Pharmacy Management Drug Policy

SUBJECT: Clinical Review Prior Authorizations (CRPA) Rx
POLICY NUMBER: PHARMACY-09
EFFECTIVE DATE: 12/2004
LAST REVIEW DATE: 08/18/2026

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.

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 10 years of age or older **AND**
2. Must have diagnosis of iron deficiency anemia documented by the following:
    a. Must have serum ferritin < 30 ug/L **OR** serum ferritin < 50 ug/L with transferrin saturation (TSAT) < 20% **AND**
    b. For patients 12 years of age and older
        i. Must have hemoglobin <12.0 g/dL for females or <13.0 g/dL for males
    c. For patients 10 to < 12 years of age
        i. Must have hemoglobin <11.5 g/dL **AND**
3. Must have serious side effects or drug failure with at least two oral iron products that contain different salt formulations (i.e., ferrous sulfate, ferrous fumarate, ferrous gluconate).
4. Initial approval will be provided for 3 months.
5. Recertification for 1 year at a time will require documentation of the following:
    a. For initial recertification, patient must have an increase in hemoglobin of ≥1 g/dL from baseline (documentation must be provided)
    b. For subsequent recertifications, documentation of continued response to therapy is required.
6. Quantity Limit: 60 capsules/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 woman less than 65 years of age
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 initial 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. The patient is less than 65 years of age
   b. Provider must acknowledge that the patient has been evaluated for serious side effects
   c. Provider must acknowledge that the patient reports increased sexual desire and satisfying events as a result of drug therapy
   d. Recertification approval will be for 1 year at a time.
9. Quantity limit of 30 tablets per 30 days

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.

Alyftrek - vanzacaftor/tezacaftor/deutivacaftor tablets

1. Must have a diagnosis of cystic fibrosis
2. Must be prescribed by or under the recommendation of a pulmonologist or cystic fibrosis specialist
3. Must be 6 years of age or older
4. Must have at least one variant in the CTFR gene that is either responsive to Alyftrek or results in the production of CFTR protein (package insert includes a full list of responsive CTFR gene variants)
5. Must have had severe intolerance or therapeutic failure to a 3-month trial of Trikafta
   a. A trial of Trikafta is not required for members with a variant that is not susceptible to Trikafta (see Trikafta package insert for a full list of responsive CTFR gene variants)

6. Quantity limits as follows:
   a. 4/20/50 mg tablets: 84 per 28 days
   b. 10/50/125 mg tablets: 56 per 28 days

Anzupgo (delgocitinib)-Rx

1. Must be at least 18 years of age
2. Must be prescribed by or in consultation with a Dermatologist
3. Must have confirmed diagnosis of moderate to severe Chronic Hand Eczema defined as the following (a+b+c):
   a. Persistent eczema located only on hand and/or wrist **AND**
      i. Investigator's Global Assessment for chronic hand eczema (IGA-CHE) score of 3 or 4 at baseline [on a scale ranging from 0 (clear) to 4 (severe)] **AND**
      ii. Hand Eczema Symptom Diary (HESD) itch score ≥ 4 points at baseline [ranging from 0 (no symptoms) to 10 (severe symptoms)]
   b. Persistent 3.a. lasts for more than 3 months **OR** relapsed twice or more often per year **AND**
   c. Pain or itchiness that causes functional deficit of daily activities
4. Provider attestation that non-pharmacological avoidance of irritants has been discussed with patients, such as wearing protective gloves or regular use of emollients/barrier creams
5. Must have documented inadequate response to guideline supported standard of care therapies defined as the following: (**A** and **B**)
   A. 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
   B. Must have had serious side effects or drug failure with an adequate trial of ONE of the following:
      i. tacrolimus ointment or pimecrolimus cream
         a) Adequate trial is defined as ≥ 6 weeks based on prescribing information
6. Must have had serious side effects or drug failure with an adequate trial of Eucrisa
   a. Adequate trial is defined as ≥ 28 days based on prescribing information
7. Quantity Limit: 30 grams per month
8. Initial approval is for 16 weeks. Recertification is approved for 1 year at a time with documented clinical benefit (e.g. improved or maintained hand eczema lesions, pain or itchiness)
9. Use of Anzupgo in combination with other Janus kinase inhibitors such as Opzelura or potent immunosuppressants will not be approved**.**

Arazlo (tazarotene lotion), Fabior (tazarotene foam), and generic tazarotene foam

1. Must be used for a diagnosis of acne **AND**
2. Must be prescribed by a dermatologist **AND**
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 **AND**
2. Must be prescribed by an infectious disease specialist or pulmonologist **AND**
3. Must have a diagnosis of Mycobacterium avium complex (MAC) lung disease as confirmed by a MAC-positive sputum culture **AND**
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 **AND**
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

Astagraf XL and generic 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 **AND**
   a. Must be 18 years of age or older **AND**
   b. Must be prescribed by a neurologist **AND**
   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 **AND**
   a. Must be 18 years of age and old **AND**
   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. **AND**
   c. Must be prescribed by or in consultation with a neurologist, psychiatrist, or psychiatric nurse practitioner. **AND**
   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 psychiatrist, neurologist, or psychiatric nurse practitioner **AND**
3. Must meet one of the following (a or b):
   a. Must have a diagnosis of agitation associated with dementia due to Alzheimer's disease **OR**

b. Must have a diagnosis of major depressive disorder (MDD) **AND**
   i. Must have drug failure with bupropion without any serious side effects **AND**
   ii. Must have serious side effects or drug failure with at least ONE other antidepressants from different drug classes **AND**
   iii. 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

4. Auvelity will not be covered for any other non-FDA approved indication
5. Quantity limits:
   a. 45mg/105mg tablets: 60 tablets per 30 days
   b. Titration Pack: 51 tablets per 30 days; Limited to 2 fills per year.
      i. Auvelity titration pack is only indicated for the treatment of dementia due to Alzheimer's disease.

Blujepa - gepotidacin

Blujepa (gepotidacin) is a newly approved agent for the treatment of uncomplicated urinary tract infections (uUTIs) and uncomplicated urogenital gonorrhea. It is not currently included in standard-of-care guideline recommendations.

- For uUTIs, current guidelines recommend nitrofurantoin, trimethoprim-sulfamethoxazole, or fosfomycin as first-line therapies, with fluoroquinolones or beta-lactams reserved for cases where these options cannot be used.
- For uncomplicated urogenital gonorrhea, guidelines recommend ceftriaxone intramuscular injection as the preferred therapy, or gentamicin IM plus a single oral dose of azithromycin, or a single oral dose of cefixime when ceftriaxone is unavailable or contraindicated.

Blujepa has not yet been incorporated into treatment guidelines, and no official consensus statement has been published. Its role within the treatment pathway for uUTIs and uncomplicated urogenital gonorrhea will continue to be evaluated by the health plan as emerging clinical evidence becomes available. Until definitive guidance supports its placement, all prerequisite requirements for Blujepa will align with current standard-of-care practices.

1. Must be 12 years of age or older **AND**
2. Must meet ONE of the following (**a or b**):
   a. Must have a diagnosis of uncomplicated urinary tract infection (uUTI) **AND**
      i. Must weigh at least 40 kg **AND**
      ii. Patient was assigned female at birth **AND**
      iii. Must have documented evidence of <u>all</u> the following (1, 2, and 3):
         1. Confirmed infection on urinalysis (e.g., positive dipstick analysis for leukocyte esterase, or ≥10 white blood cells (WBCs) per mm^3 on microscopic analysis of unspun urine, or WBC count ≥10 cells/HPF in the sediment of a spun urine) **AND**
         2. Urine culture results indicating that the uUTI is caused by at least one of the following microorganisms:
            a. *Escherichia coli*
            b. *Klebsiella pneumoniae*
            c. *Citrobacter freundii complex*
            d. *Staphylococcus saprophyticus*
            e. *Enterococcus faecalis* **AND**
         3. Susceptibility results **AND**
      iv. Must have serious side effects or drug failure of at least one agent from **THREE** of the following standards of care drug/categories (1-5). [NOTE: An exception may be made for a drug/category if there is documentation of a contraindication or anaphylaxis/hives to that drug/category **OR** susceptibility testing indicates that the drug/category would not be suitable for treatment]. Documentation must be within 60 days.

1. Nitrofurantoin
2. Fosfomycin
3. Trimethoprim/sulfamethoxazole
4. Fluoroquinolones (i.e., ofloxacin, ciprofloxacin, levofloxacin)
5. Beta-lactam agents (i.e., amoxicillin-clavulanate, cefdinir) **OR**

b. Must have a diagnosis of uncomplicated urogenital gonorrhea **AND**
   i. Must weigh at least 45 kg **AND**
   ii. Must have failure, or a documented contraindication, to the following:
      1. Ceftriaxone intramuscular injection **OR**
      2. One of the following alternative regimens only if ceftriaxone is not available or not feasible due to allergy:
         a. Gentamicin 240 mg IM injection in combination with azithromycin 2 g orally in a single dose **OR**
         b. Cefixime 800 mg orally in a single dose

3. Blujepa will not be authorized for the following:
   a. Patients with evidence of acute pyelonephritis or urosepsis defined as: fever (temperature > 38° C), chills, costovertebral angel tenderness, flank pain, bacteremia, nausea, and/or vomiting
   b. For use in complicated urinary tract infections
   c. For UTI prophylaxis
   d. For any gonococcal infections other than uncomplicated urogenital gonorrhea (ex. pharyngeal infections)
4. Recommended dosage is 1,500 mg (2 x 750 mg tablets) taken twice daily for 5 days for uUTI and 3,000 mg (4 x 750 mg tablets) taken orally followed by a second dose of 3,000 mg (4 x 750 mg tablets) approximately 12 hours later for the treatment of uncomplicated urogenital gonorrhea.
5. Approval authorization will be for 1 month to allow for completion of one treatment course. Reauthorization for the same infection will not be considered. If the request is to treat a new uUTI or gonococcal infection, the above criteria must be met.
6. Quantity Limit:
   a. For uncomplicated urinary tract infections (uUTI): 20 tablets per 5 days.
   b. For uncomplicated urogenital gonorrhea: 8 tablets per 1 day.
7. One treatment course will be authorized per 365 days.
   a. Authorization for more than one treatment course within a year will require:
      i. Documentation that previous use of Blujepa lead to resolution of uUTI or gonorrhea signs and symptoms **AND**
         1. The following only applies if the request is occurring within 1 month of a previous Blujepa treatment course:
            a. Prescriber must attest that this is a new infection and Blujepa is not being used as a continued treatment of the same uUTI or gonorrhea infection previously treated with Blujepa

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

1. The patient must meet for **ONE** of the following indications:
   a. **Treatment of vulvovaginal candidiasis (VVC)**
      i. Must have had serious side effects or drug failure to oral fluconazole

b. **Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC)**
   i. Must have had at least three episodes of vulvovaginal candidiasis (VVC) within the past 12 months **AND**
   ii. Current VVC episode must have a positive potassium hydroxide (KOH) test **AND**
   iii. Must have clinical signs and symptoms associated with VVC (redness, swelling, itching, burning, etc.) **AND**
   iv. 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**

2. 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**
3. Approved Dosage
   a. VVC: 300 mg (2 – 150 mg tablets) taken 12 hours apart for one day
   b. RVVC: 300 mg (2 – 150 mg tablets) taken 12 hours apart for one day each month for 6-months
4. Quantity Limit: 4 tablets per 30 days
5. Approval Timeframe:
   a. VVC
      i. Approval will be for 3 months. Requests for retreatment with Brexafemme beyond three months for VVC will require review as RVCC if the patient has filled 3 or more courses of treatment for VVC within the past 12 months.
   b. RVVC:
      i. Approval will be provided 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.

Brinsupri—brensocatib

1. Must be 18 years of age or older **AND**
2. Must be prescribed by, or in consultation with, a pulmonologist or infectious disease specialist experienced in treating bronchiectasis **AND**
3. Patient has a confirmed diagnosis of non-cystic fibrosis bronchiectasis (NCFB), documented by high-resolution CT scan **AND**
4. Must have documented history of ≥2 pulmonary exacerbations in the past 12 months requiring systemic antibiotics OR ≥1 exacerbation requiring hospitalization/intravenous antibiotics **AND**
5. Prescriber must attest the patient will continue to use standard airway clearance therapies, and that any indicated inhaled and/or oral antibiotics are being used, as clinically appropriate **AND**
6. For patients with comorbid asthma and/or COPD, prescriber must attest that the patient's symptoms are primarily caused by NCFB **AND**
7. Patient does NOT have cystic fibrosis **AND**
8. Patient does NOT have active nontuberculous mycobacterial (NTM) infection.
9. Initial approval will be for 12 months. Continued approval will be 12 months at a time and require documentation of clinical benefit (i.e., reduction in pulmonary exacerbations, improved symptoms)
10. Quantity Limit: 30 tablets/30 days

Bronchitol – mannitol inhalation powder

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

Brynovin – sitagliptin 25mg/mL oral solution

1. Must be 18 years of age or older **AND**
2. Must have diagnosis of type 2 diabetes mellitus **AND**
3. Must have documentation of a swallowing disorder that prevents use of oral solid dosage forms
4. Quantity limit of 120mL 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

Cardamyst - etripamil

1. Must be 18 years of age or older **AND**
2. Must be prescribed by or in consultation with a cardiologist or electrophysiologist **AND**
3. Must have a diagnosis of electrographically documented atrioventricular (AV) nodal-dependent paroxysmal supraventricular tachycardia (PSVT) (e.g. AVNRT, AVRT) **AND**
4. Must have tried and failed to respond to or tolerate a self-administered episodic medication regimen (pill-in-pocket regimen – e.g. diltiazem, verapamil, beta-blockers) which resulted in an emergency department (ED) or provider visit.
5. The recommended dosage is 70 mg, administered as two sprays, one spray in each nostril. If symptoms persist after 10 minutes, a second dose of 70 mg may be administered. Do not exceed 2 doses (140 mg) in a 24-hour period.
6. Initial approval will be provided for 1 year.
7. Recertification for 1 year at a time requires documentation of the following:
    a. PSVT Episode Documentation
        i. For patients who experienced an episode in the prior approval period, provider must attest to the following (1 and 2)
            1. Positive therapeutic response, defined as resolution of the PSVT episode after administration of Cardamyst, with no need for additional pharmacologic or medical interventions **AND**
            2. A reduction in PSVT-related ED or provider visits
        ii. For patients that did not experience an episode in the prior approval period, absence of PSVT episodes during the prior coverage period does not preclude renewal of coverage.
    b. Confirmation patient has not undergone curative cardiac ablation
8. Quantity limit of 1 carton (2 nasal sprays) per fill and a total of 4 fills per year.
    a. Additional quantities may be authorized with documentation of medical necessity.

Chenodal (chenodiol)

1. Must be 18 years of age or older **AND**
2. Must have radiolucent gallstones **AND**
3. Must have documentation of serious side effects or drug failure with ursodiol **AND**
4. Patient has increased surgical risk due to systemic disease or age **AND**
5. Initial approval for 12 months at a time. Recertification will be authorized one time only for a duration of 12 months and require evidence of clinical benefit (e.g., complete or partial dissolution of gallstones).
6. Chenodal will not be authorized for treatment beyond 24 months as safety of use has not been established beyond this timeframe.
7. Chenodall will not be authorized for use in combination with Cholbam, cholestyramine, or colestipol.
8. Quantity Limit: 90 tablets/30 days3
    a. Upon each review and dose escalation request, the allowed quantity will be reviewed in accordance with the FDA-approved weight-based dosing and, as such, will be limited to the minimum number of tablets required to obtain the appropriate daily dose/day supply.

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.
Condylox 0.5% gel and podofilox 0.5% gel
1. Must have a diagnosis of condylomata acuminata **AND** 2. Must have had serious side effects or drug failure with podofilox 0.5% topical solution **AND** 3. Requests for brand name Condylox Gel must have had serious side effects to generic podofilox 0.5% gel.
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
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 they are 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
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

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: 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.

Egrifta SV and Egrifta WR– 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 fasting blood glucose (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 oral 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 limits:
   a. Egrifta SV: 30 vials per 30 days
   b. Egrifta WR: 4 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. Esbriet, pirfenidone tablets, and pirfenidone capsules will not be authorized in combination with Ofev or nintedanib capsules 4. 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) 5. 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. 6. Quantity Limits: a. 267 mg: 270 tablets or capsules/30 days b. 801 mg: 90 tablets/30 days
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
Flector, Licart and generic diclofenac patches
1. Must have a diagnosis of acute pain related to minor strains, sprains, and bruises 2. Must have documentation of a contraindication to oral NSAIDs 3. Approval will be for 3 months, to allow short term use.

4. Quantity limit:
   a. 60 patches/30 days for Flector and generic diclofenac patches
   b. 30 patches/30 days for Licart

Gattex – teduglutide solution

1. Must be used for the treatment of Short Bowel Syndrome (SBS) with intestinal insufficiency
   a. Intestinal insufficiency must be documented by the following:
      i. Patient has required PN/IV fluids at least 3 times per week for ≥12 months to maintain hydration, electrolytes, and nutrition despite diet and fluid optimization
2. Documentation must be submitted confirming the patient has stable SBS defined as having fluid, electrolyte, and nutritional status clinically stable and not at immediate risk of decompensation, including documentation confirming the following:
   a. No recent major surgeries or bowel resections in the past 3–6 months
   b. No severe metabolic instability (e.g., recurrent dehydration, severe electrolyte disturbances, or acid-base imbalances)
3. Patients with surgical SBS (not functional) must have documentation confirming the following:
   a. Small intestine length ≥ 50 cm but ≤ 200 cm unless diagnostic features of SBS exists (criterion 1.a.i.)
4. Must be no history of malignancy of GI, hepatobiliary, or pancreatic cancers within the last 5 years.
5. 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 weekly IV/PN volume by week 24.
6. Approval beyond initial 1 year of treatment will be approved for one year and will require the following:
   a. Maintenance of at least a 20% reduction in weekly IV/PN volume or titration off parenteral support **AND**
   b. Submission of colonoscopy results demonstrating no presence of intestinal malignancy will be required at year 1
      i. Subsequent colonoscopies will be required in accordance with the recommendations in the Gattex prescribing information **AND**
   c. The patient must continue to meet the definition of stable SBS (see criterion 2) with supporting documentation required
7. Approved daily dose is 0.05mg/kg
8. 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

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:
   a. 450 mg: 30 tablets per 30 days
   b. 750 mg and 900 mg: 60 tablets per 30 days
   c. 300 mg and 600 mg: 90 tablets per 30 days

Hepcludex - buleviritide injection

1. Must be 18 years of age or older **AND**
2. Must be requested by, or under the recommendation of a gastroenterologist, hepatologist, or infectious disease specialist **AND**
3. Must have a diagnosis of chronic Hepatitis D (CHD) **AND**
4. Must have elevated alanine aminotransferase (ALT) above the upper limit of normal and/or significant fibrosis (≥F2) **AND**
5. Patient has one of the following (a or b):
   a. No cirrhosis present **OR**
   b. Compensated cirrhosis (Child-Pugh Class A) **AND**
6. The following baseline labs obtained within the past 60 days must be provided:
   a. Quantitative serum HDV RNA
   b. Alanine aminotransferase (ALT)
   c. Child-Pugh hepatic insufficiency score < 7 (Child-Pugh Class A)
      i. Hepcludex will not be approved for patients with Child-Pugh Class B or C
7. Provider attests to the following (both a and b):
   a. Patient has no current or previous (within the past 2 years) decompensated liver disease (e.g., coagulopathy, hepatic encephalopathy, esophageal varices hemorrhage) **AND**
   b. Chronic Hepatitis B infection is being managed according to standard of care
8. Initial authorization will be provided for 48 weeks.
9. Recertification of treatment for 6 months at a time will be provided with documentation of the following:
   a. For initial recertification, patient is responding positively to therapy by BOTH of the following (i and ii):
      i. A ≥ 2 $\log_{10}$ reduction in HDV RNA level from baseline or undetectable HDV RNA level by quantitative assay **AND**
      ii. A reduction or normalization of ALT
   b. For subsequent recertifications, patient continues to respond to therapy by BOTH of the following (i and ii):
      i. Continued or stable, reduction in HDV RNA or maintenance of undetectable HDV RNA levels **AND**
      ii. Continued reduction, stabilization or maintenance of normalization of ALT
         1. Continuation of Hepcludex will not be authorized for patients demonstrating sustained loss of response to therapy as defined by two consecutive increases in HDV RNA of > 2 $\log_{10}$ from Week 48 HDVRNA level.
10. Standard dosage is 8.5 mg by subcutaneous injection once daily.
11. Quantity limit of 30 vials 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 patients 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 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.

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

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. For patients aligned to 2025 formularies: Must have serious side effects or drug failure with dapagliflozin and Jardiance
      ii. For patients aligned to 2026 formularies: Must have serious side effects or drug failure with dapagliflozin **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

Inzirqo – hydrochlorothiazide oral suspension

1. Must have one of the following diagnoses **(a or b):**
   a. Hypertension
   b. Edema associated with congestive heart failure (CHF), hepatic cirrhosis or renal disease (including nephrotic syndrome) **AND**
2. Documentation must be provided why member is unable to use hydrochlorothiazide capsules/tablets
3. Quantity Limit: 1 bottle (80 mL) per 30 days.
   a. Additional quantities will be granted based on FDA-approved dosing

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

Jalyn – dutasteride and tamsulosin capsules

1. Must be 18 years of age or older **AND**
2. Must have a diagnosis of symptomatic benign prostatic hyperplasia (BPH) **AND**
3. Requests for Jalyn will require documentation of use of generic dutasteride/tamsulosin capsules that led to serious side effects or drug failure
4. Quantity Limit: 30 capsules per 30 days.

Jascayd - nerandomilast

1. For a diagnosis of idiopathic pulmonary fibrosis (IPF):
   a. Must be prescribed by, or under the recommendation of, a pulmonologist **AND**
   b. The diagnosis of idiopathic pulmonary fibrosis must be based on the following criteria:
      i. Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic, and occupational environmental exposures, connective tissue disease and drug toxicity)
      ii. The presence of UIP (usual interstitial pneumonia) pattern on high-resolution computed tomography (HRCT) 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 HRCT and surgical lung biopsy pattern in patients subjected to surgical lung biopsy
   c. For use as monotherapy, must have had serious side effects or drug failure to pirfenidone or nintedanib
   d. For use as add-on therapy, patient must have utilized antifibrotic therapy (pirfenidone or nintedanib) for at least 3 months to establish tolerability
2. For a diagnosis of progressive pulmonary fibrosis (PFF):
   a. Must be prescribed by, or under the recommendation of, a pulmonologist or rheumatologist **AND**
   b. Must have had an HRCT scan showing fibrosing lung disease within the past 12 months **AND**
   c. Must have had one of the following within one year as evidence of progression:
      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 respiratory symptoms and an increased extent of fibrotic changes on chest imaging
   d. For use as monotherapy, must have had serious side effects or drug failure to nintedanib

e. For use as add-on therapy, patient must have utilized ninetedanib monotherapy for at least 3 months to establish tolerability
f. Jascayd will not be authorized in combination with pirfenidone for the treatment of progressive pulmonary fibrosis (PPF)

3. Recommended dosage of Jascayd is 18 mg twice daily. For patients unable to tolerate 18mg twice daily, the dose may be reduced to 9mg twice daily, except for patients taking Jascayd in combination with pirfenidone for the treatment of idiopathic pulmonary fibrosis (IPF).
   a. For patients using Jascayd in combination with pirfenidone for IPF, if 18mg twice daily cannot be tolerated, patient should discontinue therapy with Jascayd.
4. Quantity Limit: 60 tablets per 30-day supply.

Journavx - suzetrizine tablets

1. Must be 18 years of age or older.
2. Quantity limit is 29 tablets per 14-day treatment course, with a maximum 7-day supply per fill.
   a. Data suggests pain improves within days for many patients with common types of acute pain in primary care or emergency department settings. Treatment may not be required for greater than 7 days and therefore is limited to a 7-day supply per fill to avoid unnecessary waste.
3. One treatment course allowed per 84 days.
   a. Additional treatment course may be covered for patients with new onset acute pain within 84 days of prior treatment course (documentation is required).

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**
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 **AND**
6. Requests for Jublia will require documentation of serious side effects or drug failure to tavaborole
7. Jublia will be covered for a maximum duration of 48 weeks of therapy.
8. Quantity Limit 4 mL per 30 days
   a. Additional quantities will be approved based on FDA-approved dosing

Jylamvo – methotrexate oral solution

1. Must meet one of the following **(a or b):**
   a. Must be a pediatric patient **AND**
      Must have a diagnosis of acute lymphoblastic leukemia (ALL) or polyarticular juvenile idiopathic arthritis (pJIA), **OR**
   b. Must be 18 years of age or older **AND**
      Must have a diagnosis of acute lymphoblastic leukemia (ALL), mycosis fungoides, relapsed or refractory non-Hodgkin lymphoma, rheumatoid arthritis, or severe psoriasis
2. All patients require a trial of **BOTH** methotrexate oral tablets and injectable methotrexate solution
   a. Members aged 7 years and under will not require a trial of methotrexate oral tablets.
   b. Members aged 8-17 years old will require documentation of an attempt and inability to swallow methotrexate oral tablets.
   c. For members 18 years of age and older unable to swallow, a speech and swallow evaluation is required to confirm a swallowing disorder
      i. For members unable to use injectable methotrexate, the patient (or caregiver for pediatric patients) must have a documented physical inability to inject. Clinical justification may include but is not limited to history of significant tremor, dexterity limitations, and cognitive impairment.
3. Quantity limit of 1 bottle (60 mL) per 30 days

4. 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 and generic 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. Tolvaptan will not be covered for patients with GFR < 15 mL/min/1.73 m^2 or those receiving dialysis
5. Requests for brand name Jynarque will require documentation of use of generic tolvaptan tablets that led to serious side effects or drug failure
6. 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 be prescribed by or under the recommendation of a pulmonologist or cystic fibrosis specialist
3. 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)
4. Must be at least 1 month of age
5. Coverage will be excluded in patients with CF who are homozygous for the F508 del mutation in the CFTR gene
6. Liver enzymes should be assessed prior to initiation of Kalydeco, every 3 months during the first year of treatment, and annually thereafter.
7. For adults and pediatric patients aged 6 years and older, quantity limit is 60 **tablets** per 30-day supply.
8. 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** OR
2. Must have a diagnosis of **heart failure (HF) with left ventricular ejection fraction (LVEF) equal to or greater than 40%**
   a. Must be at least 18 years of age
   b. Must be on, or have had an adequate prior trial of, an SGLT2 inhibitor indicated for heart failure, unless clinically inappropriate, contraindicated, or not tolerated.
   c. Approved dosing: up to 40mg once daily
3. Quantity limit of 30 tablets per 30 days.

Khindivi – hydrocortisone oral solution

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 Alkindi Sprinkle capsules

3. Khindivi 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 1 bottle (473 mL) per 30 days. Approval for increased quantity will be based on FDA approved dosing recommendations.

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

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) **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 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

Lumryz - sodium oxybate for suspension, extended release

1. Must be prescribed by, or consultation with, 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 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
   a. The use of Lumryz to reduce treatment burden (for convenience), in the absence of such clinical factors, does not meet medical necessity criteria and will not be authorized
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.

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

Lynkuet - elinzanetant

1. Must have a diagnosis of moderate to severe vasomotor symptoms (VMS) associated menopause that interfere with quality of life
2. Must meet **ONE** of the following (a or b):
   a. For patients **WITHOUT** a contraindication to menopausal hormone therapy (MHT), the patient must have had serious side effects or drug failure of at least **two** therapies proven to be effective for the treatment of vasomotor symptoms
      i. One prior therapy must be a non-hormonal agent (e.g., paroxetine, gabapentin, venlafaxine, desvenlafaxine, or citalopram) **AND**
      ii. One prior therapy must be a systemic MHT (estrogen ± progestogen)

b. For patients **WITH** a documented contraindication (e.g., personal or family history of hormone-sensitive cancer, thromboembolic disease, etc.) to menopausal hormone therapy (MHT), the patient must have had serious side effects or drug failure of at least **two** non-hormonal therapies proven to be effective for the treatment of vasomotor symptoms (e.g., paroxetine, gabapentin, venlafaxine, desvenlafaxine, or citalopram)

3. Quantity limit: 60 capsules/30 days

Mavenclad and 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.

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

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

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. 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 and memantine-donepezil ER capsules
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. Requests for brand name Namzaric ER will require documentation of serious side effects, or drug failure, with memantine-donepezil ER capsules (generic Namzaric ER) 4. Quantity limit of 30 capsules per 30 days
Nascobal and cyanocobalamin nasal spray
1. Must be 18 years of age or older **AND** 2. Must have a diagnosis of vitamin B12 deficiency or anemia due to vitamin B12 deficiency **AND** 3. Must have had serious side effects or drug failure with cyanocobalamin injection **AND** 4. Requests for brand name Nascobal nasal spray must have had serious side effects to generic cyanocobalamin nasal spray
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

Nuedexta and 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

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

Ofev and generic nintedanib capsules

1. 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
2. For a diagnosis of **Systemic Sclerosis with declining pulmonary function**:
   a. Must be prescribed by a pulmonologist or a rheumatologist
   b. Must have fibrosis of the lung based on a CT scan from within the last 12 months
   c. Must have FVC > 40% predicted
   d. Must have been treated with mycophenolate mofetil (MMF)
3. 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 within the last 12 months
   c. Must have had one of the following within one year as evidence of progression:
      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

4. Ofev and nintedanib capsules will not be authorized in combination with Esbriet, pirfenidone tablets, or pirfenidone capsules
5. Requests for brand name Ofev for the treatment of idiopathic pulmonary fibrosis or chronic fibrosing interstitial lung disease will require documentation of use of generic nintedanib capsules that led to serious side effects or drug failure
6. Quantity limit of 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

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

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

Opzelura - ruxolitinib phosphate cream

1. The diagnosis of nonsegmental vitiligo is considered 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 2 years of age or older
   b. Must be prescribed by a dermatologist
   c. Must have diagnosis of mild to moderate atopic dermatitis
      i. Baseline BSA must be provided and be <20%
      ii. 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
      i. 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.
12. 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 prescribed by or under the recommendation of a pulmonologist or cystic fibrosis specialist
3. Must be 1 year of age or older **AND**
4. Must have 2 copies of the F508del mutation in the CFTR gene **AND**
5. Quantity limits as follows:
    a. Tablets:120 tablets per 30 days
    b. Granules: 60 packets per 30 days

Orlynvah – sulopenem etazdroxil and probenecid

1. Must be 18 years of age or older **AND**
2. Patient was assigned female at birth **AND**
3. Must have a diagnosis of uncomplicated urinary tract infection (uUTI) **AND**
4. Must have documented evidence of <u>all</u> the following (a, b, and c):
    a. Confirmed infection on urinalysis (e.g., positive dipstick analysis for leukocyte esterase, or ≥10 white blood cells (WBCs) per mm^3 on microscopic analysis of unspun urine, or WBC count ≥10 cells/HPF in the sediment of a spun urine) **AND**
    b. Urine culture results indicating that the uUTI is caused by at least <u>one</u> of the following microorganisms (i, ii, **OR** iii):
        i. *Escherichia coli*
        ii. *Klebsiella pneumoniae*
        iii. *Proteus mirabilis*
    c. Susceptibility results **AND**
5. As Orlynvah is only indicated in patients who have limited or no alternative oral antibacterial treatment options, must have serious side effects or drug failure of <u>at least one agent from **THREE** of the following standards of care drug/categories (a-e).</u> [NOTE: An exception may be made for a drug/category if there is documentation of a contraindication or anaphylaxis/hives to that drug/category OR susceptibility testing indicates that the drug/category would not be suitable for treatment]. Documentation must be within 60 days.
    a. Nitrofurantoin
    b. Fosfomycin
    c. Trimethoprim/sulfamethoxazole (unless the prescriber can demonstrate evidence that the local resistance patterns exceed 20%)
    d. Fluoroquinolones (i.e., ofloxacin, ciprofloxacin, levofloxacin)
    e. Beta-lactam agents (i.e., amoxicillin-clavulanate, cefdinir) AND
6. Orlynvah <u>will not</u> be authorized for any of the following:
    a. Patients with evidence of acute pyelonephritis or urosepsis defined as: fever (temperature > 38° C), chills, costovertebral angle tenderness, flank pain, bacteremia, nausea, and/or vomiting
    b. For use in complicated urinary tract infections, or complicated intra-abdominal infections, or as step-down treatment after intravenous antibacterial treatment for either of these types of infections
    c. For UTI prophylaxis
7. Approval authorization will be for 1 month to allow for completion of one treatment course. Reauthorization for the same infection will not be considered. If the request is to treat a new uUTI infection, the above criteria must be met.

8. Quantity Limit:
    a. 10 tablets/5 days. One treatment course will be authorized per 365 days. Authorization for more than one treatment course within a year will require:
        i. Documentation that previous use of Orlynvah led to resolution of uUTI signs and symptoms **AND**
        ii. The following only applies if the request is occurring within 1 month of a previous Orlynvah treatment course:
            1. Prescriber must attest that this is a new infection and Orlynvah is not being used as continued treatment of the same uUTI infection previously treated with Orlynvah

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

Phospholine Iodide (echothiopate iodide 0.125%)

1. Must be prescribed by an ophthalmologist **AND**
2. Must have a diagnosis of elevated intraocular pressure **AND**
    a. Must have serious side-effects or drug failure to pilocarpine ophthalmic solution **OR**
3. Must have a diagnosis of accommodative esotropia **AND**
    a. Must have tried and failed to respond to spectacle correction, unless a contraindication to spectacle use is present
4. Initial approval criteria as follows:
    a. For elevated intraocular pressure, approval will be for 1 year
    b. For accommodative esotropia, approval will be for 3 months
5. Recertification of approval for 2 years at a time will require documentation of the following:
    a. For elevated intraocular pressure, documentation of positive response as demonstrated by decreased intraocular pressure
    b. For accommodative esotropia, documentation of positive response to therapy with correction of the esotropia

Pivya (pivmecillinam)

1. Must be 18 years of age or older **AND**
2. Patient was assigned female at birth **AND**
3. Must have a diagnosis of uncomplicated urinary tract infection (uUTI) **AND**
4. Must have documented evidence of all of the following (a, b, and c):
    a. Confirmed infection on urinalysis (e.g., positive dipstick analysis for leukocyte esterase, or ≥10 white blood cells (WBCs) per mm^3 on microscopic analysis of unspun urine, or WBC count ≥10 cells/HPF in the sediment of a spun urine) **AND**
    b. Urine culture results indicating that the uUTI is caused by at least one of the following microorganisms (I, ii, or iii):
        i. *Escherichia coli* **OR**
        ii. *Proteus mirabilis* **OR**
        iii. *Staphylococcus saprophyticus* **AND**
    c. Susceptibility results **AND**
5. Must have serious side effects or drug failure of at least one agent from **THREE** of the following

drug/categories (a-e). [NOTE: An exception may be made for a drug/category if there is documentation of a contraindication, or anaphylaxis/hives, to that drug/category **OR** susceptibility testing indicates that the drug/category would not be suitable for treatment]. Documentation must be within 60 days
   a. Nitrofurantoin
   b. Fosfomycin
   c. Trimethoprim/sulfamethoxazole (unless the prescriber can demonstrate evidence that the local resistance patterns exceed 20%)
   d. Fluoroquinolones (i.e., ofloxacin, ciprofloxacin, levofloxacin)
   e. Beta-lactam agents (i.e., amoxicillin-clavulanate, cefdinir) **AND**
6. Pivya will not be authorized for any of the following:
   a. For use in complicated urinary tract infections
   b. For UTI prophylaxis
7. Approval authorization will be for 1 month to allow for completion of one treatment course. Reauthorization for the same infection will not be considered. If the request is to treat a new uUTI infection, the above criteria must be met.
8. Quantity limit:
   a. 9 tablets/3 days. An exception to the quantity limit may be provided for those who require treatment up to a 7-day course of therapy (maximum 21 tablets/7 days). One treatment course will be authorized per 365 days. Authorization for more than one treatment course within a year will require:
      i. Documentation that previous use of Pivya led to resolution of uUTI signs and symptoms **AND**
      ii. <u>The following only applies if the request is occurring within 1 month of a previous Pivya treatment course</u>:
         1. Prescriber must attest that this is a new infection and Pivya is not being used as continued treatment of the same uUTI infection previously treated with Pivya.

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**
4. Quantity limit of 30 packets per 30 days.
   a. Additional quantities will be granted for the appropriate dose based on age and weight in accordance with the prescribing information

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

Quinine sulfate capsules

1. Must have a diagnosis of Malaria

Raldesy – trazodone oral solution

1. Must be 18 years of age or older **AND**
2. Must have a diagnosis of major depressive disorder (MDD) **AND**
3. Documentation must be provided why member is unable to use trazodone tablets.
4. Quantity Limit: 1 bottle (150 mL) per 30 days.
   a. Additional quantities will be granted based on FDA-approved dosing

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. Documentation must be submitted confirming the patient is unable to safely self-administer injectable medications and does not have a caregiver who can reliably administer the medication on their behalf. Clinical justification may include but is not limited to history of significant tremor, dexterity limitations, cognitive impairment.
   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 both of the following: calcitriol capsules and paricalcitol capsules

Ridaura and Auranofin capsules

1. Must be 18 years of age or older **AND**
2. Must have a diagnosis of rheumatoid arthritis **AND**
3. Must have had an insufficient response, or intolerance, to an adequate trial of full doses of one or more nonsteroidal anti-inflammatory drugs (NSAIDS).
4. Quantity limit of 60 capsules per 30 days,

An increase to 90 capsules per 30 days may be considered for those who do not achieve adequate response to therapy with 6 mg per day after six months of therapy.

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

1. Must be prescribed by, **OR** in consultation with, a neurologist
2. For Sabril, vigabatrin tablets, vigabatrin packets, and Vigadrone 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 2 of the following standard of care therapies: 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 will require documentation of use of generic vigabatrin 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, and Vigadrone is 180 tablets/packets per 30 days.
7. Quantity limit for Vigafyde is 300 mL per 30 days.

Approval for increased quantity will be based on FDA approved dosing recommendations.

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** either generic doxycycline or generic minocycline
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.

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.

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

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

Sprix - ketorolac tromethamine nasal spray

1. For a diagnosis of headaches/migraines there must be a previous trial of at least one non oral (injection or nasal spray) triptan and one other acute therapy with different mechanism of action (NSAID, DHEA, etc.)
2. For a diagnosis of general acute pain (ex. Post op pain) Sprix will only be authorized for those individuals unable to tolerate oral medications (such as oral ketorolac). Approvals for acute pain will only be for 3 months.
3. Quantity limit of 5 bottles per 30 days

Sunosi – solriamfetol tablet

1. Must be 18 years of age or older
2. Must be prescribed by, or consultation with, a neurologist, sleep specialist, or pulmonologist
3. Must have a diagnosis of excessive daytime sleepiness associated with either narcolepsy or obstructive sleep apnea (OSA). 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, or methylphenidate)

7. Sunosi will not be covered for any other non-FDA approved conditions
8. Quantity limit of 30 tablets per 30 days.

Symdeko – tezacaftor/ivacaftor tablets

1. Must have a diagnosis of cystic fibrosis
2. Must be prescribed by or under the recommendation of a pulmonologist or cystic fibrosis specialist
3. Must be 6 years or older
4. Must have 2 copies of the F508del mutation in the CFTR gene (homozygous) **OR**
5. 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).
6. 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.
7. Liver enzymes should be assessed prior to initiation of Symdeko, every 3 months during the first year of treatment, and annually thereafter.
8. 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 maximum 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 and 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
4. Coverage for dronabinol oral solution will require serious side effects or drug failure to brand name Syndros.

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

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. Will be covered for a maximum duration of 48 weeks of therapy
7. Quantity Limit 4 ml per 30 days
   a. Additional quantities will be approved based on FDA-approved dosing

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 affecting 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 prescribed by or under the recommendation of a pulmonologist or cystic fibrosis
3. Must be 2 years of age or older
4. Must have at least one variant in the CFTR gene that is responsive to Trikafta or results in the production of CFTR protein (package insert includes a full list of responsive CFTR gene variants)
5. Quantity limits as follows:
   a. 84 tablets per 28 days
   b. 56 packets per 28 days

Tryptyr – acoltremon 0.003% 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.) **AND**
4. Must have had serious side effects or drug failure of artificial tears **AND**
5. Must have had serious side effects or drug failure to cyclosporine ophthalmic emulsion **AND** Xiidra
6. Quantity Limit: 60 vials per 30-day supply.

