Intervention for Tics (CBIT) d. Must have tried and failed at least <u>two</u> of the following drugs from two different drug classes: haloperidol, pimozide, guanfacine, clonidine, aripiprazole, risperidone, ziprasidone, metoclopramide, topiramate **OR** 4. Must have a diagnosis of dystonia a. Must be 18 years of age or older b. Must be prescribed by a neurologist c. Provider attests that patient does not have chorea associated with Huntington's, Tardive dyskinesia, or Tourette's Syndrome 5. Requests for brand Xenazine will require documentation of use of generic tetrabenazine that led to serious side effects or drug failure 6. Initial approval will be for 6 months. Recertification will be for 12 months and require documentation of the following: a. For Huntington's Disease: Symptom improvement and/or stabilization of disease b. For Tardive Dyskinesia and Hyperkinetic Dystonia: Symptom improvement c. For Tourette's Syndrome: symptom improvement **AND** provider attestation that an attempt to gradually withdraw therapy has or will be made when clinically appropriate. 7. Quantity Limit: a. 12.5 mg tablets: 90 tablets per 30 days b. 25 mg tablets: 60 tablets per 30 days i. Requests for a dose greater than 50 mg per day will require submission of CYP2D6 genetic testing results 1. Patients who are intermediate metabolizers (IM) or extensive metabolizers (EM) will be approved for a quantity up to 120 tablets per 30 days for the 25 mg strength tablet 2. Patients who are poor metabolizers (PM) will not be approved for a quantity greater than 60 tablets per 30 days.
Xenleta – lefamulin tablet
1. Coverage will be granted for members who are being discharged from the hospital with a prescription for Xenleta

2. If Xenleta is being prescribed in an outpatient setting, the member must have had a consultation with an infectious disease specialist
3. Approval will be for 7 days
4. Quantity limit is 14 tablets per 7 days

Xhance – fluticasone nasal spray

*****Prior Authorization Applies to Child Health Plus (CHP) ONLY*****
****Quantity Limit Applies to Commercial/Exchange/CHP****

1. Must be 18 years of age or older **AND**
2. Must have a diagnosis of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) **AND**
3. Must have documentation of serious side effects or drug failure with mometasone
4. For a diagnosis of Chronic Rhinosinusitis without Nasal Polyps (CRSsNP), the health plan has determined that Xhance is not medically necessary due to the availability of lower costing options that are likely to produce equal therapeutic results.
5. Quantity limit of 16 mL/30 days. Additional quantities will be granted based on FDA-approved dosing.

Xphozah – tenapanor tablets

1. Must be 18 years of age or older **AND**
2. Must be prescribed by or in consultation with a nephrologist **AND**
3. Must have a diagnosis of chronic kidney disease (CKD) **AND**
4. Must be receiving maintenance dialysis for at least 3 months **AND**
5. Must have serum phosphate level of > 5.5 mg/dL **AND**
6. Step Therapy Applies: Must have had serious side effects or drug failure with:
   a. At least TWO generic phosphate binders (e.g., sevelamer, lanthanum, calcium carbonate, calcium acetate) **AND**
   b. At least ONE iron-based phosphate binder (e.g., Velphoro, Auryxia) **AND**
7. Xphozah will not be covered for any non-FDA approved indications
8. Initial approval will be for 6 months. Recertification will require evidence of a positive response to therapy (e.g., reduced serum phosphorus levels compared to pretreatment levels, serum phosphorus levels maintained at <5.5 mg/dL). Recertification will be for 12 months at a time.
9. Quantity limit: 60 tablets per 30 days

Xyrem, sodium oxybate, and
Xywav (Calcium Oxybate/Magnesium Oxybate/Potassium Oxybate/Sodium Oxybate solution)

