Appendix P
Colorado Medical Assistance Program
Prior Authorization Procedures and Criteria and Quantity Limits
For Physicians and Pharmacists

Drugs requiring a prior authorization are listed in this document. The Prior Authorization criteria are based on FDA approved indications, CMS approved compendia, and peer-reviewed medical literature.

Prior Authorization Request (PAR) Process
• Products qualify for a 3 day emergency supply in an emergency situation. In this case, call the help desk for an override.

• Pharmacy PA forms are available by visiting: https://www.colorado.gov/hcpf/provider-forms

• PA forms can be signed by anyone who has authority under Colorado law to prescribe the medication. Assistants of authorized persons cannot sign the PA form

• Physicians or assistants who are acting as the agents of the physicians can request a PA by phone

• Pharmacists from long-term-care pharmacies and infusion pharmacy must obtain a signature from someone who is authorized to prescribe drugs before they submit PA forms

• Pharmacists from long-term-care pharmacies and infusion pharmacies can request a PA by phone if specified in the criteria

• All PA’s are coded online into the PA system

• Prior Authorizations can be called or faxed to the helpdesk at
  Phone: 1-800-424-5725
  Fax: 1-888-424-5881

• Non-narcotic prescriptions may be refilled after 75% of previous fill is used. Narcotic prescriptions may be refilled after 85% of the previous fill is used. Synagis may be refilled after 92.5% of the previous fill is used.

Medical Supply Items and Medications
• All supplies, including insulin needles, food supplements and diabetic supplies are not covered under the pharmacy benefit, but are covered as medical supply items through Durable Medical Equipment (DME)

• If a medical benefit requires a PA, the PA request can be submitted through the provider application available at: http://www.coloradopar.com/carewebqi/carewebqi-portal-access.

• Effective March 4, 2013 all PARs and revisions processed by the Colorado PAR Program must be submitted using CWQI. After April 1, 2013, PARs submitted via fax or mail will not be entered into CWQI and subsequently not reviewed for medical necessity.

• DME questions should be directed to Hewlett Packard enterprises (HPE) at 844-235-2387. Only policy questions regarding Durable Medical Equipment should be directed to the state at 303-866-3406.

• Medications given in a hospital, doctor’s office or dialysis unit are to be billed directly by those facilities as a medical item. IV Fluids, meds, etc. may be billed by the pharmacy when given in a long-term care facility or by home infusion.
<table>
<thead>
<tr>
<th>Drug</th>
<th>Criteria</th>
<th>PAR Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACETAMINOPHEN CONTAINING PRODUCTS</td>
<td>A prior authorization is required for dosages of acetaminophen containing products over 4000mg/day of acetaminophen.</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Doses over 4000mg/day are not qualified for emergency 3 day supply PA</td>
<td></td>
</tr>
</tbody>
</table>
| ACNE PRODUCTS                             |Prior authorization is required for all topical tretinoin and isotretinoin products. Payment for topical tretinoin therapy and isotretinoin products will be authorized for the following diagnoses: Cystic acne, disorders of Keratinization, psoriasis, neoplasms, comedonal or acne vulgaris.  
- **Cystic acne, disorders of Keratinization, psoriasis, or neoplasms**, do **not** require previous trials and therapy failure with other legend or non-legend anti-acne products regardless of age. Approval will be granted for a one-year period.  
- The diagnosis of **comedonal** does **not** require previous trial and therapy failure with other legend or non-legend anti-acne products regardless of age. Approval will be granted for an initial three-month period. IF topical tretinoin therapy is effective after the initial approval period, a prior authorization will be granted for a one-year period.  
- A diagnosis of **acne vulgaris** **requires** previous trials and treatment failures on antibiotic and/or topical treatments. If criteria are met, a prior authorization will be granted for a one-year period.  

