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.

POLICY GUIDELINES:
1. 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 Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
2. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to approved language being added to the policy.
3. Supportive documentation of previous drug use must be submitted for any criteria that requires trial of a preferred agent, if the preferred drug is not found in claims history.
4. 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.
CURRENT CRPA DRUGS:

<table>
<thead>
<tr>
<th>Drug Name – generic name (Rx benefit)</th>
<th>Authorization Criteria</th>
</tr>
</thead>
</table>
| **Absorica – isotretinoin capsules (Rx)** | 1) Diagnosis of severe recalcitrant nodular acne. **AND**  
2) Trial and failure or contraindication to at least **two** different generic isotretinoin products (such as Amnesteem, Claravis, Myorisan, Zenatane). **AND**  
3) Requests for 25 mg or 35 mg Absorica will require a trial of a higher strength (30 mg and 40 mg) generic isotretinoin product that was effective, but resulted in side effects. |

**Aciphex - rabeprazole sprinkles (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.  

**Acticlate and generic doxycycline hyclate tablets (Rx)**

1. Must have a diagnosis of severe acne that requires oral therapy **AND**  
2. Must be prescribed by a dermatologist **AND**  
3. Must have experienced failure or intolerance to at least one topical retinoid (tretinoin, adapalene, tazarotene) **AND**  
4. Must have experienced failure or intolerance to generic minocycline **AND**  
5. Must have an inability to swallow other forms of generic doxycycline (such as doxycycline monohydrate and doxycycline hyclate capsules) **AND**  
6. Must be used in combination with topical therapy (benzoyl peroxide and/or retinoid)  
7. QL 30/30  
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.
**Pharmacy Management Drug Policy**  
**Clinical Review Prior Authorizations CRPA Rx**

---

### 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 **AND**  
   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 **AND**  
   b) The diagnosis is confirmed through radiological evidence.

3. **Approved dosing for those with a body surface area greater than 0.5 m² is 50 mcg/m² (1 million units/m²) subcutaneously 3 times a week.**

4. Doses above 50 mcg/m² will not be authorized.

---

### Addyi – flibanserin (Rx)

1. **Must be prescribed by a gynecologist or psychiatrist **AND**

2. **Must be a premenopausal Woman **AND**

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)? **AND**

4. **Must not have a history of alcohol abuse or overuse **AND**

5. **Must not be on any concurrent strong or moderate CYP3A4 inhibitors **AND**

6. **Must not have hepatic impairment **AND**

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. **QL of 30 tablets/30 days**

---

### Adzenys XR – Amphetamine (Rx)

1. **Must have a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) **AND**

2. **Must have tried and experienced failure/intolerance to all of the following formulary long-acting stimulants:**  
   - amphetamine/dextroamphetamine ER, methylphenidate SR, methylphenidate LA, methylphenidate CD, methylphenidate ER, and Vyvanse **AND**

3. **Member must have a swallowing disorder (A speech and swallow evaluation is required).**

4. **Quantity limit of 30/30**
### Ampyra and generic dalfampridine (Rx)

1. Individual must have a diagnosis of Multiple Sclerosis **AND**
2. Drug must be prescribed by a neurologist **AND**
3. Individual must be able to walk, with or without a walking device. **AND**
4. Therapy will not be authorized if the individual is bed ridden or confined to a wheel chair. **AND**
5. Patient must not have a history of seizures (this is a contraindication) **AND**
6. Patient must have a CrCl greater than 50mL/min. Please note Ampyra is contraindicated in patients with moderate to severe renal impairment **AND**
7. Initial approval will be for one year. Continuation of therapy after this time will be allowed for individuals who demonstrate improvement (increased walking speed, reduced spasticity, etc) with the medication and continue to be able to walk.
8. Quantity limit of 60/30 days and 68/34 days

### Amrix, Fexmid and equivalent generic cyclobenzaprine 7.5mg (Rx)

1. Patient must have had severe intolerance or therapeutic failure of generic cyclobenzaprine 5 or 10mg three times a day **AND**
2. Patient must have had severe intolerance or therapeutic failure of two other muscle relaxants (such as carisoprodol, baclofen, tizanadine, methocarbamol, orphenadrine and Skelaxin) **AND**
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 **AND**
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, divalproex, valproic acid, levetiracetam, and felbamate) **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).
**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 AND
   a. Must be prescribed by a neurologist
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 had a previous trial of at least one medication that is potentially effective for the treatment of TD OR 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.
**Pharmacy Management Drug Policy**

**Clinical Review Prior Authorizations CRPA Rx**

### Benlysta SC - belimumab (Rx)

1. Member must have diagnosis of active SLE disease that is seropositive (ANA = 1:80 or greater and/or anti-dsDNA=30 IU/mL or higher)
   a. Due to lab variability in standards for positive values, consideration will be given if the reported lab results do not meet the values listed above but are reported as "positive" from that lab AND
2. Must be followed by a rheumatologist
3. Individuals are excluded if they are currently receiving treatment with any B cell targeted therapy or biologic (including Humira, infliximab, Rituxan, Enbrel, Cimzia, Ocrevus, Stelara, Kineret, Actemra, Simponi)
4. Approved dosing is 200 mg once weekly
5. Initial approval will be for 12 months. Documented response to Benlysta at 12 months must be provided in order for continuation of therapy

### Bonjesta and Diclegis – doxylamine/pyridoxine (Rx)

1. Must be used for pregnancy-induced nausea and vomiting.
2. Must have had trial and failure of conservative treatment such as an OTC antihistamine (doxylamine, diphenhydramine, meclizine), ondansetron, or pyridoxine.
3. Bonjesta quantity limit is 60/30. Diclegis quantity limit is 120/30. Approval will be granted for 120 days.

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

1. Must have a diagnosis of vasomotor symptoms associated with menopause AND
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. Member must have a diagnosis of a seizure disorder AND
2. Must be 4 years of age or older AND
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

### Carac and generic fluorouracil 0.5% cream (Rx)

1. Must have a diagnosis of actinic keratosis AND
2. Must be 18 years of age or older AND
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. 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. Patient 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 **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) **AND**
3. Quantity limit of 120/30

**Cosmetic drugs (Rx)**

Including, but not limited to Alphaquin, Avage, bimatoprost 0.03%, Eldoquin, finasteride 1mg, Latisse, lidocaine-tetracaine cream, Melpaque, Mirvaso, Nuquin, Plaglis, 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. Renova (and tretinoin emollient cream) – If being used for a diagnosis of acne or actinic keratosis, then trial and failure of Retin A (NON EMOLLIENT tretinoin) is required prior to authorization of the emollient formulation
5. 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. Cosmetic conditions will be excluded.

**Cotempa XR ODT - methylphenidate ER ODT (Rx)**

1. Must have a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) **AND**
2. Must have tried and experienced failure/intolerance to all of the following formulary long-acting stimulants:
   a) amphetamine/dextroamphetamine ER, methylphenidate SR, methylphenidate LA, methylphenidate CD, methylphenidate ER, and Vyvanse **AND**
3. Member must have a swallowing disorder (A speech and swallow evaluation is required).
4. Quantity limit of 30/30

**Cuprimine- penicillamine (Rx)**

1. Must be used for an FDA approved indication: Wilson's Disease, Rheumatoid Arthritis or Cystinuria.
2. Off-label use will be evaluated by the off-label use policy criteria
3. Based on comparable indications, efficacy, safety profiles and dosing Depen will be required in place of Cuprimine unless there is adequate justification by the prescriber as to why Depen Titratabs is not clinically appropriate.
4. Quantity limit of 240/30 days. A quantity limit exception (480/30 days) can be granted for a diagnosis of Cystinuria if the patient adhere to adequate fluid intake throughout the day and night.
<table>
<thead>
<tr>
<th><strong>Cuvposa – glycopyrrolate (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must have a neurological disorder associated with drooling (such as cerebral palsy, mental retardation)</td>
</tr>
<tr>
<td>2. Must be unable to swallow glycopyrrolate tablets</td>
</tr>
<tr>
<td>3. Quantity limit of 1350 ml / 30 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Cystaran - cysteamine Ophthalmic drops (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must be prescribed by an ophthalmologist <strong>AND</strong></td>
</tr>
<tr>
<td>2. Member must have a diagnosis of corneal cysteine crystal accumulation due to cystinosis <strong>AND</strong></td>
</tr>
<tr>
<td>3. Recommended dosage is one drop of cysteamine ophthalmic solution in each eye, every waking hour.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>5. <strong>QL 4 bottles/28 days.</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Desoxyn and generic methamphetamine (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Methamphetamine is indicated for ADHD in children age 6 and older. It is also indicated for adults and children over age 12 with obesity. Based on the risk of dependence/abuse potential and the numerous alternatives available for both of these indications, methamphetamine is considered not medically appropriate for these FDA approved indications. <strong>All other off-label uses will also be considered not medically appropriate.</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Doptelet – avatrombopag (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must be prescribed by a hepatologist, gastroenterologist, or hematologist <strong>AND</strong></td>
</tr>
<tr>
<td>2. Member must be at least 18 years old <strong>AND</strong></td>
</tr>
<tr>
<td>3. Must have a diagnosis of thrombocytopenia defined as a platelet count of less than 50 x 10^9/L <strong>AND</strong></td>
</tr>
<tr>
<td>4. Must also have a diagnosis of chronic liver disease and be scheduled to undergo a procedure <strong>AND</strong></td>
</tr>
<tr>
<td>5. Must be prescribed for the appropriate dose based on platelet count prior to the scheduled procedure:</td>
</tr>
<tr>
<td>a. 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</td>
</tr>
<tr>
<td>b. 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</td>
</tr>
<tr>
<td>6. Patients should begin dosing 10-13 days prior to their procedure and undergo their procedure within 5-8 days after their last dose</td>
</tr>
<tr>
<td>7. Approval will be for 14 days</td>
</tr>
<tr>
<td>8. Doptelet is available in packs of 10 or 15 tablets</td>
</tr>
</tbody>
</table>
**Dupixent – dupilumab (Rx)**

1. Must be prescribed by or in consultation with an allergist, immunologist, or dermatologist **AND**
2. Must be ≥ 18 years of age **AND**
3. Must have a diagnosis of moderate to severe atopic dermatitis
   a. Must involve at least 10% body surface area **AND**
   b. Must have evidence of functional impact on everyday activities **AND**
4. In the past 6 months, must have had trial and failure or contraindication to:
   a. Medium to higher potency prescription topical corticosteroid therapy
      i. Adequate trial is defined as ≥ 28 days or for the maximum duration recommended by the product prescribing information (i.e 14 days for super-potent topical corticosteroids), whichever is shorter **AND**
   b. Tacrolimus ointment **AND**
   c. At least one of the following therapies:
      i. Oral cyclosporine, oral azathioprine, oral methotrexate, oral mycophenolate mofetil, or phototherapy (such as PUVA, UVA or UVB) administered in an office setting
5. QL of 8 ml for the first 28 days of therapy, then 4ml per 28 days thereafter

**Duzallo – Lesinurad/Allopurinol (Rx)**

1. Patient must have a diagnosis of gout **AND**
2. Must be receiving at least 300mg allopurinol daily (or 200mg for those with renal impairment) or 80mg febuxostat daily **AND**
3. Must have serum uric acid levels above 6.5mg/dl despite being on febuxostat or allopurinol alone **AND**
4. Patient must have had a trial and failure/intolerance to Probenecid unless patient has a sulfa allergy and/or other contraindication to Probenecid.
5. QL of 30 tablets/30 days.

**Dyanavel XR – amphetamine ER suspension (Rx)**

1. Must have a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) **AND**
2. Must have tried and experienced failure/intolerance to all of the following formulary long-acting stimulants:
   a) amphetamine/detroamphetamine ER, methylphenidate SR, methylphenidate LA, methylphenidate CD, methylphenidate ER, and Vyvanse **AND**
3. Member must have a swallowing disorder (A speech and swallow evaluation is required).
   QL of 240ml/30 days

**Dymista – azelastine/fluticasone combination spray (Rx)**

1. Must have documentation that member has been stable on the same doses of azelastine and fluticasone for the 3 months immediately preceding the request. **AND**
2. QL of 23 grams/30 days.
**Egrifta – tesamorelin inject (Rx)**

1. Individuals between 18-65 with a diagnosis of HIV-positive lipodystrophy **AND**
2. Currently receiving anti-retroviral therapy **AND**
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 **AND**
4. Current FBG <150 mg/dL
5. Individuals with the following will be excluded from coverage
   - BMI ≤20 kg/m²
   - Previously treated with insulin or with PO hypoglycemic or insulin-sensitizing agents
   - History of malignancy
   - Hypopituitarism
   - Pregnancy
6. Quantity limit of one 2mg SC injection per day (60ml/30 days)
7. Approvals will be for 6 months at a time.
   - Recertification following initial 6 months of therapy will require a minimum of 3cm reduction in waist circumference from baseline.
   - Further recertification will require maintenance of 3cm reduction of waist circumference.

**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
   - Cushingoid appearance (documentation required) OR
   - Central (truncal ) obesity (documentation required) OR
   - Undesirable weight gain defined as a ≥10% of body weight increase over a 6-month period (documentation required) OR
   - 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:
   - Hammersmith motor ability score (scored 0-40 ) OR
   - 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.
   - 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.
   - 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
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.

Endari – L-glutamine oral powder (Rx)

1. Member must be at least 5 years old **AND**
2. Must have a diagnosis of Sickle Cell Disease type hemoglobin SS or hemoglobin SB0 as determined by hemoglobin electrophoresis **AND**
3. Must be experiencing symptomatic pain that is a result of Sickle Cell Disease despite a minimum 6 month trial of hydroxyurea alone at the maximum tolerated dose that resulted in treatment failure **OR**
4. Must have experienced **two** hematologic toxicity reactions with hydroxyurea that resulted in discontinuation of therapy.
   a. Hematologic toxicity with hydroxyurea is defined by neutrophil, platelet, hemoglobin and/or reticulocyte count abnormalities concurrent with hydroxyurea use suggestive of hematologic toxicity. After the first hematologic toxicity, hydroxyurea therapy should be stopped and can be restarted with a dose reduction upon hematologic recovery. If a second hematologic toxicity is experienced, treatment should be discontinued.
5. Must have had serious side effects or drug failure with Nutrestore (L-glutamine oral powder, packaged as 5 gram powder packets)
6. Approval will be for one year. Recertification will require documentation of improvement in Sickle Cell Disease related pain and adherence to the approved regimen.
7. QL of 180/30

Enstilar – calcipotriene/betamethasone topical foam (Rx)

1. Must be prescribed by a Dermatologist **AND**
2. There must be documentation of a severe intolerance or therapeutic failure of generic calcipotriene (solution, cream, ointment) in combination with a topical steroid.
3. Initial approval will be limited to 4 weeks. Approval for future treatment courses will require documentation of improved symptoms after 4 weeks.
4. QL 120 grams/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 100 mg/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 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
2. The individual must be a non-smoker (defined as someone who has not smoked in the past month)
3. Esbriet will not be authorized in combination with Ofev
4. Quantity limit 270/30

### 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 **AND**
2. Must be prescribed by a dermatologist **AND**
3. Must have had previous trial and failure or intolerance to tretinoin and adapalene.
4. QL of 100 gm/ 30 days

### Gattex - teduglutide (Rx)
1. Must be used for the treatment of adult patients with Short Bowel Syndrome **AND**
2. Patient must be dependent on parenteral support. **AND**
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 **AND**
2. Must have a diagnosis of mildly to moderately active ulcerative colitis **AND**
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 **AND**
2. Must be prescribed for dyskinesia associated with a diagnosis of Parkinson’s disease **AND**
3. Member must be currently receiving levodopa-based therapy **AND**
4. Must have had serious side effects or drug failure with generic amantadine at a total dose of at least 200 mg per day **AND**
5. QL of 60 capsules/30 days

### Glycate and Glycopyrrolate 1.5 mg tablets (Rx)
1. Must have a diagnosis of peptic ulcer disease **AND**
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
<table>
<thead>
<tr>
<th><strong>Gralise - gabapentin ER tablet (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must have a diagnosis of post herpetic neuralgia. <strong>AND</strong></td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>3. Gralise should be titrated to an 1800 mg dose taken orally, once-daily, with the evening meal.</td>
</tr>
<tr>
<td>4. Gralise will not be approved for any other non-FDA approved indications.</td>
</tr>
<tr>
<td>5. QL 90/30 days.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Granix – fligrastim (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Zarxio (Filgrastim-sndz) is the biosimilar for the reference product for Granix. For a biological product to be labeled as a biosimilar, it must be shown that it is highly similar and has no differences from an existing FDA approved reference product (i.e. Granix) by extensively analyzing the structure, purity, chemical identity, and bioactivity. When comparing Granix and Zarxio, it has been concluded that there are no clinically meaningful differences demonstrated through human pharmacokinetic/exposure and pharmacodynamic/responses, and assessment of immunogenicity. Zarxio is the preferred formulation of filgrastim and does not require prior authorization</td>
</tr>
<tr>
<td>2. All requests for FDA approved indications must be initiated and continued with Zarxio (Filgrastim-sndz) unless there is adequate medical justification as to why Zarxio cannot be used. FDA approved indications include:</td>
</tr>
<tr>
<td>• Reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinical significant incidence of febrile neutropenia <strong>AND</strong></td>
</tr>
<tr>
<td>3. Requested dose cannot exceed the following: 5 mcg/kg/day</td>
</tr>
<tr>
<td>4. All non-FDA approved uses of Granix will be evaluated based on off-label policy criteria. If clinical criteria are met, then Zarxio will be the required product</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Hetlioz - tasimelteon (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Will be approved for members diagnosed with Non-24 Hour Sleep-Wake Disorder</td>
</tr>
<tr>
<td>a. Progress notes should be submitted demonstrating that the diagnosis was confirmed by:</td>
</tr>
<tr>
<td>i. The patient’s sleep log suggesting a circadian rhythm sleep disorder <strong>AND</strong></td>
</tr>
<tr>
<td>ii. The measurement of biomarkers (such as urinary melatonin and/or cortisol levels) to confirm a non-24-hour circadian period <strong>AND</strong></td>
</tr>
<tr>
<td>2. Diagnosis must be made by a sleep specialist <strong>AND</strong></td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>4. QL 30/30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Horizant - Gabapentin enacarbil ER tablet (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must be prescribed for a diagnosis of Restless Legs Syndrome (RLS) in adults</td>
</tr>
<tr>
<td>a. Must have had previous trial and severe intolerance/failure to either ropinirole or pramipexole AND generic gabapentin <strong>OR</strong></td>
</tr>
<tr>
<td>2. Must be prescribed for a diagnosis of Postherpetic Neuralgia (PHN) in adults</td>
</tr>
<tr>
<td>a. Must have had previous trial and severe intolerance/failure to generic gabapentin at a minimum dose of 1,800 mg per day.</td>
</tr>
<tr>
<td>3. All other non-FDA approved indications will be excluded</td>
</tr>
<tr>
<td>4. QL of 90/30 days for 300mg tablet and 60/30 days for 600mg tablet.</td>
</tr>
<tr>
<td>Impavido – miltefosine (Rx)</td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>1. Impavido must be prescribed by or recommended by an infectious disease specialist.</td>
</tr>
<tr>
<td>2. Patient must be at least 12 years of age and weight at least 30kg (66lbs).</td>
</tr>
<tr>
<td>3. Patient must have a diagnosis of visceral (due to <em>Leishmania donovani</em>), cutaneous (due to <em>Leishmania braziliensis</em>, <em>Leishmania guyanensis</em>, or <em>Leishmania panamensis</em>), or mucosal (<em>due to Leishmania braziliensis</em>) Leishmaniasis</td>
</tr>
<tr>
<td>4. Quantity limit of 84/28.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Increlex - Mecasermin, Recombinant, rh-IGF-1 (Rx)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must be prescribed by an endocrinologist or pediatric endocrinologist <strong>AND</strong></td>
</tr>
<tr>
<td>2. Patient must be 2 years old or greater <strong>AND</strong></td>
</tr>
<tr>
<td>3. Patient must have severe primary IGF-1 deficiency (Primary IGFD) defined as:</td>
</tr>
<tr>
<td>- height standard deviation score ≤ -3.0 <strong>AND</strong></td>
</tr>
<tr>
<td>- basal IGF-1 standard deviation score ≤ -3.0 <strong>AND</strong></td>
</tr>
<tr>
<td>- normal or elevated GH <strong>OR</strong></td>
</tr>
<tr>
<td>4. Patient must have growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH <strong>AND</strong></td>
</tr>
<tr>
<td>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. <strong>AND</strong></td>
</tr>
<tr>
<td>6. Increlex will not be covered for growth promotion in patients with closed epiphyses or as a substitute for growth hormone replacement therapy.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingrezza - valbenazine (Rx)</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>2. Will only be authorized for adults age 18 and older.</td>
</tr>
<tr>
<td>3. Must be prescribed by a neurologist or psychiatrist.</td>
</tr>
<tr>
<td>4. Must have had a previous trial of at least one medication that is potentially effective for the treatment of TD <strong>OR</strong> attempted an alternative method to manage the condition (such as dose reduction or discontinuation of the offending medication).</td>
</tr>
<tr>
<td>5. Initial approval will be for 6 months. Continued approval will require documentation that the individual has had an improvement in their symptoms.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>7. Quantity limit of 30/30</td>
</tr>
</tbody>
</table>
Jublia – efinaconazole solution (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. 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. Molecular genetic testing must demonstrate evidence of a LDL-R mutation, familial defective apo B100, 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
4. Must have had trial and failure/intolerance to a PCSK9 inhibitor (i.e Praluent, Repatha) AND trial and failure/intolerance to Kynamro AND
5. 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.
6. 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.
7. Will not be approved in combination with Kynamro, Praluent, or Repatha due to lack of clinical evidence demonstrating efficacy for this combination.
8. QL of 30/30 for 5mg and 10mg and 90/30 for 20mg pills.
9. Not to be approved in patients with, AST/ALT >2 times ULN or patients with previous organ transplant
10. 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 **AND**
2. Must be age 18 or older **AND**
3. Must have a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) **AND**
   - 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
5. **QL of 56/28**