1. Must be followed by a neurologist or sleep specialist
2. Must have a diagnosis of cataplexy associated with narcolepsy
   a. Must be 7 years of age or older
   b. Narcolepsy must be confirmed by a sleep study which must be provided
   c. Requests for Xyrem or Xywav must also have serious side effects or drug failure to sodium oxybate
3. Must have a diagnosis of excessive daytime sleepiness associated with narcolepsy
   a. Must be 7 years of age or older
   b. Narcolepsy must be confirmed by a sleep study which must be provided
   c. For patients 18 years of age or older must have had serious side effects, drug failure, or contraindication to TWO of the following:
      - Modafinil or armodafinil
      - A stimulant medication indicated for narcolepsy (amphetamine, dextroamphetamine/amphetamine, dextroamphetamine ER, or methylphenidate)
      - Sunosi (requires prior authorization)
   d. Requests for Xyrem or Xywav must also have had serious side effects or drug failure to sodium oxybate
4. Must have a diagnosis of idiopathic hypersomnia
   a. Must be 18 years of age or older
   b. Idiopathic hypersomnia must be confirmed by a sleep study which must be provided AND

c. Must have had serious side effects or drug failure to modafinil or armodafinil AND
d. Must have had serious side effects or drug failure to a stimulant medication AND
e. Only Xywav will be approved for idiopathic hypersomnia as Xyrem/sodium oxybate have not been studied for this diagnosis

5. Use of Xyrem/sodium oxybate and Xywav in combination will not be authorized
6. Xyrem/sodium oxybate and Xywav will not be covered for any non-FDA approved indication or diagnosis

Yosprala and aspirin-omeprazole tablet

1. Must be used for secondary prevention of cardiovascular or cerebrovascular events
2. Member must be at risk of developing aspirin-associated gastric ulcers as documented by one of the following:
   a. Age 55 years or older
   b. History of gastric ulcers
3. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic omeprazole and aspirin (as separate pills), the member will be required to use generic omeprazole and aspirin (as separate pills) unless there is adequate justification as to why these are not appropriate.

Zelapar ODT – Selegiline Hydrochloride (L-Deprenyl) tablet

1. Must have clinically documented Parkinson's disease
2. Must be currently receiving treatment with levodopa/carbidopa
3. Must be exhibiting deterioration in quality of response to levodopa/carbidopa therapy
4. Must be unable to swallow traditional tablets.
5. Quantity limit of 60 tablets per 30 days.

Zelnorm – tegaserod tablet

Please note: Zelnorm will only be approved for patients who have currently been receiving Zelnorm. On June 30th, 2022, Alfasigma USA, Inc. announced their decision to withdrawal Zelnorm from the US marketplace. According to Alfasigma USA, Inc., the decision to remove Zelnorm from the market was not based on the safety or efficacy of Zelnorm. Patients who are currently using Zelnorm will continue to have access to the product for as long as the existing supply of product remains available. Those patients who are currently receiving Zelnorm should consult with their healthcare provider about whether to remain on the treatment.

Criteria for patients who have currently been receiving Zelnorm is as follows:

1. Must have a diagnosis of IBS-C (irritable bowel syndrome with constipation)
2. Must be a woman between the ages of 18 and 64
3. Must have had serious side effects or drug failure with Linzess
4. Quantity Limit of 60 per 30 days

Zituvio and sitagliptin tablets

1. The health plan has determined that Zituvio and sitagliptin tablets are not medically necessary due to the availability of lower costing options that are likely to produce equal therapeutic results.

Zolpidem 7.5 mg capsules

1. The health plan has determined that zolpidem 7.5 mg is not medically necessary due to availability of lower costing options that are likely to produce equal therapeutic results.