*Quantity limit:*  
Duac Convenience kit is 1 unit (kit) per 30 days  
Aldara is 12 packets per 28 days |
| ADOXA TT AND CK KIT                       | A prior authorization will only be approved if a member has tried and failed on the generic oral doxycycline or topical clindamycin for a period of 3 or more months in the last 6 months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) | One year              |
| ALBUMIN                                   | Must have an FDA approved indication and given in the member’s home or in a long-term care facility for approval.  The following are FDA approved indications:  
- **Hypoproteinemia**  
- **Burns**  
- Shock due to:  
  - Burns  
  - Trauma  
  - Surgery  
  - Infection  
- Erythrocyte resuspension  
- Acute nephrosis  
- Renal dialysis  
- Hyperbilirubinemia  
- Erythroblastosis fetalis | One year              |
| ALLERGY EXTRACT PRODUCTS-Oral             | **Grastek (Timothy grass pollen allergen extract)**  
Must be between 5 and 65 years old.  
Must not be pregnant or nursing. | One year              |
**Grastek, Oralair, Ragwitek**

Must be prescribed by an allergist.

Must have a documented diagnosis to ONLY timothy grass pollen allergen extract or the Pooidae family (meadow fescue, orchard, perennial rye, Kentucky blue, and red top grasses) confirmed by positive skin test or IgE antibodies.

Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Must be willing to administer epinephrine in case of severe allergic reaction.

Must take first dose in physician’s office.

Must be started 12 weeks prior to the season if giving only seasonally.

May be taken daily for up to 3 consecutive years.

Must NOT have:

- Severe, unstable or uncontrolled asthma
- Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat
- Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before
- Been diagnosed with eosinophilic esophagitis
- Allergic to any of the inactive ingredients contained in Grastek which include gelatin, mannitol, and sodium hydroxide
- A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension.
- Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics.
- Be taken with other immunotherapy (oral or injectable)

**Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, Kentucky Blue Grass mixed pollens allergen extract)**

Must be between 10 and 65 years old.

Must not be pregnant or nursing.

Must be prescribed by an allergist.

Must have a documented diagnosis to ONLY Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass allergen extract confirmed by positive skin test or IgE antibodies.

Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Must be willing to administer epinephrine in case of severe allergic reaction.

Must take first dose in physician’s office.

Must NOT have:

- Severe, unstable or uncontrolled asthma
- Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat
- Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before
- Been diagnosed with eosinophilic esophagitis
• Allergic to any of the inactive ingredients contained in Oralair which include mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, and lactose monohydrate.

• A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension.

• Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics.

• Be taken with other immunotherapy (oral or injectable)

Ragwitek (short ragweed pollen allergen extract)

Must be between 18 and 65 years old.
Must be started 12 weeks prior to the season and only prescribed seasonally.
Must not be pregnant or nursing.
Must be prescribed by an allergist.
Must have a documented diagnosis to ONLY short ragweed pollen allergen extract or the Ambrosia family (giant, false, and western ragweed) confirmed by positive skin test or IgE antibodies.
Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
Must be willing to administer epinephrine in case of a severe allergic reaction.
Must take first dose in physician’s office.

Must NOT have:
• Severe, unstable or uncontrolled asthma
• Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat
• Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before
• Been diagnosed with eosinophilic esophagitis
• Allergic to any of the inactive ingredients contained in Ragwitek which include gelatin, mannitol, and sodium hydroxide
• A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension.
• Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics.
• Be taken with other immunotherapy (oral or injectable)

ALPHA–1 PROTEINASE INHIBITORS
Aralast, Prolastin and Zemaira

FDA approved indication if given in the member’s home or in a long-term care facility:
  ➢ Aralast: Chronic augmentation therapy in members having congenital deficiency of Alpha–1 Proteinase Inhibitor with clinically evident emphysema
  ➢ Prolastin: Emphysema associated with Alpha-1 Antitrypsin Deficiency