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
3. Inadequate control of hypertension must not be due to non-compliance with medication regimen
4. 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
5. Must use Tryvio in combination with at least three other anti-hypertensive medications. Tryvio will not be authorized as monotherapy.
6. 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.
7. 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

Twyneo - tretinoin and benzoyl peroxide cream

1. Must have a diagnosis of moderate to severe acne
2. Must be 9 years of age or older
3. Must be prescribed by a dermatologist
4. Based on comparable indications, safety profiles and similar strengths of generic tretinoin and benzoyl peroxide, the member will be required to use generic tretinoin and benzoyl peroxide as separate products unless they have tried generic tretinoin 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
6. Recertification for 1 year at a time will require documentation of improvement in symptoms while on Twyneo therapy.
7. Quantity Limit of 30 grams per 30 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 moderate to severe vasomotor symptoms (VMS) associated with menopause that interfere with quality of life
2. Must meet **ONE** of the following (a or b):
   a. For patients **WITHOUT** a contraindication to menopausal hormone therapy (MHT), the patient must have had serious side effects or drug failure of at least **two** other medications proven to be effective for the treatment of vasomotor symptoms
      i. One prior therapy must be a non-hormonal agent (e.g., paroxetine, gabapentin, venlafaxine, desvenlafaxine or citalopram)
      ii. One prior therapy must be a systemic MHT (estrogen ± progestogen)
   b. For patients **WITH** a documented contraindication (e.g., personal or family history of hormone-sensitive cancer, thromboembolic disease, etc.) to menopausal hormone therapy (MHT), the patient must have had serious side effects or drug failure of at least **two** non-hormonal therapies proven to be effective for the treatment of vasomotor symptoms (e.g., paroxetine, gabapentin, venlafaxine, desvenlafaxine, or 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 sacubitril/valsartan)

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) **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

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
8. Approved Dosing: See prescribing information
9. Quantity Limit: 18 tablets per treatment course

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 prescribed by, or in consultation with, an Infectious Disease or GI specialist **AND**
3. Must be used to prevent the recurrence of Clostridioides difficile infection (CDI) **AND**
4. The patient must have a diagnosis of **at least 2** recurrent episodes of Clostridioides difficile infection (CDI) (three or more total episodes within a 12-month period) **AND**
5. The patient must have had a positive stool test for the presence of Clostridioides difficile toxin within the past 30 days **AND**
6. Current CDI must be controlled following completion of at least 10 days of standard of care antibiotic therapy (e.g., vancomycin, fidamoxacin) **AND**
7. Administration must occur within 2 to 4 days following the completion of an antibiotic course used for CDI treatment **AND**
8. Provider attests patient will conduct bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution on the day prior to taking the first dose of Vowst **AND**
9. Must have had a trial of Rebyota (prior authorization required) **AND**
10. Patient must not be immune compromised
11. Retreatment with Vowst for the same CDI will not be covered
12. Vowst will not be covered for the treatment of Clostridioides difficile infection (CDI) or any other non-

FDA approved indications

13. Approval will be for 1 month
    a. All approvals are valid only when it is confirmed that Vowst will be administered within the required timeframe relative to the CDI antibiotic course (i.e., therapeutic window of administration). As such, providers must confirm, prior to approval (on initial or appeal), that the member will receive the therapy within the therapeutic window of administration. If the therapeutic window of administration has expired, the request will not be approved.
14. Approved dosing: 4 capsules per day for 3 consecutive days
15. 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**
    a. Must have a diagnosis of chronic **Plaque Psoriasis AND**
        i. Must be at least 18 years of age **AND**
        ii. Must have a maximum body surface area (BSA) involvement of 20% **AND**
        iii. 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
            1. Trial of topical therapies do not have to occur simultaneously (in combination), but consideration will be granted if the topical therapies were trialed together
        iv. Initial approval will be granted for 12 weeks
        v. Recertification for 1 year at a time requires documentation of improvement (initial recertification) and/or maintenance of improvement from baseline; **OR**
    b. Must have a diagnosis of moderate to severe **Atopic Dermatitis AND**
        i. Must be at least 2 years of age **AND**
        ii. Must meet one of the following:
            1. Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) of ≥ 3
            2. An Eczema Area and Severity Index (EASI) score ≥6
            3. Baseline BSA less than 35% **AND**
        iii. Must meet ALL the following:
            1. Must have had serious side effects or drug failure with an adequate trial of ONE generic topical steroid
                a) 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
            2. Must have had serious side effects or drug failure with an adequate trial of ONE of the following: tacrolimus ointment or pimecrolimus cream
                a) Adequate trial is defined as ≥ 6 weeks based on prescribing information
            3. Must have had serious side effects or drug failure with an adequate trial of Eucrisa
                a) Adequate trial is defined as ≥ 28 days based on prescribing
        iv. Approval will be granted for 8 weeks
        v. Recertification of the first approval after 8 weeks of use will require documentation of improvement in disease (decreased BSA and/or vIGA-AD score)
        vi. 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 Vtama
2. Vtama will not be approved for any non-FDA approved indications
3. 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 initial 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, or in consultation with, a neurologist or sleep specialist
2. Must be 6 years of age or older **AND**
3. Must meet one of the following (a or b):
   a. Must have a diagnosis of cataplexy associated with narcolepsy
   b. Must have a diagnosis of excessive daytime sleepiness associated with narcolepsy **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 of 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 of 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

*****<u>Prior Authorization</u> Applies to Child Health Plus (CHP) ONLY*****
****<u>Quantity Limit</u> 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.

Ximino and minocycline ER capsules (generic Ximino)

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.

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. Must have had serious side effects or drug failure with at least TWO phosphate binders (e.g., sevelamer, lanthanum, calcium carbonate, calcium acetate, Velphoro, or Auryxia)
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 and sodium oxybate oral solution

1. Must be prescribed by or in consultation with a neurologist or sleep specialist
2. Must be 7 years of age or older **AND**
3. Must meet one of the following (a or b):
    a. Must have a diagnosis of cataplexy associated with narcolepsy
        i. Narcolepsy must be confirmed by a sleep study which must be provided
        ii. Requests for brand Xyrem must have documentation of serious side effects or drug failure to sodium oxybate
    b. Must have a diagnosis of excessive daytime sleepiness associated with narcolepsy
        i. Narcolepsy must be confirmed by a sleep study which must be provided
        ii. For patients 18 years of age or older must have had serious side effects, drug failure, or contraindication to Sunosi (requires prior authorization)
        iii. Requests for brand Xyrem must have documentation of serious side effects or drug failure to sodium oxybate
4. Use of Xyrem/sodium oxybate, Xywav and/or Lumryz in combination will not be authorized
5. Xyrem/sodium oxybate will not be covered for any non-FDA approved indication or diagnosis
6. Quantity limit of 540 mL per 30 days.

Xywav - Calcium Oxybate/Magnesium Oxybate/Potassium Oxybate/Sodium Oxybate solution

1. Must be prescribed by or in consultation with a neurologist or sleep specialist
2. Must meet one of the following (a, b, or c):
    a. Must have a diagnosis of cataplexy associated with narcolepsy
        i. Must be 7 years of age or older
        ii. Narcolepsy must be confirmed by a sleep study which must be provided
        iii. Must have serious side effects or drug failure to sodium oxybate
    b. Must have a diagnosis of excessive daytime sleepiness associated with narcolepsy
        i. Must be 7 years of age or older
        ii. Narcolepsy must be confirmed by a sleep study which must be provided
        iii. For patients 18 years of age or older must have had serious side effects, drug failure, or contraindication to Sunosi (also requires prior authorization)
        iv. Must have had serious side effects or drug failure to sodium oxybate
    c. Must have a diagnosis of idiopathic hypersomnia
        i. Must be 18 years of age or older
        ii. Idiopathic hypersomnia must be confirmed by a sleep study which must be provided **AND**
        iii. Must have had serious side effects or drug failure to modafinil or armodafinil **AND**
        iv. Must have had serious side effects or drug failure to a stimulant medication **AND**
7. Use of Xyrem/sodium oxybate, Xywav and/or Lumryz in combination will not be authorized
8. Xywav will not be covered for any non-FDA approved indication or diagnosis
9. Quantity Limit of 540 mL per 30 days.