Zonalon and doxepin 5% cream

1. Must have a diagnosis of pruritis due to atopic dermatitis or lichen simplex chronicus
2. Must have had serious side effects or drug failure with 2 oral antihistamines such as cetirizine and fexofenadine
3. Must have had serious side effects or drug failure with 2 topical steroids such as clobetasol and betamethasone
4. Approval will be for 1 month to allow for a single 8-day treatment

5. Future approvals will require documentation to show that the patient is not using this treatment continuously

Zonisade – zonisamide oral suspension

1. Must have a diagnosis of a seizure disorder
2. Must be 16 years of age or older
3. Must have a swallowing disorder (a speech and swallow evaluation are required) that prevents the patient from using generic zonisamide capsules
4. Must have tried and experienced failure or intolerance to one other generic antiepileptic medication appropriate for the diagnosis
5. Quantity Limit: 900 mL/30 days

Zontivity – vorapaxar tablet

1. Must have a history of Myocardial Infarction
2. Must be prescribed by a cardiologist
3. Must not have a history of stroke
4. Must be used concomitantly with Plavix (clopidogrel) and aspirin
5. Must weigh 60 kg or more due to increased risk of bleeding in individuals weighing less than 60kg
6. Quantity limit of 30/30

Zoryve – roflumilast topical cream and topical foam

1. Must be prescribed by a dermatologist
2. Zoryve 0.3% CREAM for a diagnosis of chronic plaque psoriasis must meet the following:
   a. Must be at least 6 years of age **AND**
   b. Must have a **MAXIMUM** body surface area (BSA) involvement of 20% **AND**
   c. Must have had serious side effects or drug failure of a minimum 4-week trial of a medium/high potency topical steroid AND a minimum 4-week trial of a topical vitamin D analog
      i. Trial of topical therapies do not have to occur simultaneously (in combination), but consideration will be granted if the topical therapies were trialed together
3. Zoryve 0.3 % FOAM for a diagnosis of seborrheic dermatitis must meet the following:
   a. Must be at least 9 years of age **AND**
   b. Must have moderate to severe seborrheic dermatitis
      i. Moderate to severe disease must be documented based on an Investigator Global Assessment (IGA) score of 3 or 4 on a 5-point scale from 0 to 4 **AND**
   c. Must have had serious side effects or drug failure to a topical antifungal (such as ciclopirox or ketoconazole) for at least 4 weeks **AND**
   d. Must have had serious side effects or drug failure to a topical corticosteroid used in combination with a topical antifungal for at least 2 weeks
4. Zoryve 0.15% CREAM for a diagnosis of atopic dermatitis must meet the following:
   a. Must be at least 6 years of age AND
   b. Must have mild to moderate disease
      i. Mild to moderate disease must be documented based on the validated investigator global assessment for atopic dermatitis (vIGA-AD) with a score of 2 or 3 (see references for link to assessment tool)
   c. Must have had serious side effects or drug failure with an adequate trial of ONE generic topical steroid (alclometasone, amcinonide, betamethasone, clobetasol, desonide, desoximetasone, diflorasone, fluocinolone, fluocinonide-E, fluticasone, halobetasol, hydrocortisone 2.5%, hydrocortisone valerate, hydrocortisone butyrate, mometasone, prednicarbate, triamcinolonone) **OR** ONE of the following: tacrolimus ointment or pimecrolimus cream
      i. An adequate trial of a topical steroid is defined as ≥ 28 days or for the maximum duration recommended by the product prescribing information (i.e., 14 days for super-potent topical corticosteroids), whichever is shorter
      ii. An adequate trial of tacrolimus ointment or pimecrolimus cream is defined as ≥ 6 weeks based

on prescribing information
   d. Must have had serious side effects or drug failure with an adequate trial of Eucrisa
      i. An adequate trial is defined as ≥ 28 days based on prescribing information
5. Zoryve will not be approved for any non-FDA approved indications including use of the cream for seborrheic dermatitis, the foam for plaque psoriasis or atopic dermatitis, the 0.15% cream for plaque psoriasis or the 0.3 % cream for atopic dermatitis
6. Initial approval will be provided for 3 months
   a. Recertification for 12 months at a time requires documentation of improvement (initial recertification) and/or maintenance of improvement from baseline.
7. Quantity limit: 60 grams per 30 days

POLICY GUIDELINES:

1. Unless otherwise stated above within the individual drug criteria, approval time-period will be for 2 years.
   - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.
2. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. Utilization Management are contract dependent and coverage criteria may be dependent on contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
4. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
   - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
   - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
   - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
   - The required prescription drug(s) is (are) not in the patient’s best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
   - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
   - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

5. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
6. Prescription homeopathic medications including, but not limited to: Arnica Gel, Psorizide Forte, Sleep Medicine, Hylira Gel and Vertigoheel are only covered when they are FDA approved for safety and efficacy. Most prescription homeopathic medications have their sales regulated by the FDA but are not FDA approved for safety and efficacy for any particular condition.
7. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to criteria being added to the policy.
8. Supportive documentation of previous drug use must be submitted for any criteria that require a trial of a preferred agent if the preferred drug is not found in claims history.
9. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

UPDATES:

Date	Revision
12/24	Revised
11/21/2024	Reviewed & P&T Committee Approval
11/24	Revised
09/24	Revised
08/15/2024	Reviewed & P&T Committee Approval
08/24	Revised
07/24	Revised
05/24	Revised
04/24	Revised
03/24	Revised
02/24	Revised/P&T Approval
01/24	Revised
12/23	Revised
11/23	Revised/P&T Approval
10/23	Revised
9/23	Revised
8/23	Revised/P&T Approval
7/23	Revised
6/23	Revised
5/23	Revised/P&T Approval
4/23	Revised
3/23	Revised
2/23	Revised/ P&T Approval
1/23	Revised
12/22	Revised
11/22	Revised/P&T Approval
10/22	Revised
9/22	Revised/P&T Approval
8/22	Revised
7/22	Revised/P&T Approval
6/22	Revised
5/22	Revised/P&T Approval
3/22	Revised
2/22	Revised/P&T Approval

1/22	Revised
12/21	Revised
11/21	Revised/P&T Approval
10/21	Revised
9/21	Revised/P&T Approval
8/21	Revised
7/21	Revised/P&T Approval
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7/20	Revised
6/20	Revised
5/20	Revised/P&T Approval
4/20	Revised
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10/19	Revised
9/19	Revised/P&T Approval
8/19	Revised
7/19	Revised
6/19	Revised
5/19	Revised/P&T Approval
2/19	Revised/P&T Approval
1/19	Revised
12/18	Revised
11/18	Revised/P&T Approval
9/18	Revised/P&T Approval

REFERENCES:

In addition to the full prescribing information for each individual drug, the following references have been utilized in creating drug specific criteria:

Arikayce –
1. Griffith, David E, et al, “An Official ATS/IDSA Statement: Diagnosis, Treatment, and Prevention of Nontuberculous Mycobacterial Diseases”, American Journal of Respiratory and Critical Care Medicine, 2007; 175, 4

Opzelura –
(1) Validated Investigator Global Assessment scale for Atopic Dermatitis (vIGA-AD) https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf

Qualaquin-
1. Questions and Answers about the FDA’s Enforcement Action Against Unapproved Quinine Products- http://www.fda.gov/cder/drug/unapproved_drugs/quinineQA.pdf

Solodyn –
1. Zaenglein et al. Expert Committee Recommendations for Acne Management. Pediatrics. Sept 2006. 118(3) 1188-99.
2. Leyden, J et al. Comparison of tazarotene and minocycline maintenance therapies in acne vulgaris: a multicenter, double-

blind, randomized, parallel-group study. Archives of Dermatology. 2006 May;142(5):605- 12.
3. James, WD. Acne (clinical practice). NEJM. 2005 April 7;352(12):1463-72.
4. Gollnick H, Cunliffe W, Berson D, Dreno B, Finlay A, Leyden JJ, Shalita AR, Thiboutot D. Management of acne: a report from a Global Alliance to Improve Outcomes in Acne. J Am Acad Dermatol. 2003 Jul;49(1 Suppl):S1-37.

Zoryve-

1. Validated Investigator Global Assessment scale for Atopic Dermatitis (vIGA-AD) https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf