Pharmacy Management Drug Policy

SUBJECT: Clinical Review Prior Authorizations (CRPA) Rx
POLICY NUMBER: PHARMACY-09
EFFECTIVE DATE: 12/04
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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. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

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 FLRx 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.

CURRENT CRPA DRUGS:

Drug Name – generic name (Rx benefit) **Authorization Criteria**
Abilify Mycite – aripiprazole tablets with sensor (Rx)
1. Must have a diagnosis of Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder. 2. Must have attempted to use generic aripiprazole tablets with non-compliance documented in prescriber notes. Prescriber notes must also document the prescriber's attempted medication adherence counseling. 3. Must have had serious side effects or drug failure with long-acting injectable Abilify Maintena or have a medical reason why a long-acting injectable would not be appropriate 4. The prescriber must attest that other atypical antipsychotics (such as risperidone, olanzapine, ziprasidone, quetiapine, and paliperidone ER) would not be as effective as aripiprazole or would be expected to cause similar compliance issues experienced with standard aripiprazole tablets. 5. Approval will be for 3 months. Recertification will require prescriber notes to confirm the patient has had an improvement in compliance and response to treatment. 6. Quantity limit: 30 per 30 days 7. Please note: FDA labeling states the ability of Abilify Mycite to improve patient compliance or modify aripiprazole dosage has not been established.
Absorica and Absorica LD – isotretinoin capsules (Rx)
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, Amnesteem, Claravis, Myorisan, and Zenatane). 3. Requests for 8 mg, 16 mg, 24 mg, 25 mg, 28 mg, 32 mg or 35 mg strengths of Absorica/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.
Aciphex Sprinkle - rabeprazole sprinkle capsules (Rx)
1. Must be prescribed for a diagnosis of GERD 2. Must be between the ages of 1 and 11 3. Must have had a trial of both generic lansoprazole and omeprazole capsules (both of which can be opened and sprinkled) 4. Will not be authorized for individuals age 12 or older. 5. Quantity limit of 60 per 30 days.

Acticlate and generic doxycycline hyclate tablets (Rx)

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.

Actimmune – Interferon Gamma-1B (Rx)

1. For the treatment of Chronic Granulomatous Disease
    a) The prescribing physician is an infectious disease specialist or a hematologist/oncologist
    b) Diagnosis has been confirmed through neutrophil function tests
    c) Combination therapy with antibiotics (i.e, trimethoprim/sulfamethoxazole) and/or antifungals (i.e., itraconazole) has been shown to reduce the risk of severe infections.
2. In the treatment of severe, malignant osteopetrosis
    a) The prescribing physician is an orthopedic surgeon, hematologist or an endocrinologist
    b) The diagnosis is confirmed through radiological evidence.
3. Approved dosing for those with a body surface area greater than 0.5 m^2 is 50 mcg/m^2 (1 million units/m^2) subcutaneously 3 times a week.
4. Doses above 50 mcg/m^2 will not be authorized.

Addyi – flibanserin (Rx)

1. Must be prescribed by a gynecologist or psychiatrist
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 of 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. 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.
8. Drug will be excluded on the Medicaid benefit
9. Quantity limit of 30 tablets per 30 days

Aklief – trifarotene cream (Rx)

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

Amrix, Fexmid and equivalent generic cyclobenzaprine (Rx)

1. Member must have had severe intolerance or therapeutic failure of generic cyclobenzaprine 5 or 10mg three times a day
2. Member must have had severe intolerance or therapeutic failure of two other muscle relaxants (such as carisoprodol, baclofen, tizanadine, methocarbamol, orphenadrine and Skelaxin)
3. Amrix and Fexmid should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available and because muscle spasm associated with acute, painful musculoskeletal conditions is generally of short duration and specific therapy for longer periods is seldom warranted. Based on this a quantity limit of 21 pills per 90 days will be imposed on Amrix and 189 pills per 90 days will be imposed on Fexmid.

Aptiom – eslicarbazepine acetate (Rx)

1. Member must have a diagnosis of seizure disorder
2. Must have had previous trial and failure or intolerance to generic oxcarbazepine and one other generic anti-epileptic (including but not limited to: gabapentin, lamotrigine, phenytoin, carbemazepine, divaloproex, valproic acid, levetiracetam, and felbamate)
3. QL of 30/30 days for 200mg,400mg and 800mg tablet, 60/30 days for 600mg tablet

Arcalyst - rilonacept (Rx)
1. Must have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) with one of the following conditions a. Familial Cold Autoinflammatory Syndrome (FCAS) also known as Familial Cold Urticaria **or** b. Muckle-Wells Syndrome (MWS) 2. Patient must be at least 12 years of age 3. Patient does not have an infection and is not at high risk for infection 4. Patient is not on concurrent therapy with any of the following – Ilaris, Kineret, Enbrel, Humira, infliximab or Simponi 5. Dose is not to exceed a one time loading dose of 320mg subcutaneously (given as 2 separate 160mg injections at 2 different sites) followed by once weekly dosing of a single 160mg sq injection. **Note** – it is not known whether Arcalyst is effective in patients with Neonatal-Onset Multisystem Inflammatory Disease (NOMID), also referred to as Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA).
Arikayce – liposomal amikacin for inhalation (Rx)
1. Must be prescribed by an infectious disease specialist or pulmonologist 2. Member must have a diagnosis of Mycobacterium avium complex (MAC) lung disease as confirmed by a MAC-positive sputum culture 3. Member 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 4. Arikayce must be used as part of a multi-drug regimen and will not be approved for use as a single agent 5. 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 6. 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. 7. Quantity limit: 236 ml/28 days
Astagraf XL – tacrolimus ER24H capsules (Rx)
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 90/30 for 0.5mg capsules, 120/30 for 1mg capsules, and 180/30 for 5 mg capsules.

Austedo – deutetrabenazine (Rx)

1. Patient must have Huntington's Chorea
    a. Must be prescribed by a neurologist **OR**
2. Must have a diagnosis of tardive dyskinesia
    a. Will only be authorized for adults age 18 and older.
    b. Must have a diagnosis of tardive dyskinesia defined as a history of ≥ 6 months (or ≥ 1 month in patients over 60 years of age) total cumulative neuroleptic exposure (continuous or discontinuous), presence of at least "moderate" abnormal involuntary movements in one or more body areas or at least "mild" movements in two or more body areas, and absence of other conditions that might produce abnormal involuntary movements.
    c. Must be prescribed by a neurologist or psychiatrist.
    d. Must have attempted an alternative method to manage the condition (such as dose reduction or discontinuation of the offending medication).
    e. Initial approval will be for 6 months. Continued approval will require documentation that the individual has had an improvement in their symptoms.
3. Austedo will not be covered in combination with Xenazine
4. QL: 6mg tablets: 60/30**,** 9mg tablets: 120/30, 12mg tablets: 120/30

Auvi-Q – epinephrine injection (Rx)

1. The health plan has determined that Auvi-Q is not medically necessary due to availability of less costly alternative treatment options that are likely to produce equal therapeutic results.
2. Exceptions to criteria #1 may be granted if:
    a. The member is blind and unable to properly use a standard epinephrine auto injector after a reasonable trial has been attempted **OR**
    b. The request is for Auvi-Q 0.1 mg and the member weighs less than 15 kg. Approval for Auvi-Q 0.1 mg will be for 1 year. Recertification will require office notes to document the member's weight is still less than 15 kg.

Bonjesta, Diclegis, and generic doxylamine/pyridoxine (Rx)

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. Bonjesta quantity limit is 60/30. Diclegis quantity limit is 120/30. Approval will be for 120 days.

Brisdelle and generic paroxetine mesylate capsules – paroxetine 7.5mg capsules (Rx)

1. The member must have a diagnosis of vasomotor symptoms associated with menopause
2. Must have had an adequate trial of generic paroxetine hydrochloride tablets and at least one other medication proven to be effective for the treatment of vasomotor symptoms (such as gabapentin, clonidine, venlafaxine, or topical or oral estrogens like estradiol tablets, estradiol patches, and Premarin).
3. Quantity limit of 30/30

Briviact – brivaracetam (Rx)

1. The member must have a diagnosis of a seizure disorder
2. Must be 4 years of age or older
3. Must have had serious side effects or drug failure with two other seizure medications (such as topiramate, levetiracetam, and lamotrigine).
4. QL of 60/30

Cablivi – caplacizumab-yhdp (Rx)
1. The prescription must be written by a hematologist 2. The member must be at least 18 years of age or older 3. Must have a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) 4. Must be used in combination with plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or rituximab) 5. If the above criteria are met, Cablivi will be approved under the medical benefit for administration while the patient is receiving plasma exchange. Cablivi will be approved under the pharmacy benefit for 30 days of treatment following the last plasma exchange the patient received. 6. Requests for additional therapy up to a maximum 28 additional days will be considered for recertification if the provider submits documentation of remaining signs of persistent underlying disease (such as suppressed ADAMTS13 activity levels)
Carac and generic fluorouracil 0.5% cream (Rx)
1. The member must have a diagnosis of actinic keratosis 2. Must be 18 years of age or older 3. Must have had a previous trial of imiquimod that resulted in serious side effects or drug failure 4. Approval will be for 4 weeks
Carbinoxamine 6 mg and Ryvent
1. The member must have had drug failure or serious side effects or drug failure with carbinoxamine 4 mg, clemastine, and diphenhydramine 2. Quantity Limit of 120/30
Chlorzoxazone 250 mg (Rx)
1. Must have had a trial of generic chlorzoxazone 500mg which resulted in clinical effectiveness but also significant drowsiness causing impairment of activities of daily living 2. Patient must have had severe intolerance or therapeutic failure of at least two other muscle relaxants in addition to chlorzoxazone (such as cyclobenzaprine, baclofen, tizanidine, methocarbamol, orphenadrine) 3. Quantity limit of 120/30
Consensi – amlodipine/celecoxib (Rx)
1. The member must have a diagnosis of hypertension AND osteoarthritis 2. Must be 18 years of age or older 3. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic amlodipine and celecoxib, the member will be required to use generic amlodipine and celecoxib (as separate pills) unless there is adequate justification as to why these are not appropriate.

Cosmetic drugs (Rx) **Including, but not limited to Alphaquin, Avage, bimatoprost 0.03%, finasteride 1mg, Latisse, lidocaine-tetracaine cream, Melpaque, Mirvaso, Pliaglis, Propecia, Refissa, Renova, Rhofade, tretinoin emollient cream 0.05%, Tri- Luma, Vaniqa**
1. Certain medications that are used primarily for cosmetic purposes are maintained on the CRPA drug list 2. Approval for prior authorization of these medications requires documentation that the condition is causing a physical impairment in activities of daily living. 3. Examples of diagnosis considered cosmetic and therefore not covered would include (but not limited to): vitiligo, hirsutism, hypotrichosis, hyperpigmentation, alopecia, melasma, solar lentigines 4. For Medicaid members over the age of 35, topical retinoids including Avita, Retin-A, Tretinoin, Tretin-X, Atralin, Differin, Adapalene, and Retin-A Micro will require documentation that they are being used for a diagnosis of acne.
Cuprimine and generic penicillamine capsules (Rx)
1. Must be used for an FDA approved indication: Wilson's Disease, Rheumatoid Arthritis or Cystinuria. 2. Based on comparable indications, efficacy, safety profiles and dosing, penicillamine tablets (the generic for Depen) will be required unless there is adequate justification by the prescriber as to why penicillamine tablets are not clinically appropriate. 3. Quantity limit of 240/30 days. A quantity limit exception (480/30 days) can be granted for a diagnosis of Cystinuria
Cuvposa – glycopyrrolate (Rx)
1. Must have a neurological disorder associated with drooling (such as cerebral palsy, mental retardation) 2. Must be unable to swallow glycopyrrolate tablets 3. Quantity limit of 1350 ml / 30 days
Cystaran - cysteamine Ophthalmic drops (Rx)
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 cysteamine ophthalmic solution in each eye, every waking hour. 4. Product 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. QL 4 bottles/28 days.
Diacomit – stiripentol
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 4. Must be taken in conjunction with clobazam

Doptelet – avatrombopag (Rx)
1. Member must be at least 18 years old 2. Must have a diagnosis of chronic liver disease and be scheduled to undergo a procedure a. Must also have a diagnosis of thrombocytopenia defined as a platelet count of less than 50 x 10^9/L b. Must be prescribed by a hepatologist, gastroenterologist, or hematologist c. Must be prescribed for the appropriate dose based on platelet count prior to the scheduled procedure: i. For patients with a platelet count between 40 and 50 x 10^9/L, Doptelet can be approved at a dose of 2 tablets per day for 5 days ii. For patients with a platelet count less than 40 x 10^9/L, Doptelet can be approved at a dose of 3 tablets per day for 5 days d. Patients should begin dosing 10-13 days prior to their procedure and undergo their procedure within 5-8 days after their last dose e. Approval will be for 14 days **OR** 3. Must have a diagnosis of chronic (lasting at least 3 months) idiopathic thrombocytopenia purpura (ITP) a. Must be prescribed by a hematologist b. Must have a current platelet count less than 30 x 10^9/L c. Must have had an insufficient response (defined as a platelet count of less than 20 x 10^9/L, or greater but with bleeding symptoms) to the following treatments: i. Corticosteroids **AND** ii. Immunoglobulins (IVIG) or splenectomy d. Doptelet should not be used to normalize platelet counts 4. Quantity limit of 15 tablets per 30 days. For a diagnosis of chronic ITP, a quantity of 60 tablets per 30 days will be allowed
Duobrii – halobetasol and tazarotene lotion (Rx)
4. Must be prescribed by a dermatologist 5. The member must have a diagnosis of plaque psoriasis 6. Must be 18 years of age or older 7. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic tazarotene and halobetasol, the member will be required to use generic tazarotene and halobetasol unless there is adequate justification as to why these are not appropriate.
Dymista and generic azelastine/fluticasone combination spray (Rx)
1. Must have documentation that member has been stable on the same doses of azelastine and fluticasone used as separate nasal sprays for the 3 months immediately preceding the request. 2. QL of 23 grams/30 days.

Egrifta – tesamorelin inject (Rx)

1. Individuals between 18-65 with a diagnosis of HIV-positive lipodystrophy
2. Currently receiving anti-retroviral therapy
3. Waist circumference ≥ 95 cm (37.4 inches) and a waist-to-hip ratio ≥ 0.94 for men **OR** Waist circumference ≥ 94 cm (37.0 inches) and a waist-to-hip ratio ≥ 0.88 for women
4. Current FBG <150 mg/dL
5. Individuals with the following will be excluded from coverage
    1. BMI ≤20 kg/m^2
    2. Previously treated with insulin or with PO hypoglycemic or insulin-sensitizing agents
    3. History of malignancy
    4. Hypopituitarism
    5. 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. **For Managed Medicaid, the use of Egrifta is considered cosmetic and will not be covered.**

Emflaza – deflazacort (Rx)

1. Must be prescribed by or in consultation with a provider who specializes in the treatment of Duchenne Muscular dystrophy (DMD) and/or neuromuscular disorders AND
2. Must have a diagnosis of DMD with a confirmed mutation of the DMD gene AND
3. Must have had trial of prednisone for ≥ 6 months (documentation required) and at least one of the following intolerable adverse effects
    a. Cushingoid appearance (documentation required) OR
    b. Central (truncal) obesity (documentation required) OR
    c. Undesirable weight gain defined as a ≥10% of body weight gain increase over a 6-month period (documentation required) OR
    d. Diabetes and/or hypertension that is unable to be managed OR
4. Member must have had previous treatment with steroids and experienced unmanageable side effects that required hospitalization or significant clinical intervention (examples included steroid induced mania, sepsis, etc) AND
5. A baseline score of motor function/muscle strength must be provided using one of the following scales:
    a. Hammersmith motor ability score (scored 0-40) OR
    b. Medical Research Council testing for muscular strength (MRC, reported as an index score)
6. Initial approval will be for 12 months. Subsequent approvals for 12 months at a time will require documentation of less than a 1 point decrease from Hammersmith motor ability score or MRC index.
7. The recommended dosage of Emflaza is 0.9 mg/kg/day. Quantity of Emflaza tablets will be limited to 30 tablets per 30 days and Emflaza suspension will be limited to 30 ml per 30 days.
    a. If tablets are used, dose should be rounded up to the nearest possible dose. If suspension is used, dose should be rounded up to the nearest tenth of a milliliter.
    b. Requests for additional quantity of Emflaza liquid suspension will only be allowed for children age 7 years and under whose weight warrants an increased quantity Children over 8 years of age will require documentation of an attempt and inability to swallow a pill (whole or crushed)

Emverm – mebendazole tablet (Rx)
1. Must have a diagnosis of Enterobius vermicularis (pinworm) a. Must have had a trial and failure or intolerance to pyrantel pamoate and Albenza. b. Quantity limit is 2 tablets per 30 day supply. **OR** 2. Must have a diagnosis of Trichuris trichiura (whipworm) a. Must have had a trial and failure or intolerance to Albenza. b. Quantity limit is 6 tablets per 30 day supply. **OR** 3. Must have a diagnosis of Ascaris lumbricoides (common roundworm) a. Must have a trial and failure or intolerance to two of the following: Albenza, pyrantel pamoate, and ivermectin. b. Quantity limit is 6 tablets per 30 day supply. Note that a one-time dose of 500mg (5 tablets) can also be utilized. **OR** 4. 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 Albenza. b. Quantity limit is 6 tablets per 30 day supply. Note that a one-time dose of 500mg (5 tablets) can also be utilized.
Enstilar – calcipotriene/betamethasone topical foam (Rx)
1. Must be prescribed by a dermatologist 2. The member must have had serious side effects or drug failure with calcipotriene/betamethasone ointment (the generic for Taclonex ointment) 3. Initial approval will be limited to 4 weeks. Approval for future treatment courses will require documentation of improved symptoms after 4 weeks. 4. Quantity Limit of 120 grams per 30 days
Envarsus XR – tacrolimus ER tablet (Rx)
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 other 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
Epaned - enalapril 1mg/1mL solution (Rx)
1. Epaned will be allowed for children age 7 years and under 2. Children age 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 age 7 years and under will be until the child turns 8. Approval for children age 8-17 years old will be until the child turns 18. 5. QL 1200mL/30 days

Epidiolex – cannabidiol (Rx)
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 Lennox-Gastaut syndrome or Dravet syndrome 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
Esbriet - pirfenidone (Rx)
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. c) Specific combinations of HRCT and surgical lung biopsy pattern in patients subjected to surgical lung biopsy 3. The individual must be a non-smoker (defined as someone who has not smoked in the past month) 4. Esbriet will not be authorized in combination with Ofev
Esomeprazole Strontium (Rx)
1. Must have documented intolerance to at least 2 first-line proton pump inhibitors at maximum dosage (Omeprazole 40mg, Pantoprazole 40mg, Lansoprazole 30 mg) AND 2. Must have documented intolerance to esomeprazole (generic for Nexium) at a dose of 40mg. 3. QL 30/30 days
Extavia – Interferon Beta-1b (Rx)
1. Must be prescribed by a neurologist 2. Must have a diagnosis of relapsing remitting MS 3. Must have documentation of clinical failure or severe intolerance to Betaseron and two of the following preferred agents (Avonex, Copaxone, Rebif or Tecfidera)
Fabior – tazarotene foam (Rx)
1. Must be used for a diagnosis of Acne 2. Must be prescribed by a dermatologist 3. Must have had previous trial and failure or intolerance to tretinoin and adapalene. 4. QL of 100 gm/ 30 days
Firdapse – amifampridine (Rx)
1. Must be prescribed by a neurologist or neuromuscular specialist 2. Must be 18 years of age or older 3. Must have a diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) confirmed by electromyography OR calcium channel antibody testing 4. Based on comparable indications, efficacy, safety profiles and equivalent formulation and strength Ruzurgi will be the required amifampridine product unless there is adequate justification by the prescriber as to why Rizurgi is not clinically appropriate 5. Quantity limit 250 tablets per 30 days

Gattex - teduglutide (Rx)
1. Must be used for the treatment of Short Bowel Syndrome 2. Patient must be dependent on parenteral support. 3. There must be no history of malignancy within the last 5 years. 4. Initial approval of GATTEX will be for six months. Further approval for another 6 months will require evidence of at least a 20% reduction in baseline IV/PN volume by week 24. 5. Open ended coverage beyond 1 year of treatment will require maintenance of at least a 20% reduction in IV/PN volume and submission of colonoscopy results demonstrating no presence of intestinal malignancy. 6. Recommended daily dose is 0.05mg/kg 7. Quantity limit of 60 vials per 30 days
Giazo – balsalazide (Rx)
1. Must be male and 18 years of age or older 2. Must have a diagnosis of mildly to moderately active ulcerative colitis 3. Must have had trial of and failure/intolerance to generic balsalazide. 4. QL of 180 tablets/30 days
Gocovri – amantadine ER (Rx)
1. Must be prescribed by a neurologist 2. Must be prescribed for dyskinesia associated with a diagnosis of Parkinson's disease 3. Member must be currently receiving levodopa-based therapy 4. Must have had serious side effects or drug failure with generic amantadine at a total dose of at least 200 mg per day 5. QL of 60 capsules/30 days
Glycate and Glycopyrrolate 1.5 mg tablets (Rx)
1. Must have a diagnosis of peptic ulcer disease 2. Must have a previous trial and failure or intolerance to generic glycopyrrolate 1 mg AND 2 mg tablets in addition to two other generic medications used to treat peptic ulcer disease (including but not limited to: lansoprazole, omeprazole, pantoprazole, famotidine, and ranitidine). 3. Glycate and glycopyrrolate 1.5 mg tablets will not be covered for any other non-FDA approved indication, including sialorrhea (excessive drooling) and hyperhidrosis (excessive sweating) 4. QL of 150/30 days
Gralise - gabapentin ER tablet (Rx)
1. Must have a diagnosis of post herpetic neuralgia. 2. Must have documented trial and failure or intolerance to generic immediate-release oral gabapentin at a minimum dose of 1800mg per day for PHN. 3. Gralise should be titrated to an 1800 mg dose taken orally, once-daily, with the evening meal. 4. Gralise will not be approved for any other non-FDA approved indications. 5. QL 90/30days.

Hetlioz - tasimelteon (Rx)

1. Will be approved for members diagnosed with 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
2. Diagnosis must be made by a sleep specialist
3. Based on the patient population used in clinical studies evaluating the efficacy of Hetlioz, Hetlioz will only be approved in patient's that are totally blind.
4. QL 30/30

Horizant - Gabapentin enacarbil ER tablet (Rx)

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

Impavido – miltefosine (Rx)

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

Inbrija – levodopa inhalation (Rx)

1. Must be prescribed by a neurologist
2. Must have a diagnosis of Parkinson's Disease with "wearing off symptoms"
3. Must be currently taking oral carbidopa/levodopa at a minimum dosage of 100 mg of carbidopa
4. Must have attempted increasing the dose and dosing frequency of oral carbidopa/levodopa
5. The Quantity Limit is 120 capsules for inhalation per 30 days. Based on the maximum recommended dosing, requests for up to 300 capsules per 30 days will be considered when clinically justified

Increlex - mecasermin, Recombinant, rh-IGF-1 (Rx)

1. Must be prescribed by an endocrinologist or pediatric endocrinologist
2. Patient must be 2 years old or greater
3. Patient must have severe primary IGF-1 deficiency (Primary IGFD) defined as:
   - height standard deviation score $\leq$ -3.0
   - basal IGF-1standard deviation score $\leq$ -3.0
   - normal or elevated GH **OR**
4. Patient must have growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH
5. Normal dose of 40-120mcg/kg SQ twice daily given 20 minutes before or after a meal or snack to avoid hypoglycemia. Doses greater than 120mcg/kg will not be covered
6. Increlex will not be covered for growth promotion in patients with closed epiphyses or as a substitute for growth hormone replacement therapy.

Ingrezza - valbenazine (Rx)

1. Must have a diagnosis of tardive dyskinesia defined as a history of ≥ 6 months (or ≥ 1 month in patients over 60 years of age) total cumulative neuroleptic exposure (continuous or discontinuous), presence of at least "moderate" abnormal involuntary movements in one or more body areas or at least "mild" movements in two or more body areas, and absence of other conditions that might produce abnormal involuntary movements.
2. Will only be authorized for adults age 18 and older.
3. Must be prescribed by a neurologist or psychiatrist.
4. Must have attempted an alternative method to manage the condition (such as dose reduction or discontinuation of the offending medication).
5. Initial approval will be for 6 months. Continued approval will require documentation that the individual has had an improvement in their symptoms.

6. 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 tablets should be used thereafter.

7. Quantity limit of 30/30

Jornay PM - methylphenidate ER (Rx)

1. Member must be 6 years of age or older
2. Must have a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)
3. Must have had serious side effects or drug failure with TWO of the following formulary long-acting stimulants: amphetamine/dextroamphetamine ER, methylphenidate ER, dexmethylphenidate ER, Vyvanse
4. Prescriber must submit progress notes to document before-school functional impairment and/or difficulties performing a morning routine

Jublia – efinaconazole solution (Rx)

1. Must be prescribed by a podiatrist or dermatologist
2. Must have a diagnosis of onychomycosis of the toenail with pain that impairs activities of daily living
3. Must have a positive KOH stain or positive culture (on Sabouraud's medium or dermatophyte test medium (DTM))
4. Must have had failure or intolerance to oral terbinafine or a contraindication to oral therapy.
5. Jublia will be covered for a maximum duration of 48 weeks of therapy.
6. QL 4ml / 30 days

Juxtapid - lomitapide (Rx)

1. Must be ≥18 years of age with a diagnosis of homozygous familial hypercholesteremia AND
    a. Moleuclar genetic testing must demonstrate evidence of a LDL-R mutation, familial defective apo B_{100}, or a PCSK9 mutation in both LDL-R alleles **OR**
    b. Must have history of an untreated LDL-C concentration >500mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents **OR**
    c. Must have untreated total cholesterol >500mg/dL AND triglycerides <300mg/dL AND both parents with documented untreated total cholesterol >250mg/dL **AND**
2. Must have an LDL level of at least 130mg/dL despite previous concurrent use of:
    a. Highest available dose of high-intensity statin therapy (atorvastatin 80mg/day or Crestor 40mg/day) concurrently with Zetia OR
    b. Highest available dose of high-intensity statin therapy (atorvastatin 80mg/day or Crestor 40mg/day) with apheresis AND

1) Must have had trial and failure/intolerance to a PCSK9 inhibitor (i.e Praluent, Repatha) AND

2) Must currently be a non-smoker documented by a negative cotinine urine test.
   a) If a member is using nicotine replacement products but is no longer smoking, then urine anabasine measurements should also be ordered and must be negative.
3) Must be prescribed by a lipid specialist (as identified by the American Board of Clinical Lipidology) Initial approval will be for 8 weeks. Further approval will require evidence of at least a 30% reduction in baseline LDL level. Recertification will be required yearly thereafter.
4) Will not be approved in combination with Kynamro, Praluent, or Repatha due to lack of clinical evidence demonstrating efficacy for this combination.
5) QL of 30/30 for 5mg and 10mg and 90/30 for 20mg pills.
6) Not to be approved in patients with, AST/ALT >2 times ULN or patients with previous organ transplant
11. Not to be approved in patients with documented diagnosis of any of the following hepatic disorders: biopsy proven cirrhosis, non-alcoholic steatohepatitis, alcoholic liver disease, autoimmune hepatitis, primary biliary cirrhosis, primary sclerosing cholangitis, Wilson's disease, hemochromatosis, or alpha1-anti-trypsin deficiency
12. Not to be approved in patients concurrently using corticosteroids or betaine
13. Female patients of child-bearing potential must have a negative pregnancy test

Jynarque – tolvaptan (Rx)

1. Must be prescribed by a nephrologist
2. Must be age 18 or older
3. Must have a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD)
   a. Must have rapidly progressing ADPKD as defined by one of the following:
      i. A confirmed GFR decline of at least 5 mL/min/1.73 m2 per year over 1 year and/or 2.5 mL/min/1.73 m2 per year over a period of 5 years **OR**
      ii. A total kidney volume increase of at least 5% per year confirmed by at least 3 repeated ultrasound or MRI measurements taken at least 6 months apart
4. Will not be covered for patients with GFR < 15 ml/min/1.73 m2 or those receiving dialysis

Kalydeco - ivacaftor (Rx)

1. Individual must have a diagnosis of Cystic fibrosis **AND**
2. Must have a A1067T, A455E, D110E, D110H, D1152H, D1270N, D579G, E193K, E56K, F1074L, F1052V , G1069R, G1244E, G1349D, G178R, G551D, G551S, K1060T, R117C, R117H, L206W, P67L, R1070Q, R1070W, R74W, R347H, R352Q, S549N, S549R, S945L, S977F, S1251N, S1255P, 2789+5G→A, 3272-26A→G, 3849+10kbC→T, 711+3A→G, or E831X mutation in the CFTR gene as demonstrated by a FDA-cleared CF mutation test **AND**
3. Must be at least 12 months of age
4. Coverage will be excluded in patients with CF who are homozygous for the F508 del mutation in the CFTR gene
5. Liver enzymes should be assessed prior to initiation of Kalydeco, every 3 months during the first year of treatment, and annually thereafter.
6. For adults and pediatric patients age 6 years and older, quantity limit is 60 **tablets** per 30 day supply.
7. Oral **granule packets** are only approved for children between 2 and 6 years old with a quantity limit of 60 packets per 30 day supply for a maximum of 150mg/day. Patients who require higher doses must use oral tablets

Katerzia - amlodipine oral suspension (Rx)
1. Coverage will be allowed for children 6 or 7 years old 2. Children age 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 age 6 or 7 years old will be until the child turns 8. Approval for children age 8-17 years old will be until the child turns 18. 5. Quantity limit of 300 mL per 30 days
Kerydin - tavaborole (Rx)
1. Must be prescribed by a podiatrist or dermatologist **AND** 2. Must have a diagnosis of onychomycosis of the toenail with pain that impairs activities of daily living **AND** 3. Must have a positive KOH stain or positive culture (on Sabouraud's medium or dermatophyte test medium (DTM)) **AND** 4. Must have had failure or intolerance to oral terbinafine or a contraindication to oral therapy. 5. Kerydin will be covered for a maximum duration of 48 weeks of therapy. 6. QL 10ml / 30 days
Keveyis – dichlorphenamide (Rx)
1. Diagnosis must be made by a neurologist or muscle disease specialist. 2. Member must have a diagnosis of primary **hypo**kalemic periodic paralysis **AND** a. The diagnosis must be confirmed by BOTH of the following: i. A genetic test confirming a skeletal muscle calcium or sodium channel mutation **AND** ii. Serum potassium concentration of less than 3.5 mEq/L during a paralytic attack b. Must have had trial and failure with prescription potassium supplementation **AND** c. The patient must have had a trial with oral acetazolamide therapy that did not result in improvement in severity or frequency of attacks **OR** 3. Member must have a diagnosis of primary **hyper**kalemic periodic paralysis **AND** a. The diagnosis must be confirmed by BOTH of the following: i. A genetic test confirming a skeletal muscle sodium channel mutation **AND** ii. Serum potassium concentration of greater than 5.0 mEq/L during a paralytic attack **AND** b. The patient must have had a trial with oral acetazolamide therapy that did not result in improvement in severity or frequency of attacks 4. For hypokalemic or hyperkalemic periodic paralysis, initial approval will be for 2 months. Recertification will require a documented improvement in the frequency or severity of attacks while taking Keveyis. Recertification will be approved for 1 year. 5. Initial dosing is one 50 mg tablet twice daily. Keveyis can be titrated up to a maximum of 200mg daily. 6. Quantity limit of 120 tablets per 30 days

Korlym - mifepristone (Rx)

1. Member must have a diagnosis of endogenous Cushing's syndrome
2. Must also have a diagnosis of type 2 diabetes mellitus or glucose intolerance
3. Must have failed surgery or is not a candidate for surgery
4. Must be prescribed by an endocrinologist
5. Patients who meet the criteria for approval for treatment with Korlym will be approved for 12 months. Recertification will require patients to have stabilization/decrease in A1C or objective clinical response.
6. Women of child-bearing age must have a negative pregnancy test prior to the start of therapy and must not be nursing. Non-hormonal contraception must be used while on therapy.
7. Recommended initial dosing is 300mg once daily with a meal.
8. Increase in 300mg increments to a maximum of 1200mg once daily based on clinical response and tolerability. Do not exceed 20mg/kg per day.
9. Hypokalemia should be corrected prior to treatment and monitored for during treatment. Patients should also be closely monitored for signs and symptoms of adrenal insufficiency.
10. Korlym is contraindicated for use in patients that are pregnant, are receiving simvastatin or lovastatin and CYP 3A substrates with a narrow therapeutic range, receiving concurrent long-term corticosteroid use, or have a history of unexplained vaginal bleeding/endometrial changes.
11. Quantity limit of 120 tablets per 30 days.

Kynamro - mipomersen (Rx)

1. Approved for patients ≥12 years of age with a diagnosis of homozygous familial hypercholesteremia
    a. Moleuclar genetic testing must demonstrate evidence of a LDL-R mutation, familial defective apo B_{100}, or a PCSK9 mutation in both LDL-R alleles **OR**
    b. Must have history of an untreated LDL-C concentration >500mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents **OR**
    c. Must have untreated total cholesterol >500mg/dL AND triglycerides <300mg/dL AND both parents with documented untreated total cholesterol >250mg/dL **AND**
2. Must have an LDL level of at least 130mg/dL despite previous concurrent use of:
    a. Highest available dose of high-intensity statin therapy (atorvastatin 80mg/day or Crestor 40mg/day) concurrently with Zetia **OR**
    b. Highest available dose of high-intensity statin therapy (atorvastatin 80mg/day or Crestor 40mg/day) with apheresis **AND**
3. Must have had trial and failure/intolerance to a PCSK9 inhibitor (i.e. Praluent, Repatha) AND
4. Must currently be a non-smoker documented by a negative cotinine urine test.
    a. If a member is using nicotine replacement products but is no longer smoking, then urine anabasine measurements should also be ordered and must be negative.
5. Must be prescribed by a lipid specialist (as identified by the American Board of Clinical Lipidology)
6. Initial approval will be 8 weeks. Further approval will require evidence of at least a 25% reduction in baseline LDL level. Will require recertification yearly thereafter.
7. Will not be approved in combination with Juxtapid, Praluent or Repatha due to lack of clinical evidence demonstrating efficacy for this combination.
8. Quantity limit of 4 injections per month.
9. Not to be approved in patients with: history of significant hepatic disease, AST/ALT>1.5 ULN, NYHA class III or IV heart failure

Lamisil Oral Granules - terbinafine (Rx)

1. Patient must have had severe intolerance or therapeutic failure of at least one other oral antifungal medication.

Lorzone and generic chlorzoxazone 375 mg and 750 mg (Rx)
1. Patient must have had a trial of generic chlorzoxazone 500mg **AND** 2. Patient must have had severe intolerance or therapeutic failure of at least two other muscle relaxants in addition to chlorzoxazone (such as cyclobenzaprine, baclofen, tizanidine, methocarbamol, orphenadrine) 3. Quantity limit of 120/30 or 136/34 DS
Lyrica CR – pregabalin ER (Rx)
1. Must have a diagnosis of Postherpetic Neuralgia (PHN) or Diabetic Peripheral Neuropathy (DPN) 2. Must have had serious side effects or drug failure with duloxetine or gabapentin **AND** 3. Must have had serious side effects or drug failure with immediate release Lyrica 4. Lyrica CR will not be covered for any other non-FDA approved indications
Mavenclad - cladribine (Rx)
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 a) For a diagnosis of relapsing MS, the member must have had serious side effects or drug failure with two of the following: Avonex, Copaxone, Gilenya, Mayzent, Rebif, Tecfidera or Plegridy 3. Approval will be for 1 year. Recertification for the second treatment course will require documentation supporting disease response to Mavenclad 4. Mavenclad will not be approved for use beyond 2 years as the FDA states treatment beyond 2 years may further increase the risk of malignancy 5. Quantity Limit: 10 tablets per 28 days. Maximum 2 fills per 334 days.
Moxatag - amoxicillin trihydrate ER (Rx)
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
Mulpleta – lusutrombopag (Rx)
1. Must be prescribed by a hepatologist, gastroenterologist, or hematologist 2. Member must be at least 18 years old 3. Must have a diagnosis of thrombocytopenia defined as a platelet count of less than 50 x 10^9/L 4. Must also have a diagnosis of chronic liver disease and be scheduled to undergo a procedure 5. Patients should begin dosing 8-14 days prior to their procedure and undergo their procedure within 2-8 days after their last dose 6. Approval will be for 14 days

Myalept - metreleptin (Rx)
1. Diagnosis of either congenital or acquired generalized lipodystrophy AND at least one of the following co-morbidities: diabetes mellitus, hypertriglyceridemia, and/or increased fasting insulin 2. A1C > 7% despite adequate drug therapy (trial of combination diabetic drug therapy) OR triglycerides > 200 mg/dL despite adequate drug therapy (trial of a high dose statin and a fibrate agent). 3. Initial approval will be for 4 months. Initial recertification approval will require documentation of an improvement in A1C of at least 1 percentage point and/or an improvement in triglycerides of at least 20%. Subsequent approvals will require documentation of maintained triglyceride/ A1C improvement. 4. Treatment with metreleptin is contraindicated in patients with general obesity not associated with congenital leptin deficiency and will not be authorized 5. Treatment with metreleptin for HIV associated lipodystrophy will not be authorized
Mytesi - crofelemer (Rx)
1. Indicated for the symptomatic relief of NON-INFECTIOUS diarrhea (one or more watery bowel movements per day) in patients with HIV/AIDS on anti-retroviral therapy 2. Drug therapy will not be authorized for individuals who have a history of ulcerative colitis, Crohn's disease, celiac sprue, chronic pancreatitis, malabsorption, or any other GI disease associated with diarrhea. 3. Patients must have had ADEQUATE TRIAL and failure or intolerance to TWO of anti-diarrheal medications (loperamide, diphenoxylate, and bismuth subsalicylate) unless contraindication is present. 4. Recommended daily dose is 125mg twice daily with, or without food 5. Quantity limit of 60 tablets/30 days. 6. Recertification will be required after initial 16 week approval to assess for improvement in symptoms. If no improvement in frequency of water bowel movements is noted, further therapy will not be authorized.
Namzaric ER – donepezil/memantine (Rx)
1. Must have a diagnosis of moderate to severe Alzheimer's disease **AND** 2. Must have documented stabilization on *both* Memantine (IR or ER) *and* Donepezil for the **3** months immediately preceding the request. 3. Quantity limit of 30 capsules per 30 days
Natpara- parathyroid hormone (Rx)
1. Must be prescribed by an endocrinologist 2. Must be an adult patient with a diagnosis of hypoparathyroidism, defined as hypocalcemia (calcium concentration below the lower limit of normal) and documented parathyroid levels below the lower limit of normal range, both levels recorded on 2 separate occasions within the past 12 months 3. Must confirm that there is no evidence of Vitamin D deficiency. If 25 (OH) D levels are below lower limit of normal, treatment with Natpara will not be authorized until serum 24(OH) D level returns to normal 4. Must be experiencing symptoms of disease while currently receiving calcium and vitamin D supplementation which is causing intolerable side effects, and unable to achieve target serum calcium levels (8-9mg/dL) 5. Lab results with reference ranges must be submitted 6. The starting dose is 50 µg injected once daily in the thigh and then individualized to achieve albumin-corrected serum calcium between 8 to 9 mg/dL

Neupro – rotigotine patch (Rx)

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

Nexletol - bempedoic acid (Rx)

1. Must be prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist
2. Member must be 18 years of age or older
3. Must have one of the following diagnoses:
    a. **Clinical atherosclerotic cardiovascular disease (ASCVD)**
        i. Must have a history of acute coronary syndrome, myocardial infarction (MI), stable or unstable angina, coronary/other arterial revascularization, stroke, TIA, peripheral arterial disease or other documented atherosclerotic disease (such as coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, or carotid plaque with ≥ 50% stenosis) **OR**
    b. **Heterozygous Familial Hypercholesterolemia (HeFH)**
        i. Molecular genetic testing must demonstrate evidence of an LDL-R mutation, familial defective apo B_{100} **OR**
        ii. Diagnosis must be confirmed as "definite" according the World Health Organization Criteria (Dutch Lipid Network) OR Simon-Broome Register Diagnostic Criteria. Documentation of the criteria which confirms this diagnosis much be submitted.
4. **The patient has initiated all the following lifestyle modifications:**
    a. Must currently be a non-smoker (defined as someone who has not smoked in the past 6 months)
        i. Non-smoker is defined as someone who has not smoked in the past 6 months
    b. Patient must be initiated on a heart-healthy diet
    c. Patient must engage in physical activity (at their level of ability) for at least 30 minutes most days of the week
5. **Documentation of baseline LDL-C level must be provided -** measurement must occur within 60 days prior to treatment.
6. **The patient must have failed to reach target LDL-C while receiving treatment with high-intensity statin therapy (atorvastatin 80mg/day or rosuvastatin 40mg/day), or maximally tolerated statin therapy, in combination with ezetimibe (if not contraindicated) for at least 8 weeks:**
    a. LDL-C must be ≥ 70 mg/dL
    b. Patient must be compliant with their previous statin and ezetimibe therapy. Prescription drug claims from the last 6 months will be assessed for medication adherence. If pharmacy refill history is not available, a recent pharmacy profile will be requested. Progress notes documenting usage of sample medication may also be requested. A threshold of 80% PDC (Percent Days Covered) is typically defined as being compliant with drug therapy.
    c. If patient is unable to tolerate statin therapy, documentation in progress notes must include:
        i. A contraindication to statin therapy according to FDA labeling **OR**
        ii. History of statin-related rhabdomyolysis
            1. Must have symptoms consistent with rhabdomyolysis (i.e.; muscle pain, swelling, and weakness, dark urine) **AND**
            2. Must have Creatine kinase (CK) level ≥ 10 times the upper limit of normal (ULN), Myoglobinuria, or acute renal failure (increase in serum creatinine >0.5 mg/dL) AND
            3. Member was receiving a statin at the time of the event and symptoms resolved upon discontinuation of the statin **OR**

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

7. **If the patient can tolerate statins, Nexletol must be prescribed in combination with the maximum tolerated dose of a statin AND ezetimibe**
a. Simvastatin >20mg and pravastatin >40mg should be avoided with bempedoic acid due to increased risk of myopathy.
8. **Nexletol will not be approved in combination with a PCSK9 inhibitor as there no data showing safety and efficacy with this combination.**
9. **Approval Timeframes**
1. Approval will be for 12 weeks for initial requests and 12 months for recertification requests.
a. **Initial Recertification requires:**
i. Demonstrated adequate reduction in LDL cholesterol defined as:
1. ≥18% reduction in LDL after 4-8 weeks of Nexletol therapy as compared to baseline LDL level or reduction to LDL goal for patients with a diagnosis of ASCVD **OR**
2. An adequate reduction in LDL level after 4-8 weeks of Nexletol therapy as compared to baseline LDL level for patients with a diagnosis of HeFH **AND**
ii. Continued adherence to a high intensity statin at maximum tolerated dose, or maximally tolerated statin, AND ezetimibe **AND**
iii. Continued adherence to lifestyle modifications (non-smoker, diet, and exercise)
b. **Subsequent Recertifications require:**
i. Documentation that confirms the patient has maintained an adequate reduction in LDL cholesterol compared to baseline (The LDL level must have been measured within the past 12 months) **AND**
ii. Continued adherence to a high intensity statin at maximum tolerated dose, or maximally tolerated statin, AND ezetimibe **AND**
iii. Continued adherence to lifestyle modifications (non-smoker, diet, and exercise)

Nitromist and Gonitro - nitroglycerin (Rx)

1. Must have previous trial of sublingual Nitroglycerin tablets (Nitrostat).
2. The quantity limit for Nitromist is 1 bottle (8.5grams) per 30 days. The quantity limit for Gonitro powder is 36 packets per 30 days

Northera - droxidopa (Rx)
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 will not be approved for nonneurogenic causes of OH, which include hypovolemia, cardiac pump failure, venous pooling, and drugs. 4. QL 180 capsules/30 days
Nourianz - istradefylline (Rx)
1. Must be prescribed by a neurologist 2. Must have a diagnosis of Parkinson's Disease with "wearing off symptoms" 3. Must be currently taking a regimen of oral carbidopa/levodopa 4. Must have attempted increasing the dose and dosing frequency of oral carbidopa/levodopa 5. Must have had serious side effects or drug failure with one of the following: pramipexole, ropinirole, entacapone, tolcapone, selegeline, or rasagiline 6. Quantity limit of 30 tablets per 30 days
Nuedexta – dextromethorphan/quinidine (Rx)
1. Diagnosis of Pseudobulbar Affect (PBA) diagnosed by a neurologist, psychiatrist or geriatrician 2. Symptoms of involuntary and inappropriate outbursts of laughter and/or crying 3. Requests will be evaluated for drug drug interactions. 4. Quantity limit of 60 capsules per 30 days
Nuplazid – pimavanserin (Rx)
1. Member must have a diagnosis of Parkinson's disease psychosis (PDP) 2. Medication must be prescribed by a neurologist, psychiatrist or geriatrician 3. Nuplazid will not be approved for any other non-FDA approved indication, including dementia related psychosis. 4. Nuplazid is not recommended in patients with hepatic impairment or severe renal impairment (CrCL< 30ml/min) 5. Quantity limit is 30/30 for 10 mg and 34 mg tablets. Quantity limit is 60/30 for 17 mg tablets
Nuzyra – omadacycline (Rx)
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. Approval will be for 14 days

Ocaliva - obeticholic acid (Rx)

1. Must be prescribed by a gastroenterologist or hepatologist **AND**
2. Must be age 18 year or older **AND**
3. Must have a diagnosis of primary biliary cholangitis (PBC)
    a. Must have at least 2 of the following:
        i. Positive antimitochondrial antibodies (AMA)
        ii. History of increased ALP levels
        iii. Liver biopsy consistent with PBC **AND**
4. Must have had an inadequate response to ursodiol for a period of at least 12 months
    a. Inadequate response is defined as:
        i. ALP that is ≥ 1.67 times the upper limit of normal (ULN = 118 U/L for females and 124 U/L for males) **OR**
        ii. Total bilirubin level that is greater than 1-times ULN but less than 2 times ULN (ULN=1.1 mg/dL for females and 1.5mg/dL for males) **OR**
5. Must be unable to tolerate ursodiol:
    a. Can be used as monotherapy
6. For initial therapy, the patient's Child-Pugh score must be submitted for review.
    a. Patients with moderate to severe hepatic impairment (Child-Pugh B and C) must be initiated at a dose of 5 mg **weekly**. The dose can be increased to a maximum of 10 mg twice weekly if needed in these patients.
7. The initial approval will be for 6 months. Approval beyond 6 months will require documentation that the member has responded to therapy. Response to therapy is 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% **AND**
    c. Total bilirubin ≤ ULN (1.1 mg/dL for females and 1.5mg/dL for males) total bilirubin ≤ ULN (1.1 mg/dL for females and 1.5mg/dL for males)
8. QL 30 tablets/30 days

Ofev - nintedanib (Rx)

1. The member must be a non-smoker (defined as someone who has not smoked in the past month)
2. For a diagnosis of idiopathic pulmonary fibrosis (IPF):
    a. Must be prescribed by a pulmonologist
    b. The diagnosis of IPF must be based on the following criteria:
        i. Exclusion of other known causes of interstitial lung disease (ILD) (e.g., environmental exposures, connective tissue disease and drug toxicity).
        ii. The presence of a UIP (usual interstitial pneumonia) pattern on high-resolution computed tomography (HRCT) in patients not subjected to surgical lung biopsy.
        iii. Specific combinations of HRCT and surgical lung biopsy pattern in patients subjected to surgical lung biopsy
3. For a diagnosis of systemic sclerosis with declining pulmonary function:
    a. Must be prescribed by a pulmonologist or a rheumatologist
    b. Must have fibrosis affecting at least 10% of the lung based on a HRCT scan from within the last 12 months
    c. Must have been treated with azathioprine, mycophenolate mofetil (MMF), or prednisone
4. For a diagnosis of chronic fibrosing interstitial lung disease with a progressive disease phenotype
    a. Must be prescribed by a pulmonologist
    b. Must have had a HRCT scan showing fibrosing lung disease with a disease extent of at least 10% within the last 12 months
    c. Must have been treated with azathioprine, mycophenolate mofetil (MMF), prednisone, n-acetylcysteine (NAC), rituximab, cyclophosphamide, cyclosporine, or tacrolimus and have had one of the following while on this treatment:
        i) A decline in forced vital capacity (FVC) predicted of at least 10%
        ii) A decline in forced vital capacity (FVC) predicted of at least 5% with worsening respiratory symptoms
        iii) A decline in forced vital capacity (FVC) predicted of at least 5% with increasing extent of fibrotic changes shown on chest imaging
        iv) Worsening of respiratory symptoms as well as increasing extent of fibrotic changes shown on chest imaging
5. Ofev will not be authorized in combination with Esbriet
6. Quantity limit 60/30

Onexton, Acanya and generic BPO/clindamycin combination gel (Rx)

1. Diagnosis of moderate to severe acne
2. Prescribed by a dermatologist
3. Failure or intolerance of generic benzoyl peroxide/clindamycin gel (generic for Benzaclin) and a generic topical retinoid for a minimum of 3 months of therapy documented by progress notes or pharmacy fill history.

Onmel - itraconazole tablet (Rx)

1. Must be prescribed by a Podiatrist or Dermatologist
2. Must have a diagnosis of onychomycosis with pain that impairs activities of daily living.
3. Must have a positive KOH stain or positive culture (on Sabouraud's medium or dermatophyte test medium (DTM))
4. Must have had failure or intolerance to itraconazole and terbinafine.
5. QL of 84 tablets/365 days.

Oravig - miconazole buccal tablet (Rx)
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. QL 14 tablets/ 30 days.
Orilissa – elagolix tablets (Rx)
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 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. 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 c. Neither of the above coexisting conditions: 150 mg once daily for a MAXIMUM of 24 months 8. 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 improvement (meaningful reductions in dysmenorrhea pain and non-menstrual pelvic pain). 9. 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. 10. Quantity Limits: 200 mg tablets: 56/28 150 mg tablets – 28/28
Orkambi- lumacaftor/ivacaftor (Rx)
1. Individual must have a diagnosis of Cystic Fibrosis **AND** 2. Must be 2 years or older **AND** 3. Must have 2 copies of the F508del mutation in the CFTR gene, as demonstrated by an FDA-cleared CF mutation test **AND** 4. Quantity Limit of 120 tablets per 30 days

Osmolex – amantadine ER (Rx)
1. Must be prescribed by a neurologist 2. Must be prescribed for either: a. Parkinson's disease **OR** b. Drug-induced extrapyramidal reactions **AND** 3. Must have had serious side effects or drug failure with generic amantadine

Otrexup - methotrexate injection (Rx)
1. Member must have a diagnosis of severe, active rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), or severe, recalcitrant, disabling psoriasis **AND** 2. Member must have an inability to self-inject generic methotrexate **AND** 3. Must have documented intolerance or failure to oral methotrexate

Oxervate – cenegermin-bkbj ophthalmic solution (Rx)
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

Oxtellar XR - oxcarbazepine ER tablet (Rx)
1. Member must be 6 years of age or older **AND** 2. Oxtellar must be used for the treatment of seizures **AND** 3. Patient must have had trial and failure/intolerance to generic oxcarbazepine AND one other generic anti-epileptic (including but not limited to: gabapentin, carbamazepine, lamotrigine, phenytoin, topiramate, divalproex, valproic acid, levetiracetam, and felbamate 4. Oxtellar will not be approved for any other non-FDA approved indications. 5. Recommended daily dose is 1,200mg to 2,400mg/day. Adults should initiate with a dose of 600mg/day and increase at weekly intervals at 600mg/day increments to achieve the recommended daily dose. 6. Children between 6-17 years of age should titrate to target dose over 2-3 weeks. Initiate with 8mg/kg-10mg/kg once per day and increase in weekly increments of 8-10mg/kg, not to exceed 600mg.

Ozobax – baclofen oral solution (Rx)
1. Member must be 12 years of age or older 2. Must have documentation of a swallowing disorder which prevents the use of all oral pills (a speech and swallow evaluation is required)

Procysbi - cysteamine capsules and packets (Rx)

1. Drug must be prescribed a nephrologist or genetic specialist. AND
2. Patient must have a diagnosis of nephropathic cystinosis AND
3. Procysbi will not be approved for patients with hypersensitivity to penicillamine AND
4. Member must have had documented intolerability to Cystagon (immediate-release cysteamine). Intolerability is defined as severe nausea, vomiting, anorexia, fever or lethargy that interferes with activity of daily living.
5. Based on comparable efficacy between the medications, Procysbi will not be authorized for those who fail to adhere to the standard Cystagon dosing regimen. The underlying cause of the non-adherence should be addressed and resolved.
6. Recommended maintenance dose is 1.3 gram/m^2/day in 2 divided doses, every 12 hours, recommended initial dosing in cysteamine-naïve patients is 1/6-1/4 of the maintenance dose of Procysbi.
7. Procysbi should be taken at least 2 hours after and at least 30 minutes before eating.
8. QL of 180/30 days for the 75mg capsules and 60/30 for the 25mg capsules.

Promacta - eltrombopag (Rx)

1. Member must have a diagnosis of chronic (lasting at least 3 months) idiopathic thrombocytopenia purpura (ITP) **AND**
2. Must have current a platelet count less than 30 x 10^9/L
3. Must have had an insufficient response (defined as a platelet count of less than 20 x 10^9/L or greater with bleeding symptoms) to the following treatments:
    a. Corticosteroids **AND**
    b. Immunoglobulins (IVIG) or splenectomy **OR**
4. A diagnosis of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy **OR**
5. A diagnosis of severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy (antithymocyte globulin (ATG) alone or in combination with cyclosporine and/or a corticosteroid)
    a. Diagnosis of severe aplastic anemia must be documented by:
        i. A marrow biopsy showing <25 percent of normal cellularity **OR**
4. A marrow biopsy showing <50 percent normally cellularity in which <30 percent of the cells are hematopoietic and at least two of the following are present: absolute reticulocyte count <40,000/microL, absolute neutrophil count (ANC) <500/microL, or platelet count <20,000/microL.
5. Promacta will not be authorized in combination with direct acting antiviral agents (such as Victrelis) approved for the treatment of chronic Hep C genotype 1 infection. Safety and efficacy have not been established.
6. Promacta should not be used to normalize platelet counts
7. Promacta must be prescribed by a hematologist
8. The starting dose of Promacta for chronic ITP and severe aplastic anemia is 50mg once daily for most patients, for patients of East Asian ancestry or patients with moderate or severe hepatic insufficiency, the starting dose is 25mg once daily. Adjust the daily dose to achieve and maintain a platelet count of greater than or equal to 50 x 10^9/L in order to reduce the risk of bleeding. Do not exceed 75mg/day for ITP or 150mg/day for severe aplastic anemia.
9. Quantity limit of 30/30

Qbrelis – Lisinopril solution 1mg/ml (Rx)
1. Qbrelis will be allowed for children 7 years of age and under. 2. Children age 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 age 7 years old and under will be until the child turns 8. Approval for children age 8-17 years old will be until the child turns 18. 5. QL 1200mL/30 days
Qualaquin - quinine capsule (Rx)
1. Must have a diagnosis of Malaria
Qudexy XR - topiramate ER capsule (Rx)
1. Member must have a diagnosis of seizure disorder **AND** 2. Must have had previous trial and failure or intolerance to generic topiramate and one other generic anti-epileptic (including but not limited to: gabapentin, lamotrigine, phenytoin, carbemazepine, divaloproex, valproic acid, levetiracetam, and felbamate) **OR** 3. Must be used for prophylaxis of migraine headaches **AND** a. Must have had serious side effects or drug failure with generic immediate-release topiramate b. Must have had serious side effects or drug failure with two other medications used to prevent migraines (including, but not limited to tricyclic antidepressants, beta blockers, anticonvulsants, or Botox). 4. Qudexy XR will not be approved for any non-FDA approved indication 5. QL 30 capsules/30 days
Rasuvo – methotrexate injection (Rx)
1. Member must have a diagnosis of severe, active rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), or severe, recalcitrant, disabling psoriasis 2. Member must have an inability to self-inject generic methotrexate 3. Must also have documented intolerance or failure to oral methotrexate
Rayos - prednisone tablet, gastro-resistant (Rx)
1. Must have a trial of and failure/intolerance to prednisone AND methylprednisolone
Ruzurgi – amifampridine (Rx)
1. Must be prescribed by a neurologist or neuromuscular specialist 2. Must be 6 years of age or older 3. Must have a diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) confirmed by electromyography OR calcium channel antibody testing 4. Quantity limit 300 tablets per 30 days

Rytary- carbidopa/levodopa (Rx)
1. Must have a diagnosis of Parkinson's disease, post-encephalitic Parkinsonism, or Parkinsonism following carbon monoxide/manganese intoxication 2. Must have motor fluctuations despite carbidopa/levodopa with entacapone therapy 3. Quantity limit will vary by dosage strength: a. 23.75mg/95 mg: 150 capsules/30 days b. 36.25mg/145mg: 300 capsules/30 days c. 48.75mg/195 mg: 300 capsules/30 days d. 61.25 mg/245mg: 300 capsules/30 days
Sabril and generic vigabatrin (tablets and packets) (Rx)
1. Must be followed by a Neurologist 2. Must have a diagnosis of infantile spasms and be between 1 month and 2 years of age **OR** 3. Must have a diagnosis of refractory complex partial seizures and have tried at least 3 of the following: carbamazepine, sodium valproate, lamotrigine, or oxcarbazepine.
Seysara – sarecycline tablets (Rx)
1. Must have a diagnosis of moderate to severe acne that requires oral therapy 2. Must be prescribed by a dermatologist 3. Must have experienced serious side effects or drug failure with a topical retinoid (such as tretinoin, adapalene, tazarotene) AND generic minocycline AND generic doxycycline 4. Must be used in combination with topical therapy (benzoyl peroxide and/or retinoid) 5. Quantity Limit 30 per 30 days 6. Initial approval will be for 12 weeks Recertification criteria: To limit antibiotic resistance, patients should not use oral antibiotics chronically. The following criteria are based on guidelines set forth by the Global Alliance to Improve Outcomes in Acne and the American Academy of Dermatology. 1. Patients should continue the use of a topical therapy to maintain remission of new acne lesions when antibiotic therapy is discontinued. 2. Patient progress notes documenting a flare in symptoms will need to be submitted for review by the clinical staff. 3. If patients have a flare of inflammatory lesions after the initial 12 week course then they will be allowed to retreat as long as they have been using a topical maintenance therapy. Retinoids are the preferred maintenance agent or as an alternative, a combination of benzoyl peroxide and a topical antibiotic is acceptable. 4. Recertification will be approved for one year.

Signifor SC - pasireotide (Rx)

1. Must be prescribed by an endocrinologist **AND**
2. Must have a diagnosis of Cushing's disease and either not be a candidate for surgery or have had treatment failure with previous surgery.
3. Not a candidate for surgery is defined as either having a medical contraindication to surgery or having a tumor which is surgically unapproachable
4. Not for use in patients who had pituitary irradiation within the previous 10 years
5. Initial approval will be for 3 months. Continuation of therapy will not be allowed in patients who do not achieve at least a 50% reduction in mean urine free cortisol (mUFC) after 3 months
6. For individuals who achieve a 50% reduction in mUFC after 3 months, recertification will be required every 12 months to monitor for signs of continued efficacy
7. Usual dosage is 0.3 to 0.9mg SC twice a day
8. Quantity limit of 60 doses per 30 days

Sitavig - acyclovir buccal tablet (Rx)

1. Must have a diagnosis of herpes labialis AND
2. Must have had previous failure or intolerance to at least TWO of the following: acyclovir, famciclovir, and valacyclovir.
3. QL 2 tabs/30 days

Sivextro – tedizolid phosphate (Rx)

1. Infectious Disease specialists are exempt from Prior Authorization on tedizolid
2. 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.
3. 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*.
4. 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.
5. The quantity limit is #6 per 30 days and the authorization will be for a 6-day time period.
6. Tedizolid will only be approved for adults aged 18 and older.
7. Sivextro should not be used for a prophylactic indication as it is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. Coverage for prophylactic therapy is excluded.
8. Sivextro is a reversible inhibitor of monoamine oxidase (MAO) in vitro. The interaction with MAO inhibitors could not be evaluated in Phase 2 and 3 trials, as subjects taking such medications were excluded from the trials.

Solaraze and generic diclofenac 3% gel

1. Must have a diagnosis of actinic keratosis
2. Must have had a previous trial of imiquimod that resulted in serious side effects or drug failure
3. Diclofenac 3% will not be authorized for any other diagnosis including osteoarthritis and other acute pain conditions such as minor strains, sprains and contusions.
4. Approval will be for 90 days

Solodyn, Minolira, Ximino, and generic minocycline ER (Rx)

1. Diagnosis of moderate to severe acne
2. 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 30/30
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.

Soma 250mg (Rx) - carisoprodol 250mg

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

Somavert - pegvisomant (Rx)

1. Must have a diagnosis of acromegaly
2. Must be prescribed by endocrinologist
3. Must have had failure of surgery, radiation and medical therapies
4. IGF-1 levels and liver tests should be monitored and Somavert should be discontinued if LT's are greater than 3 times ULN

Sorilux and generic calcipotriene foam (Rx)
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 calcipotriene and a high potency topical steroid (such as augmented betamethasone, betamethasone, clobetasol, desoximetasone, diflorasone, fluocinonide, or halobetasol) 4. Quantity limit of 1 canister per 30 days
Sotylize - sotalol solution (Rx)
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
Spritam – levetiracetam rapidly disintegrating tablet (Rx)
3. Must have a diagnosis of a seizure disorder 4. Must have tried and experienced failure/intolerance to generic levetiracetam solution 5. Must have tried and experienced failure/intolerance to one other antiepileptic medication appropriate for the diagnosis 6. Member must have a swallowing disorder (a speech and swallow evaluation is required) 7. QL of 120/30 for the 750mg tablets and 60/30 for all other strength tablets.
Suprenza - phentermine disintegrating tablet (Rx)
1. Used as a short-term adjunct for weight reduction in obese patients 2. Member must be physically unable to swallow phentermine tablets or capsules. 3. Quantity limit of 90/365 days.
Sunosi - solriamfetol (Rx)
1. Member must be 18 years of age or older 2. Must be prescribed by a neurologist, sleep specialist, or pulmonologist 3. Must have a diagnosis of excessive daytime sleepiness associated with either narcolepsy, obstructive sleep apnea (OSA)**,** or hypersomnolence of central origin. The diagnosis must be confirmed by a sleep study which must be submitted for review 4. For a diagnosis of OSA, the prescriber must attest that the patient's underlying airway obstruction has been treated with continuous positive airway pressure for at least one month prior to initiating Sunosi 5. Must have had serious side effects or drug failure with modafinil or armodafinil or have a contraindication to these drugs 6. If the diagnosis is narcolepsy, must also have had serious side effects or drug failure with a stimulant medication indicated for narcolepsy (amphetamine, dextroamphetamine/amphetamine, dextroamphetamine ER, or methylphenidate) 7. Sunosi will not be covered for any other non-FDA approved conditions

Symdeko - Tezacaftor/Ivacaftor (Rx)
1. Member must have a diagnosis of Cystic Fibrosis 2. Must be 6 years or older 3. Must have 2 copies of the F508del mutation in the CFTR gene (homozygous), as demonstrated by a FDA-cleared CF mutation test **OR** 4. Must have at least one mutation in the CFTR gene that is responsive to Symdeko based on *in vitro* data and/or clinical evidence. a. Responsive mutations include: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3AG, E831X, S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5GA, 3272-26AG, 3849+10kbCT 5. Recommended dosage one tablet containing texacafter 100mg/ivacaftor 150mg in the morning and one tablet containing ivacaftor 150 mg in the evening, approximately 12 hours apart. Symdeko should be taking with fat-containing food. 6. Liver enzymes should be assessed prior to initiation of Symdeko, every 3 months during the first year of treatment, and annually thereafter. 7. QL 56 tablets per 28 days (Available in 56 count tablet cartons containing 4 weekly wallets, each with 7 tezacaftor/ivacaftor and 7 ivacaftor tablets).
Syndros – dronabinol oral solution (Rx)
1. Covered for a diagnosis of anorexia associated with weight loss in patients with AIDS **OR** 2. Covered for a diagnosis of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments 3. For either diagnosis the member must have an inability to swallow oral pills
Synera – lidocaine/tetracaine patch (Rx)
1. Must be used as local dermal analgesia on intact skin for superficial venous access or for superficial dermatological procedures 2. QL of 30 patches / 30 days
Syprine and generic trientine capsules (Rx)
1. Must have a diagnosis of Wilson's Disease 2. Must have had serious side effects or drug failure with penicillamine tablets (the generic for Depen) 3. Quantity limit of 240 per 30 days
Taclonex Scalp and generic calcipotriene/betamethasone suspension (Rx)
1. Must be prescribed by a Dermatologist **AND** 2. There must be documentation of severe intolerance or therapeutic failure of generic calcipotriene (solution, cream, ointment) in combination with a topical steroid 3. Initial approval will be limited to 8 weeks. Approval for future treatment courses will require documentation of improved symptoms after 8 weeks. 4. Quantity Limit of 60 grams per 30 days

Tavalisse – fostamatinib (Rx)
1. Must be prescribed by a hematologist 2. Member must be at least 18 years old 3. Must have a diagnosis of chronic (lasting at least 3 months) idiopathic thrombocytopenia purpura (ITP) **AND** 4. Must have a current platelet count less than 30 x 10^9/L **AND** 5. Must have had an insufficient response (defined as a platelet count of less than 20 x 10^9/L, or greater but with bleeding symptoms) to the following treatments: a. Corticosteroids **AND** b. Immunoglobulins (IVIG) or splenectomy 6. Tavalisse should not be used to normalize platelet counts 7. The starting dose of Tavalisse is 100 mg twice daily. After 4 weeks, the dose can be increased to 150 mg twice daily to achieve a platelet count of at least 50 x 10^9/L to reduce the risk of bleeding 8. Quantity Limit of 60 per 30 days
Testosterone Products (including Android, Methitest, Methyltestosterone, Natesto, Striant, testosterone gel, testosterone solution, and Xyosted) (Rx)
****These requirements only apply to Managed Medicaid members**** 1. Must have documentation of clinical signs/symptoms of testosterone deficiency from prior to starting testosterone replacement therapy, such as: decreased sex drive, loss of muscle mass, reduced beard growth, decreased testicular size, gynecomastia, erectile dysfunction, cognitive impairment and reduced bone mineral density AND 2. Must have documentation of at least 2 early morning total testosterone levels <300 ng/dL from prior to starting testosterone replacement therapy 3. Testosterone therapy will be authorized for a diagnosis of gender dysphoria without the above clinical criteria

Therapeutic Kits and Convenience Packs (Rx) – Includes, but not limited to:

ACTIVE-PAC/GABAPENTIN
ADV ALLERGY COLLECTION KIT
AGONEAZE
ANODYNE LPT
APRIZIO PAK
BESER KIT
CAPSFENAC PAK
CENTANY AT
CLINDACIN ETZ
CLINDACIN PAC
CLODAN
CNL8 NAIL
COMFORT PAC-IBUPROFEN
COMFORT PAC-MELOXICAM
COMFORT PAC-NAPROXEN
COMFORT PAC-TIZANIDINE
CYCLO/GABA10/300 PACK
CYCLOBENZAPRINE COMFORT PAC
CYPROHEPTADINE SYRUP DOSE CUP
DERMA SILKRX DICLOPAK
DERMA SILKRX SDS PAK
DERMACINRX CINLONE-I CPI
DERMACINRX CLORHEXACIN
DERMACINRX DPN PAK
DERMACINRX EMPRICAINE
DERMACINRX INFLAMMATRAL PAK
DERMACINRX LEXITRAL PHARMA PAK
DERMACINRX PHN PAK
DERMACINRX PRIZOPAK & SURGICAL PHARMAPAK
DERMACINRX SILA PAK
DERMACINRX SILAZONE
DERMACINRX THERAZOLE PAK
DERMACINRX TICANASE PAK
DERMACINRX ZRM PAK
DERMAWERX SDS
DERMAWERX SURGICAL PLUS PAK
DERMAZONE 0.1% KIT
DERMAZYL KIT
DEXABLISS
DEXAMETHASONE DOSE PACK
DEXPAK
DICLO GEL/XRYLIX SHEETS
DICLOFEX DC
DICLOPAK
DICLOTRAL PAK
DICLOZOR KIT
DICLOPR
DICLOSAICIN
DICLOVIX
DIMENTHO
DITHOL
DOLOTRANZ
DXEVO
DYNAMIC
DYNAMIC PLUS PAK
ELLZIA PAK
ESOMEP-EZS
FLEXIPAK
GABACAINE
HALONATE KIT & PAC
INFLAMMACIN
INFLAMMATION REDUCTION PACK
KETODAN
KRISTALOSE/GENERIC LACTULOSE PACKETS
LEVA SET
LEXIXRYL
LIDOPAC
LIDOPRIL & LIDOPRIL XR
LIDO-PRILO CAINE PACK
LIDOTRANS 5 PAK
LIDOXIB KIT
LIPROZONEPAK
LIVIXIL PAK
LMR PLUS
LOCORT 7 & 11 DAY THERAPY PAK
LOPROX KIT
LORVATUS PHARMAPAK
MEDOLOR PAK
MESALAMINE KIT
MORGIDOX 1X50MG KIT
MIGRANOW
MINOCIN KIT
NEURCAINE
NUCARACLINPAK
NUCARARXPAK
NUDERMRXPAK
NUDICLO SOLUTAB & TABPAK
NUDROXIPAK
NUTRIARX
NUVAKAAN
NYATA
OMECLAMOX-PAK
OMEGA-3/D-3 WELLNESS PACK
PAINGO KFT
PEDIADERM HC
PEDIZOLPAK
PRE ATTACHED LTA
PREVIDOLRX ANALGESIC PAK
PRILOLID
PRILO PATCH
QUINIXIL
QUINOSONE
READYSHARP BUPIVACAINE
READYSHARP DEXAMETHASONE
READYSHARP KETOROLAC
READYSHARP LIDOCAINE
READYSHARP METHYLPREDNISOLONE
RELADOR PAK & RELADOR PAK PLUS
ROSADAN (Cream)
ROSADAN (Gel)
ROWASA
RRB Pak
RRB PAK SANADERMRX SKIN REPAIR SOLUTION
SANADERMRX SKIN REPAIR
SILALITE PAK
SILAZONE PHARMAPAK
SILAZONE-II KIT
SOLUPAK
SURE RESULT DSS PREMIUM PACK
SURE RESULT O3D3 SYSTEM
SURE RESULT TAC PAK
SYNALAR TS
TAPERDEX
TICALAST
TICASPRAY
TOVET KIT
TOXICOLOGY SALIVA COLLECTION
TRI-SILA
TRIXYLITRAL
ULTRAVATE X CREAM & OINTMENT
VACUSTIM BLACK
VACUSTIM SILVER
VOPAC MDS
WHYTEDERM SURGIPAK & TDPAK
WHYTEDERM TRILASIL PAK
XELITRAL PACK
XENAFLAMM KIT
XRYLIDERM
XRYLIX
ZEYOCAINE
ZODEX

Therapeutic Kits and Convenience Packs (Continued)

1. The member must have documented intolerance or therapeutic failure to three (3) formulary alternatives used to treat the same diagnosis as requested for the therapeutic kit or convenience pack.
2. Must be used for a non-cosmetic purpose. A non-cosmetic indication is defined as a condition that causes physical impairment in a member's ability to perform activities of daily living.
3. If the kit includes an FDA approved drug which is currently available as an individual product, the member must have previously failed a trial with that exact product/manufacturer before the convenience kit will be covered.
4. For kits which include supplies, **including but not limited to finger cots, bandages, gauze, occlusive dressings, tape, OTC medications**, which are available over the counter, the member must have documentation the equivalent items available over the counter were not effective for treatment or resulted in severe intolerance when used according to manufacturer recommendations.
5. All criteria must be met and documented via progress notes. Requests that do not include progress notes which verify that all criteria have been met will not be approved.

Tolsura – itraconazole tablets (Rx)

1. Must have one of the following diagnoses:
   a) Histoplasmosis
   b) Pulmonary or Extrapulmonary Blastomycosis
   c) Pulmonary or Extrapulmonary Aspergillosis
2. Must have had serious side effects or drug failure with generic itraconazole 100 mg tablets for any of these three diagnoses
3. If the diagnosis is aspergillosis, must also have had serious side effects or drug failure with amphotericin B
4. Quantity Limit 120/30

Tretin-X 0.0375% and 0.075% - tretinoin (Rx)

1. Must be prescribed by a Dermatologist
2. Must have a diagnosis of acne vulgaris
3. Must have a minimum of a 4 week trial and failure or severe intolerance to tretinoin 0.025% and 0.05% if requesting Tretin-X 0.0375% **OR** a 4 week trial and failure or severe intolerance to tretinoin 0.05% and 0.1% if requesting Tretin-X 0.075% **AND**
4. Must have a trial and failure or severe intolerance to adapalene gel

Trianex and triamcinolone 0.05% ointment (the generic equivalent of Trianex) (Rx)

1. Must have a skin condition that effects at least 30% of the body surface area
2. Must have had drug failure with triamcinolone 0.025% ointment
3. Must have had serious side effects with triamcinolone 0.1% ointment
4. Quantity limit of 430 grams per 30 days

Trikafta – elexacaftor/ivacaftor/tezacaftor (Rx)

1. Member must have a diagnosis of Cystic Fibrosis
2. Must be 12 years of age or older
3. Must have at least one copy of the F508del mutation in the CFTR gene, as demonstrated by an FDA-cleared CF mutation test
4. Quantity Limit of 84 tablets per 28 days

Trokendi XR – topiramate ER capsule (Rx)
1. Member must have a diagnosis of seizure disorder **AND** a. Must have had previous trial and failure or intolerance to generic immediate-release topiramate and one other generic anti-epileptic (including but not limited to: gabapentin, lamotrigine, phenytoin, carbamazepine, divalproex, valproic acid, levetiracetam, and felbamate) **OR** 2. Must be used for prophylaxis of migraine headaches **AND** a. Must have had serious side effects or drug failure with generic immediate-release topiramate b. Must have had serious side effects or drug failure with two other medications used to prevent migraines (including, but not limited to tricyclic antidepressants, beta blockers, anticonvulsants, or Botox). 3. Trokendi XR will not be approved for any non-FDA approved indication 4. QL of 90/30 days
Uceris Foam - budesonide rectal foam (Rx)
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 3. Must have documentation of clinical failure or intolerance to both topical mesalamine (enema or suppository) and topical hydrocortisone (enema or suppository) 4. The recommended dosage is 1 metered dose administered twice daily for 2 weeks followed by 1 metered dose administered once daily for 4 weeks. 5. Quantity limit of 3 canisters per 30 days (maximum of 4 canisters for total treatment course). 6. 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.
Veltin, Ziana and generic clindamycin/tretinoin gel (Rx)
1. Patient must have had severe intolerance or therapeutic failure of clindamycin 1% gel and tretinoin gel used in combination as separate products

Vyleesi - bremelanotide injection (Rx)

1. Must be prescribed by a gynecologist or psychiatrist
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 of 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. 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.
5. Drug will be excluded on the Medicaid benefit
6. Quantity limit of 4 injections/30 days

Xatmep – methotrexate oral solution (Rx)

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 either methotrexate tablets or solution (administered either IM or orally).
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.
6. Per methotrexate prescribing information, for patients unable to swallow tablets, there are 2 alternative methods:
    a. Disperse oral tablets: Place tablet in a half glass of noncarbonated water; do not crush tablet. Stir until dispersed, and then have the patient drink the mixture immediately. To ensure that the entire dose is administered, rinse the inside of the container with another half glass of water and have the patient drink immediately.
    b. Methotrexate oral solution: Dilute methotrexate solution for injection with water immediately prior to oral administration (final concentration not specified)

Xenleta – lefamulin (Rx)
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
Wakix – pitolisant (Rx)
1. Member must be 18 years of age or older 2. Must be prescribed by a neurologist or sleep specialist 3. Must have a diagnosis narcolepsy with excessive daytime sleepiness. The diagnosis must be confirmed by a sleep study, which must be submitted for review 4. Member must have had serious side effects or drug failure with the following (a, b, AND c): a. Modafinil or armodafinil b. A stimulant medication indicated for narcolepsy (amphetamine, dextroamphetamine/amphetamine, dextroamphetamine ER, or methylphenidate) c. Sunosi (also requires prior authorization) 5. Wakix will only be approved for daytime sleepiness associated with narcolepsy and will not be approved to treat any other non-FDA approved conditions 6. Quantity limit of 60 tablets per 30 days
Xerese – acyclovir/hydrocortisone (Rx)
1. Member must have a diagnosis of recurrent herpes labialis 2. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic acyclovir and hydrocortisone creams the member will be required to use generic acyclovir and hydrocortisone creams unless there is adequate justification as to why these are not appropriate. 3. Will not be covered in children under 12 years old as there have been no safety/efficacy studies in this population
Xhance – fluticasone nasal spray (Rx)
1. Member must have a diagnosis of nasal polyps. All other diagnoses will be excluded from coverage 2. Must be 18 years of age or older 3. There must be documentation of serious side effects or drug failure with mometasone 4. Prior authorization applies to Managed Medicaid and Child Health Plus plans only 5. Quantity Limit of 32 ml/30 days
Xyrem - sodium oxybate (Rx)
1. Must have a diagnosis of cataplexy or excessive daytime sleepiness associated with narcolepsy a. Narcolepsy must be confirmed by a sleep study which must be provided 2. Member must be followed by a neurologist or sleep specialist 3. If the member is 18 years or older and the diagnosis is excessive daytime sleepiness associated with narcolepsy, must have had serious side effects or drug failure with the following (a, b, AND c): a. Modafinil or armodafinil b. A stimulant medication indicated for narcolepsy (amphetamine, dextroamphetamine/amphetamine, dextroamphetamine ER, or methylphenidate) c. Sunosi (also requires prior authorization)

Yosprala and aspirin-omeprazole (Rx)
1. Must be used for secondary prevention of cardiovascular or cerebrovascular events 2. Member must be at risk of developing aspirin-associated gastric ulcers as documented by one of the following: a. Age 55 years or older b. History of gastric ulcers 3. Based on comparable indications, efficacy, safety profiles, and equivalent strengths of generic omeprazole and aspirin (as separate pills), the member will be required to use generic omeprazole and aspirin (as separate pills) unless there is adequate justification as to why these are not appropriate.
Zelapar ODT – Selegiline Hydrochloride (L-Deprenyl) (Rx)
1. Must have clinically documented Parkinson's disease 2. Must be currently receiving treatment with levodopa/carbidopa 3. Must be exhibiting deterioration in quality of response to levodopa/carbidopa therapy 4. Must be unable to swallow traditional tablets. 5. Quantity limit of 60 tablets per 30 days.
Zelnorm – tegaserod (Rx)
1. Must have a diagnosis of IBS-C (irritable bowel syndrome with constipation) 2. Must be a woman between the ages of 18 and 64 3. Must have had serious side effects or drug failure with Linzess 4. Quantity Limit of 60/30
Zontivity – vorapaxar (Rx)
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

POLICY GUIDELINES:

1. Unless otherwise stated above within the individual drug criteria, approval time period will be for 2 years.
    - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e.; generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
2. Prior-authorization is contract dependent.
3. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
4. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
5. Prescription homeopathic medications including, but not limited to: Arnica Gel, Psorizide Forte, Sleep Medicine, Hylira Gel and Vertigoheel are only covered when they are FDA approved for safety and efficacy. Most prescription homeopathic medications have their sales regulated by the FDA, but are not FDA approved for safety and efficacy for any particular condition.
6. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to criteria being added to the policy.
7. Supportive documentation of previous drug use must be submitted for any criteria that require a trial of a preferred agent, if the preferred drug is not found in claims history.

8. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

UPDATES:

Date	Revision
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
8/18	Revised
7/18	Revised
6/18	Revised
5/18	Revised/P&T Approval
4/18	Revised
3/18	Revised/P&T Approval
2/18	Revised
1/18	Revised

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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Increlex –
1. Guevara-Aguirre J, et al, "A randomized, double blind, placebo-controlled trial on safety and efficacy of recombinant human insulin-like growth factor-1 in children with growth hormone receptor deficiency", Journal of Clinical Endocrinology & Metabolism, 1995;80:1393-8
2. Backeljauw PF, et al, "Therapy for 6.5-7.5years with recombinant insulin-like growth factor 1 in children with growth hormone insensitivity syndrome: A clinical research center study.", Journal of Clinical Endocrinology & Metabolism, 2001;86:1504-10

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

Solodyn –
1. Zaenglein et al. Expert Committee Recommendations for Acne Management. Pediatrics. Sept 2006. 118(3)

1188-99.
2. Leyden, J et al. Comparison of tazarotene and minocycline maintenance therapies in acne vulgaris: a multicenter, double-blind, randomized, parallel-group study. Archives of Dermatology. 2006 May;142(5):605-12.
3. James, WD. Acne (clinical practice). NEJM. 2005 April 7;352(12):1463-72.
4. Gollnick H, Cunliffe W, Berson D, Dreno B, Finlay A, Leyden JJ, Shalita AR, Thiboutot D. Management of acne: a report from a Global Alliance to Improve Outcomes in Acne. J Am Acad Dermatol. 2003 Jul;49(1 Suppl):S1-37.

Somavert –

1. Ezzat S. Pharmacological approach to the treatment of acromegaly. Neurosurgery Focus. 2004; 14(4):E3.