Yosprala - 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.

Zelsuvmi – berdazimer 10.3% topical gel

1. Must be 1 year of age or older **AND**
2. Must be prescribed by or in consultation with a dermatologist **AND**
3. Must have a diagnosis of molluscum contagiosum (MC) **AND**
4. Must have documentation of at least ONE of the following:
    a. Member is experiencing itching or pain
    b. Concomitant bacterial infection
    c. Concomitant atopic dermatitis (AD)
    d. Concern for contagion (e.g., other siblings, daycare) and lesions cannot be reasonably covered using a bandage
    e. Member is immunocompromised (e.g., patients with HIV/AIDS, patients taking immunosuppressive drugs for cancer, transplantation, etc., and children who have underdeveloped immunocompetency)
5. Must have documentation of treatment failure to at least one of the following treatment modalities (a, b, or c) or clinical justification why they cannot be used:
    a. Cryotherapy
    b. Curettage
    c. Podofilox
6. Approval will be provided for 12 weeks.
7. Re-authorization is not permitted. Members must meet the initial approval criteria.

8. Quantity Limit: 1 kit (31 grams) per 30 days.
    a. Requests for additional quantities may be considered when submitted documentation supports a clinically significant lesion burden that warrants use beyond the allowed quantity limit. Approved quantities will be limited to the minimum number of kits necessary for treatment.

Zipsor and diclofenac potassium 25 mg capsules

1. Must have a diagnosis of acute pain **AND**
2. Must have documentation of a trial of a higher strength (minimum 50 mg) of oral generic diclofenac, which led to intolerance
3. Approval will be for 1 month, to afford short term use
4. Quantity limit is 120 capsules per 30 days

Zonalon, Prudoxin, 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 2 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 and Zoryve 0.05% CREAM for a diagnosis of Atopic Dermatitis must meet the following:
   a. Must be at least 6 years of age for Zoryve 0.15% CREAM or age 2-5 years old for Zoryve 0.05% CREAM **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, 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 0.3% FOAM for a diagnosis of plaque psoriasis of the scalp and body must meet the following:
   a. Must be at least 12 years of age **AND**
   b. Must have mild to severe plaque psoriasis of the scalp and body as defined below (must meet criteria i-iii):
      i. Must have at least 10% of the scalp and up to 20% of non-scalp areas, for a total of 25% or less of the scalp and body areas, not including palms and/or soles **AND**
      ii. A minimum Scalp-Investigator Global Assessment (S-IGA) score of 3 (moderate) **AND**
      iii. A minimum Body-IGA (B-IGA) score of 2 (mild).
   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 it the topical therapies are trialed together
6. Zoryve will not be approved for any non-FDA approved indications including use of the cream for seborrheic dermatitis, the foam for atopic dermatitis, the 0.15% cream for plaque psoriasis or the 0.3 % cream for atopic dermatitis
7. 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.
8. Quantity limit: 60 grams per 30 days

Zunveyl- benzgalantamine tablets

1. Must have a diagnosis of mild to moderate Alzheimer's disease **AND**
2. Must be 18 years of age or older **AND**
3. Must have serious side effects or drug failure to TWO different generic acetylcholinesterase inhibitors: donepezil, galantamine, or rivastigmine
4. Quantity Limit: 60 tablets/30 days

Zyflo and zileuton tablets

1. Must be requested by or in consultation with an Allergist/immunologist or Pulmonologist **AND**
2. Must be 12 years and older **AND**
3. Must be used for the prophylaxis and chronic treatment of asthma **AND**

4. Patient must be a non-smoker. Non-smoker is defined as someone who has not smoked in the preceding 6 months **AND**
5. Must have had serious side effects, drug failure of or contraindication to zafirlukast AND montelukast
6. Quantity Limit of 120 tablets per 30 days

POLICY GUIDELINES:

1. Unless otherwise stated above within the individual drug criteria, approval time-period will be for 2 years.
2. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other objective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. 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 remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
   a. Coverage criteria may be dependent on contract renewal date.
   b. Coverage of drugs listed in this policy are contract dependent.
   c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit.
   d. Not all contracts/benefits cover all medical infusible drugs.
4. This policy is applicable to drugs that are included on a specific drug formulary (Pharmacy benefit only). If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
5. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
6. 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.
7. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
8. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
9. For Fully Insured Commercial and Exchange products only: New York State insurance requirements prohibit negative mid-plan-year formulary changes. Therefore, members enrolled in non-calendar-year plans (e.g., July-July renewals) may continue to follow the prior plan year's formulary tier structure and corresponding utilization-management criteria until their group's renewal date.
   a. Pharmacy Benefit Formulary ID Alignment
      i. 2025 Commercial/Exchange Formulary IDs: 5181,5899,2981
      ii. 2026 Commercial/Exchange/Essential Plan/Child Health Plus Formulary IDs: 2950,6262,3295,6264,6060,2977,5930

10. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
11. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.

UPDATES:

Date	Revision
08/18/2026	Revised
08/13/2026	Reviewed / P&T Committee Approval
08/07/2026	Revised
07/29/2026	Revised
06/18/2026	Revised
06/01/2026	Revised
05/22/2026	Revised
05/18/2026	Revised
05/14/2026	Reviewed / P&T Committee Approval
04/17/2026	Revised
03/06/2026	Revised
02/13/2026	Revised
02/12/2026	Reviewed / P&T Committee Approval
01/30/2026	Revised
01/08/2026	Revised
01/01/2026	Revised
11/13/2025	Reviewed / P&T Committee Approval
10/30/2025	Revised
10/27/2025	Revised
10/16/2025	Revised
10/06/2025	Revised
09/30/2025	Revised
08/21/2025	Revised
08/14/2025	Reviewed / P&T Committee Approval
08/08/2025	Revised
07/24/2025	Revised
06/18/2025	Revised
05/21/2025	Revised
05/08/2025	Reviewed / P&T Committee Approval
04/28/2025	Revised
04/09/2025	Revised
03/13/2025	Revised
03/06/2025	Revised
02/21/2025	Revised
01/27/2025	Revised
01/01/2025	Revised
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
6/21	Revised
5/21	Revised/P&T Approval
4/21	Revised
3/21	Revised
2/21	Revised/P&T Approval
1/21	Revised
11/20	Revised/P&T Approval
10/20	Revised
9/20	Revised/P&T Approval
8/20	Revised
7/20	Revised
6/20	Revised
5/20	Revised/P&T Approval
4/20	Revised
3/20	Revised
2/20	Revised
1/20	Revised
12/19	Revised
11/19	Revised/P&T Approval

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 –
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