### Kalydeco - ivacaftor (Rx)

1. Individual must have a diagnosis of Cystic fibrosis **AND**
3. Must be at least 2 years 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

### 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 **hypokalemic** 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 **AND**
   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 **hyperkalemic** 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 **OR**
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 **AND**
2. **Must also** have a diagnosis of type 2 diabetes mellitus or glucose intolerance **AND**
3. **Must have** failed surgery or is not a candidate for surgery **AND**
4. **Must be** prescribed by an endocrinologist **AND**
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 orlovastatin 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
   - Molecular genetic testing must demonstrate evidence of a LDL-R mutation, familial defective apo B100, or a PCSK9 mutation in both LDL-R alleles **OR**
   - 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**
   - 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:
   - Highest available dose of high-intensity statin therapy (atorvastatin 80mg/day or Crestor 40mg/day) concurrently with Zetia **OR**
   - 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.
   - 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 - chlorzoxazone (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) **AND**
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) **AND**
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 **AND**
4. Lyrica CR will not be covered for any other non-FDA approved indications

### Moxatag - amoxicillin trihydrate ER (Rx)

1. Prescribed by an infectious disease **OR**
2. Diagnosis of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes* in adults and children 12 years of age and older **AND**
3. Quantity limit of 10 tablets / 30 days
### Mulpleta – lusutrombopag (Rx)

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

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) (Formerly Fulyzaq)

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 **AND**
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 AND
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 AND
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 AND
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) AND
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

**Neupogen – filgrastim (Rx)**

1. Zarxio (Filgrastim-sndz) is the biosimilar for the reference product for Neupogen. For a biological product to be labeled as a biosimilar, it must be shown that it is highly similar and has no differences from an existing FDA approved reference product (i.e. Neupogen) by extensively analyzing the structure, purity, chemical identity, and bioactivity. When comparing Neupogen and Zarxio, it has been concluded that there are no clinically meaningful differences demonstrated through human pharmacokinetic/exposure and pharmacodynamic/responses, and assessment of immunogenicity. Zarxio is the preferred formulation of filgrastim and does not require prior authorization
2. All requests for FDA approved indications must be initiated and continued with Zarxio (Filgrastim-sndz) unless there is adequate medical justification as to why Zarxio cannot be used. FDA approved indications include:
   - Patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever (to reduce the incidence of infection)
   - Following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML) (to reduce the time to neutrophil recovery and the duration of fever)
   - Patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia)
   - To mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
   - To reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
   - To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)
     - The use of Zarxio will not be required in patients with Acute Radiation Syndrome
3. Requested dose cannot exceed the following:
   - Myelosuppressive chemotherapy: 5mcg/kg/day
   - AML: 5mcg/kg/day
Pharmacy Management Drug Policy  
Clinical Review Prior Authorizations CRPA Rx

- BMT: 10mcg/kg/day
- Peripheral blood progenitor cell collection: 10 mcg/kg/day
- Congenital Neutropenia: 12 mcg/kg/day (in rare instances, a higher dose may be needed)
- Idiopathic or Cyclic Neutropenia: 5mcg/kg/day
- Acute radiation Syndrome: 10 mcg/kg/day

4. All non-FDA approved indications of Neupogen will be evaluated based on off-label policy criteria. If clinical criteria are met, then Zarxio will be the required product
   - The use of Zarxio will not be required for the mobilization of donor hematopoietic progenitor cells in the allogeneic setting

Neupro – rotigotine patch (Rx)

1. Must have FDA-approved diagnosis of Parkinson disease or moderate to severe Restless legs syndrome AND
2. Intolerance or contraindication to both oral pramipexole AND ropinirole. This requirement is waived upon documentation of an inability to swallow. AND
3. Quantity limit of 1 patch per day.

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.

Nivestym – filgrastim-aafi (Rx)

1. Zarxio (Filgrastim-sndz) is the biosimilar for the reference product for Nivestym. For a biological product to be labeled as a biosimilar, it must be shown that it is highly similar and has no differences from an existing FDA approved reference product (i.e. Nivestym) by extensively analyzing the structure, purity, chemical identity, and bioactivity. When comparing Nivestym and Zarxio, it has been concluded that there are no clinically meaningful differences demonstrated through human pharmacokinetic/exposure and pharmacodynamic/responses, and assessment of immunogenicity. Zarxio is the preferred formulation of filgrastim and does not require prior authorization
2. All requests for FDA approved indications must be initiated and continued with Zarxio (Filgrastim-sndz) unless there is adequate medical justification as to why Zarxio cannot be used. FDA approved indications include:
   - To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.
   - For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML).
   - To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT).
   - For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
   - For chronic administration to reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.
3. Requested dose cannot exceed the following:
• Myelosuppressive chemotherapy: 5mcg/kg/day
• AML: 5mcg/kg/day
• BMT: 10mcg/kg/day
• Peripheral blood progenitor cell collection: 10 mcg/kg/day
• Congenital Neutropenia: 12 mcg/kg/day (in rare instances, a higher dose may be needed)
• Idiopathic or Cyclic Neutropenia: 5mcg/kg/day

4. All non-FDA approved indications of Nivestym will be evaluated based on off-label policy criteria. If clinical criteria are met, then Zarxio will be the required product. The use of Zarxio will not be required for the mobilization of donor hematopoietic progenitor cells in the allogeneic setting.

Northera - droxidopa (Rx)
1. Must be prescribed for a diagnosis of Neurogenic Orthostatic Hypotension (NOH) AND
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

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 60/30

Nuplazid – pimavanserin (Rx)
1. Member must have a diagnosis of Parkinson’s disease psychosis (PDP) AND
2. Medication must be prescribed by a neurologist, psychiatrist or geriatrician AND
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.
## 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. Ocaliva must be prescribed in combination with ursodiol AND
   b. 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. Open-ended 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)
8. QL 30 tablets/30 days

## Ofev - nintedanib (Rx)

1. 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
2. The individual must be a non-smoker (defined as someone who has not smoked in the past month)
3. Esbriet will not be authorized in combination with Ofev
4. Quantity limit 60/30
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Rx Status</th>
<th>Approval Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Onexton, Acanya and generic BPO/clindamycin combination gel (Rx)</strong></td>
<td></td>
<td>1. Diagnosis of moderate to severe acne AND  2. Prescribed by a dermatologist AND  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.</td>
</tr>
<tr>
<td><strong>Onmel - itraconazole tablet (Rx)</strong></td>
<td></td>
<td>1. Must be prescribed by a Podiatrist or Dermatologist AND  2. Must have a diagnosis of onychomycosis 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 itraconazole and terbinafine.  5. QL of 84 tablets/365 days.</td>
</tr>
<tr>
<td><strong>Oravig - miconazole buccal tablet (Rx)</strong></td>
<td></td>
<td>1. Must be ≥ 18 years of age AND  2. Must be used for the treatment of oropharyngeal candidiasis AND  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.</td>
</tr>
<tr>
<td><strong>Orilissa – elagolix tablets (Rx)</strong></td>
<td></td>
<td>1. Must be 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 a prescription strength nonsteroidal anti-inflammatory drug (NSAID) used in combination 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: 200 mg twice daily for a MAXIMUM of 6 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 will be for 18 months for patients without dyspareunia or 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). Recertification will not be approved for patients with dyspareunia or moderate hepatic impairment as 6 months is the total lifetime treatment duration in patients with these coexisting conditions.  9. Quantity Limits: 200 mg tablets: 56/28  150 mg tablets – 28/28</td>
</tr>
</tbody>
</table>
### 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 a FDA-cleared CF mutation test **AND**
4. Orkambi should be used with caution in patients with advanced liver disease and should be used only if the benefits are expected to outweigh the risks
5. Liver enzymes should be assessed prior to initiation of Orkambi, every 3 months during the first year of treatment, and annually thereafter
6. QL 120 tablets per 30 days

### Osmolex – amantadine ER (Rx)
1. Must be prescribed by a neurologist **AND**
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
4. QL of 30/30

### 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

### 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.
**Procysbi - Cysteamine Oral capsule, gastro-resistant (Rx)**

1. Drug must be prescribed by a nephrologist or genetic specialist. **AND**
2. Patient must have a diagnosis of nephropathic cystinosis **AND**
3. Patient must be age 2 years or older **AND**
4. Procysbi will not be approved for patients with hypersensitivity to penicillamine **AND**
5. 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.
6. 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.
7. Recommended maintenance dose is 1.3 gram/m²/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.
8. Procysbi should be taken at least 2 hours after and at least 30 minute before eating.
9. 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 (greater than 3-4 months) idiopathic thrombocytopenia purpura (ITP) who have had an insufficient response (defined as a platelet count of less than 20 x 10⁹/L or greater with bleeding symptoms) to the following treatments:
   a. Corticosteroids **AND**
   b. Immunoglobulins (IVIG) **AND**
   c. Rituximab (Rituxan) OR splenectomy **OR**
2. A diagnosis of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. **OR**
3. 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) **prom**
   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 has 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 10⁹/L in order to reduce the risk of bleeding. Do not exceed 75mg/day for ITP or 150mg/day for severe aplastic anemia.
9. The starting dose of Promacta for Chronic Hepatitis C associated thrombocytopenia is 25 mg once daily for all patients. Adjust to achieve a target platelet count required to initiate antiviral therapy. Do not exceed a daily dose of 100mg.
10. 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 (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 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 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, divalproex, valproic acid, levetiracetam, and felbamate) OR
3. Must be used for prophylaxis of migraine headaches in adult patients AND
   a. Must have a trial and failure to generic immediate-release topiramate
   b. Must have a trial and failure of two other preventative medications (including, but not limited to tricyclic antidepressants, beta blockers or other anticonvulsants).
4. Qudexy XR will not be approved for any non-FDA approved indication
5. QL 30 capsules/30 days

Quillichew ER – methylphenidate chewable (Rx)
1. Must have a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) AND
2. Must have tried and experienced failure/intolerance to all of the following formulary long-acting stimulants:
   a) amphetamine/detroamphetamine ER, methylphenidate SR, methylphenidate LA, methylphenidate CD, methylphenidate ER, and Vyvanse AND
3. Member must have a swallowing disorder (A speech and swallow evaluation is required).
4. QL of 30 tab/30 days for 20mg strength and 60 tab/30 days for 30mg strength

Quillivant - methylphenidate ER suspension (Rx)
1. Must have a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) AND
2. Must have tried and experienced failure/intolerance to all of the following formulary long-acting stimulants:
   a) amphetamine/detroamphetamine ER, methylphenidate SR, methylphenidate LA, methylphenidate CD, methylphenidate ER, and Vyvanse AND
3. Member must have a swallowing disorder (A speech and swallow evaluation is required)
4. QL of 360ml/ 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 AND
2. Member must have an inability to self-inject generic methotrexate AND
3. Must 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.

### Rytary - carbidopa/levodopa (Rx)
1. Must have a diagnosis of Parkinson’s disease, post-encephalitic Parkinsonism, or Parkinsonism following carbon monoxide/manganese intoxication AND
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 packets (Rx)
1. Must be followed by a Neurologist AND
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.
4. Quantity limit of 180/30 for the tablets.

### 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/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 microorganisms: *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 **AND**
2. Prescribed by a dermatologist **AND**
3. Failure or intolerance of at least one topical retinoid (tretinoin, adapalene or tazarotene) **AND**
4. Failure or intolerance to doxycycline **AND**
5. Development of vestibular side effects with a trial of generic immediate release minocycline
6. Quantity limit of 30/30
7. 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 **AND**
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, methocarbamol, orphenadrine and Skelaxin **AND**
3. Quantity limit of 120/30 or 136/34 DS

### Somavert - pegvisomant (Rx)

1. Diagnosis of acromegaly **AND**
2. Prescribed by endocrinologist **AND**
3. Failure of surgery, radiation and medical therapies **AND**
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 - calcipotriene foam (Rx)

1. Diagnosis of plaque psoriasis **AND**
2. Written by a dermatologist **AND**
3. Trial and failure to calcipotriene **AND**
4. Trial and failure to a high potency topical steroid amcinonide,(such as augmented betamethasone, betamethasone, clobetasol, desoximetasone, difloraasone, fluocinonide,or halobetasol)
5. Quantity limit of 1 canister per 30 days.
### Sotylize - sotalol solution (Rx)
1. Prescribed by a Cardiologist **AND**
2. Diagnosis of life-threatening ventricular arrhythmias or maintenance of normal sinus rhythm in patients with highly symptomatic atrial fibrillation/flutter **AND**
3. Documentation of a swallowing or absorptive disorder which results in an inability to use all oral dosage forms such as sotalol tablets. **AND**
4. Quantity limit of 1920 mL per 30 days

### Spritam – levetiracetam rapidly disintegrating tablet (Rx)
1. Must have a diagnosis of a seizure disorder **AND**
2. Must have tried and experienced failure/intolerance to generic levetiracetam solution **AND**
3. Must have tried and experienced failure/intolerance to one other antiepileptic medication appropriate for the diagnosis **AND**
4. Member must have a swallowing disorder (A speech and swallow evaluation is required). **AND**
5. 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 **AND**
2. Member must be physically unable to swallow phentermine tablets or capsules. **AND**
3. Quantity limit of 90 pills/365 days.

### Symdeko- Tezacaftor/Ivacaftor (Rx)
1. Individual must have a diagnosis of Cystic Fibrosis **AND**
2. Must be 12 years or older **AND**
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.
5. Coverage will be excluded for patients under the age of 12 years.
6. 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.
7. Liver enzymes should be assessed prior to initiation of Symdeko, every 3 months during the first year of treatment, and annually thereafter.
8. 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 **AND**
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 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. Off-label use will be evaluated by the off-label use policy criteria
3. Must have had a previous trial of Depen (penicillamine) with documented clinical failure or severe intolerance that resulted in cessation of therapy.
4. Quantity limit of 240/30 days.

### Taclonex Scalp – calcipotriene/betamethasone suspension (Rx)
1. Must be prescribed by a Dermatologist AND
2. There must be documentation of a 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. QL 60 grams/30 days

### Tavalisse – fostamatinib (Rx)
9. Must be prescribed by a hematologist
10. Member must be at least 18 years old
11. Member must have a diagnosis of chronic (greater than 3-4 months) idiopathic thrombocytopenia purpura (ITP) and 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) AND
   c. Rituximab OR splenectomy
12. 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.
13. QL 60/30
## Testosterone Products (including Androderm, Androgel, Androxy, Android, Axiron, First-Testosterone, Fortesta, Methitester, methyltestosterone, Natesto, Striant, Testim, Testosterone gel, Testred, Vogelxo) (Rx)

<table>
<thead>
<tr>
<th>1. For a male with a diagnosis of testosterone deficiency there must be:</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. clinical signs/symptoms of testosterone deficiency such as: decreased sex drive, loss of muscle mass, reduced beard growth, decreased testicular size, gynecomastia, unable to maintain erection; cognitive impairment or reduced BMD documented in patient progress notes <strong>AND</strong></td>
</tr>
<tr>
<td>b. documentation of at least 2 early morning serum testosterone levels &lt;300ng/dL within the past 12 months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. For males who are already receiving replacement therapy for testosterone deficiency, authorization will be granted if the following is documented:</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Diagnosis of testosterone deficiency prior to initiation of replacement therapy.</td>
</tr>
<tr>
<td>b. Documentation of normal serum testosterone levels (range between 400-700 ng/dL) on two separate occasions while receiving replacement therapy <strong>OR</strong></td>
</tr>
</tbody>
</table>

| 3. Testosterone therapy will be authorized for a diagnosis of gender dysphoria without the above clinical criteria. |

<table>
<thead>
<tr>
<th>4. In addition to the above, use of a preferred topical testosterone product will be required as first line therapy:</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. For Commercial and NYSOH Group and Individual Markets, Androgel OR Androderm will be required prior to approval of any other topical testosterone product (Axiron, Fortesta, Testim, Testosterone gel, Vogelxo)</td>
</tr>
<tr>
<td>b. For Managed Medicaid, a trial of BOTH generic testosterone topical gel and generic testosterone topical solution will be required prior to approval of any brand name topical testosterone product (Androderm, Fortesta, Androgel, Axiron, Testim, Vogelxo)</td>
</tr>
</tbody>
</table>
### Therapeutic Kits and Convenience Packs (Rx) – Includes, but not limited to:

<table>
<thead>
<tr>
<th>ACTIVE-PAC/GABAPENTIN</th>
<th>DICLOPR</th>
<th>PREVIDOLRX ANALGESIC PAK</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADV ALLERGY COLLECTION KIT</td>
<td>DITHOL</td>
<td>PRILOLID</td>
</tr>
<tr>
<td>AGONEAZE</td>
<td>DOLOTRANZ</td>
<td>READYSHARP BUPIVACAINE</td>
</tr>
<tr>
<td>ANODYNE LPT</td>
<td>DYNAMI C</td>
<td>READYSHARP DEXAMETHASONE</td>
</tr>
<tr>
<td>CENTANY AT</td>
<td>DYNAMI C PLUS PAK</td>
<td>READYSHARP KETOROLAC</td>
</tr>
<tr>
<td>CLINDACIN ETZ</td>
<td>ELLZIA PAK</td>
<td>READYSHARP LIDOCAINE</td>
</tr>
<tr>
<td>CLINDACIN PAC</td>
<td>ESOMEP-EZS</td>
<td>READYSHARP METHYLPRDNI SOLONE</td>
</tr>
<tr>
<td>CLODAN</td>
<td>FLEXI PAK</td>
<td>RELADOR PAK &amp; RELADOR PAK PLUS</td>
</tr>
<tr>
<td>CNL8 NAIL</td>
<td>HALONATE KIT &amp; PAC</td>
<td>ROSADAN (Cream)</td>
</tr>
<tr>
<td>COMFORT PAC-IBUPROFEN</td>
<td>INFLAMMATION REDUCTION PACK</td>
<td>ROSADAN (Gel)</td>
</tr>
<tr>
<td>COMFORT PAC-MELOXICAM</td>
<td>KRYSTALOSE/GENERIC LACTULOSE PACKETS</td>
<td>ROWASA</td>
</tr>
<tr>
<td>COMFORT PAC-NAPROXEN</td>
<td>LEVA SET</td>
<td>RRB Pak</td>
</tr>
<tr>
<td>COMFORT PAC-TIZANIDINE</td>
<td>LEXIXRYL</td>
<td>RRB PAK SANADERMRX SKIN REPAIR</td>
</tr>
<tr>
<td>CYCLO/GABA10/300 PACK</td>
<td>LDOPAC</td>
<td>SOLUTION</td>
</tr>
<tr>
<td>CYCLOBENZAPRINE COMFORT PAC</td>
<td>LDOPRIL &amp; LDOPRIL XR</td>
<td>SANADERMRX SKIN REPAIR</td>
</tr>
<tr>
<td>CYPROHEPTADINE SYRUP DOSE CUP</td>
<td>LI DO-PRIMO CAINE PACK</td>
<td>SILALITE PAK</td>
</tr>
<tr>
<td>DERMA SILKRX DICLOPAK</td>
<td>LI DOTRANS 5 PAK</td>
<td>SILAZONE PHARMAPAK</td>
</tr>
<tr>
<td>DERMA SILKRX SDS PAK</td>
<td>LIDOXIB KIT</td>
<td>SILAZONE-II KIT</td>
</tr>
<tr>
<td>DERMACINRX CLORHEXACIN</td>
<td>LI PROZONEPAK</td>
<td>SOLUPAK</td>
</tr>
<tr>
<td>DERMACINRX DPN PAK</td>
<td>LIVIXIL PAK</td>
<td>SURE RESULT DSS PREMIUM PACK</td>
</tr>
<tr>
<td>DERMACINRX EMPI CAINE</td>
<td>LOCORT 7 &amp; 11 DAY THERAPY PAK</td>
<td>SURE RESULT O3D3 SYSTEM</td>
</tr>
<tr>
<td>DERMACINRX INFLAMMATRAL PAK</td>
<td>LOPEROX KIT</td>
<td>SURE RESULT TAC PAK</td>
</tr>
<tr>
<td>DERMACINRX LEXITRAL PHARMA PAK</td>
<td>LORVATUS PHARMAPAK</td>
<td>SYNALAR TS</td>
</tr>
<tr>
<td>DERMACINRX PHN PAK</td>
<td>MEDOLOR PAK</td>
<td>TAPERDEX</td>
</tr>
<tr>
<td>DERMACINRX PRIZOPAK &amp; SURGICAL PHARMAPAK</td>
<td>MENSELAMINE KIT</td>
<td>TICALAST</td>
</tr>
<tr>
<td>DERMACINRX SILA PAK</td>
<td>MORGIDOX 1X50MG KIT</td>
<td>TICASPRAY</td>
</tr>
<tr>
<td>DERMACINRX SILAZONE</td>
<td>MIGRANOW</td>
<td>TOXICOLOGY SALIVA COLLECTION</td>
</tr>
<tr>
<td>DERMACINRX THERAZOLE PAK</td>
<td>MINOCIN KIT</td>
<td>TRI-SILA</td>
</tr>
<tr>
<td>DERMACINRX TICANASE PAK</td>
<td>NEURCAINE</td>
<td>TRIXYLITRAL</td>
</tr>
<tr>
<td>DERMACINRX ZRM PAK</td>
<td>NORTRIPTYLINE DOSE CUP</td>
<td>ULTRAVATE X CREAM &amp; OINTMENT</td>
</tr>
<tr>
<td>DERMAWEXX SDS</td>
<td>NUDICLO SOLUTAB &amp; TABPAK</td>
<td>VACUSTIM BLACK</td>
</tr>
<tr>
<td>DERMAWEXX SURGICAL PLUS PAK</td>
<td>NUDROXIPAK</td>
<td>VACUSTIM SILVER</td>
</tr>
<tr>
<td>DERMAZONE 0.1% KIT</td>
<td>NUTRIARX</td>
<td>VOPAC MDS</td>
</tr>
<tr>
<td>DERMAZYL KIT</td>
<td>NYATA</td>
<td>WHYTEDERM SURGIPAK &amp; TDPAK</td>
</tr>
<tr>
<td>DEXAMETHASONE DOSE PACK</td>
<td>OMECLAMOX-PAK</td>
<td>WHYTEDERM TRILASIL PAK</td>
</tr>
<tr>
<td>DEXPAK</td>
<td>OMEGA-3/D-3 WELLNESS PACK</td>
<td>XELITRAL PACK</td>
</tr>
<tr>
<td>DICLO GEL/XRYLIX SHEETS</td>
<td>PAINGO KFT</td>
<td>XENAFLAMM KIT</td>
</tr>
<tr>
<td>DICLOPAK</td>
<td>PEDIADERM HC</td>
<td>XRYLIDERM</td>
</tr>
<tr>
<td>DICOTRAL PAK</td>
<td>PEDIPROX-4 NAIL</td>
<td>XRYLIX</td>
</tr>
<tr>
<td>DICLOZOR KIT</td>
<td>PRE ATTACHED LTA</td>
<td>ZEYOCAINE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ZODEX</td>
</tr>
</tbody>
</table>
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.

### Tretin-X.0375% and 0.075% - tretinoin (Rx)

1. Must be prescribed by a Dermatologist AND
2. Must have a diagnosis of acne vulgaris AND
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.

### 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, carbemazepine, divalproex, valproic acid, levetiracetam, and felbamate) OR
2. Must be used for prophylaxis of migraine headaches in adult patients AND
   a. Must have a trial and failure to generic immediate-release topiramate
   b. Must have a trial and failure of two other preventative medications (including, but not limited to tricyclic antidepressants, beta blockers or other anticonvulsants).
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.

### Uceris tablets and generic budesonide ER tablets (Rx)

1. Must be prescribed by a gastroenterologist **AND**
2. Must have a diagnosis of active, mild to moderate ulcerative colitis. Oral uceris tablets are only approved for UC and therefore, all other indications are excluded from coverage **AND**
3. Must have had failure or intolerance oral mesalamine and currently experiencing disease flare **AND**
4. Must demonstrate MORE than 1 flare-up per year requiring steroid therapy. If patient has 1 or fewer flare ups per year, generic systemic corticosteroids should be used, unless patient has a contraindication to traditional corticosteroids.
5. Initial approval will be limited to 8 weeks. Approval for future treatment courses will require documentation that remission (UCDAI score ≤ 1) was achieved after the initial 8 weeks and that the patient has failed to maintain remission while on an immunomodulator (azathioprine or mercaptopurine) or biologic.
6. Future treatment courses will be approved for 365 days at a time. Recertification will require concurrent treatment with an immunomodulator (azathioprine or mercaptopurine) or biologic.
7. Quantity limit of 30/30

### Veltin, Ziana and generic clindamycin/tretinoin gel (Rx)

1. Patient must have had severe intolerance or therapeutic failure of both clindamycin gel and tretinoin gel used in combination.
<table>
<thead>
<tr>
<th>Xatmep – methotrexate oral solution (Rx)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must have a diagnosis of acute lymphoblastic leukemia (ALL) or polyarticular juvenile ideopathic arthritis (pJIA).</td>
</tr>
<tr>
<td>2. Children 7 years of age and under will require a trial of either methotrexate tablets or solution (administered either IM or orally).</td>
</tr>
<tr>
<td>3. Children 8-17 years of age will require a trial of BOTH methotrexate oral tablets and injectable solution (administered either IM or orally).</td>
</tr>
<tr>
<td>a. For members unable to swallow tablets, a speech and swallow evaluation is required to confirm a swallowing disorder.</td>
</tr>
<tr>
<td>b. For members unable to use injectable methotrexate, the patient’s caregiver must have a documented physical inability to inject.</td>
</tr>
<tr>
<td>4. For the diagnosis of JIA, the member must have had an adequate trial and failure of a full dose NSAID (minimum 12 weeks).</td>
</tr>
<tr>
<td>5. Coverage of Xatmep is excluded for patients 18 and older.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Xerese – acyclovir/hydrocortisone (Rx)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Diagnosis of recurrent herpes labialis</td>
</tr>
<tr>
<td>2. Adults (18 years of age and older) must have severe intolerance or therapeutic failure to both oral famciclovir and valacyclovir</td>
</tr>
<tr>
<td>3. Children (12-18 years of age) must have severe intolerance or therapeutic failure of oral valacyclovir</td>
</tr>
<tr>
<td>4. Children under 12 will not be allowed coverage based on no safety or efficacy studies in this population</td>
</tr>
<tr>
<td>5. Quantity limit of 1 tube per 30 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Xhance – fluticasone nasal spray (Rx)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Member must have a diagnosis of nasal polyps. All other diagnoses will be excluded from coverage AND</td>
</tr>
<tr>
<td>2. Must be 18 years of age or older AND</td>
</tr>
<tr>
<td>3. There must be documentation of serious side effects or drug failure with 2 of the following intranasal products: mometasone, budesonide (Rhinocort allergy), flunisolide, triamcinolone, beclomethasone, ciclesonide, generic fluticasone.</td>
</tr>
<tr>
<td>4. Quantity Limit of 32 ml/30 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Xyrem - sodium oxybate (Rx)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Diagnosis of cataplexy secondary to narcolepsy confirmed by a sleep study and patient must be followed by a neurologist or sleep specialist OR</td>
</tr>
<tr>
<td>2. Excessive daytime sleepiness associated with narcolepsy meeting all of the following criteria:</td>
</tr>
<tr>
<td>a. Narcolepsy confirmed by sleep study which must be provided</td>
</tr>
<tr>
<td>b. Followed by Neurologist or Sleep Specialist</td>
</tr>
<tr>
<td>c. Must have failed at least a 4 week trial of Provigil</td>
</tr>
<tr>
<td><strong>Zecuity- sumatriptan (Rx)</strong></td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>1. Must be used for the acute treatment of migraine with or without aura in patients 18 years of age or older <strong>AND</strong></td>
</tr>
<tr>
<td>2. Must have tried at least one oral triptan (sumatriptan, zolmitriptan, naratriptan or rizatriptan) that led to significant nausea and/or vomiting <strong>AND</strong></td>
</tr>
<tr>
<td>3. Must had trial and failure/intolerance to one nasal triptan product (sumatriptan or zolmitriptan) <strong>AND</strong> one injectable triptan product (sumatriptan) <strong>AND</strong></td>
</tr>
<tr>
<td>4. Zecuity will not be approved for the prevention of migraine attacks <strong>AND</strong></td>
</tr>
<tr>
<td>5. QL 4 patches per 30 days.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Zelapar ODT – Selegiline Hydrochloride (L-Deprenyl) (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must have clinically documented Parkinson’s disease <strong>AND</strong></td>
</tr>
<tr>
<td>2. Must be currently receiving treatment with levodopa/carbidopa <strong>AND</strong></td>
</tr>
<tr>
<td>3. Must be exhibiting deterioration in quality of response to levodopa/carbidopa therapy <strong>AND</strong></td>
</tr>
<tr>
<td>4. Must be unable to swallow traditional tablets. <strong>AND</strong></td>
</tr>
<tr>
<td>5. QL 60 tablets per 30 days.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Zontivity – vorapaxar (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Must have a history of Myocardial Infarction <strong>AND</strong></td>
</tr>
<tr>
<td>2. Must be prescribed by a cardiologist <strong>AND</strong></td>
</tr>
<tr>
<td>3. Must not have a history of stroke <strong>AND</strong></td>
</tr>
<tr>
<td>4. Must be used concomitantly with Plavix (clopidogrel) and aspirin <strong>AND</strong></td>
</tr>
<tr>
<td>5. Must weigh 60kg or more due to increased risk of bleeding in individuals weighing less than 60kg <strong>AND</strong></td>
</tr>
<tr>
<td>6. Quantity limit of 30/30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Zurampic – lesinurad (Rx)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient must have a diagnosis of gout <strong>AND</strong></td>
</tr>
<tr>
<td>2. Must be receiving at least 300mg allopurinol daily (or 200mg for those with renal impairment) or 80mg febuxostat daily. <strong>AND</strong></td>
</tr>
<tr>
<td>3. Must have serum uric acid levels above 6.5mg/dl despite being on allopurinol or febuxostat. <strong>AND</strong></td>
</tr>
<tr>
<td>4. Patient must have had a trial and failure/intolerance to probenecid unless patient has a sulfa allergy and/or other contraindication to Probenecid. <strong>AND</strong></td>
</tr>
<tr>
<td>5. Must be used in combination with allopurinol or febuxostat. <strong>AND</strong></td>
</tr>
<tr>
<td>6. QL of 30 tablets/30 days.</td>
</tr>
</tbody>
</table>

**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.
   • 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 Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.

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 Coverage Exception Evaluation Policy for All Lines of Business Formularies 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.

UPDATES:

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/18</td>
<td>Revised/P&amp;T Approval</td>
</tr>
<tr>
<td>8/18</td>
<td>Revised</td>
</tr>
<tr>
<td>7/18</td>
<td>Revised</td>
</tr>
<tr>
<td>6/18</td>
<td>Revised</td>
</tr>
<tr>
<td>5/18</td>
<td>Revised/P&amp;T Approval</td>
</tr>
<tr>
<td>4/18</td>
<td>Revised</td>
</tr>
<tr>
<td>3/18</td>
<td>Revised/P&amp;T Approval</td>
</tr>
<tr>
<td>2/18</td>
<td>Revised</td>
</tr>
</tbody>
</table>
References:
In addition to the full prescribing information for each individual drug, the following references have been utilized in creating drug specific criteria:

**Increlex**
2. Backeljauw PF, et al, "Therapy for 6.5-7.5 years 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**

**Solodyn**

**Somavert**