Lifetime
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANOREXIANTS (Diet Pills)</td>
<td>Belviq (lorcaserin) Contryz (naltrexone/bupropion) Qsymia (phentermine/topiramate ER) Saxenda (liraglutide) Xenical (Orlistat)</td>
<td>Weight loss drugs are not a covered benefit.</td>
</tr>
<tr>
<td>ANTI-ANEMIA DRUGS (Oral and injectable drugs)</td>
<td>FDA approved indication: Iron Deficiency Anemia Injectable Drugs [i.e.: Infed (iron dextran), Venofer, Ferrlecit] Diagnosis of iron deficiency anemia when oral preparations are ineffective or cannot be used. Must be administered in a member’s home or in a long-term care facility.</td>
<td>Lifetime</td>
</tr>
<tr>
<td>ANTI-COAGULANTS - ORAL</td>
<td>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</td>
<td>One year</td>
</tr>
<tr>
<td>ANTI-DEPRESSANTS</td>
<td>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</td>
<td>One year</td>
</tr>
<tr>
<td>ANTIEMETICS</td>
<td>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</td>
<td>One year</td>
</tr>
<tr>
<td>ANTI-HERPETICS</td>
<td>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</td>
<td>One year</td>
</tr>
<tr>
<td>ANTI-HISTAMINES WITH DECONGESTANTS (Rx)</td>
<td>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</td>
<td>One year</td>
</tr>
<tr>
<td>ANTIHYPERTENSIVES</td>
<td>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</td>
<td>One year</td>
</tr>
<tr>
<td>ANTIPLATELETS</td>
<td>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</td>
<td>One year</td>
</tr>
<tr>
<td>ATYPICAL ANTIPSYCHOTICS (Injectable)</td>
<td>Abilify Maintena, Invega Sustenna, Geodon and Risperdal Consta, Zypraxa Relprevv</td>
<td>One year</td>
</tr>
<tr>
<td>ATYPICAL ANTIPSYCHOTICS (oral)</td>
<td>A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility or in a member’s home. Oral atypical antipsychotic criteria can be found on the Preferred Drug List.</td>
<td>One year</td>
</tr>
<tr>
<td>BACTROBAN (mupirocin)</td>
<td>Nasal Cream and Ointment (Generic Bactroban Ointment does not require a prior authorization) Bactroban Cream (mupirocin calcium cream) must be prescribed for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm² in total area), impetigo, infected eczema or folliculitis caused by susceptible strains of Staphylococcus aureus and Streptococcus pyogenes. Bactroban Nasal Ointment (mupirocin calcium) must be prescribed for the eradication of nasal colonization with methicillin-resistant Staphylococcus aureus in adult patients and health care workers as part of a comprehensive infection control program to reduce the risk of infection among patients at high risk of methicillin-resistant S. aureus infection during institutional outbreaks of infections with this pathogen.</td>
<td>Cream: One year Nasal Ointment: Lifetime</td>
</tr>
<tr>
<td>BARBITURATES</td>
<td>Medicare-Medicaid enrollees Barbiturates will require prior authorization for all Medicaid members. Beginning on January 1, 2013, the Colorado Medicaid Program will no longer be allowed to cover barbiturates for Medicare-Medicaid enrollees (dual-eligible members).</td>
<td>One year</td>
</tr>
</tbody>
</table>
primary members, barbiturates will be approved for use in epilepsy, cancer, chronic mental health disorder, sedation, treatment of insomnia, tension headache, muscle contraction headache and treatment of raised intracranial pressure. All other uses will require manual review.

For Phenobarbital see the section titled Phenobarbital.

**BENLYSTA** (belimumab)

A prior authorization may be approved only when documentation has been received indicating that the drug is being administered in the member’s home or long-term care facility. The member must also meet the following criteria:

- Diagnosis of autoantibody positive SLE with organ involvement; AND
- Incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids; AND
-Maintenance of standard therapy while on BENLYSTA.

**BENZODIAZEPINES**

Medicare-Medicaid enrollees

Benzodiazepines will no longer be a Medicaid benefit for Medicare-Medicaid enrollees (dual-eligible members). The claims are no longer excluded from Medicare part D coverage, and thus must be billed to Medicare part D. The Colorado Medicaid Program will no longer be allowed to cover these medications beginning on January 1, 2013. Coverage will remain in effect for Medicaid primary members.

**BISPHOSPHONATES**

(Injectable)

Didronel, Boniva, Aredia, Miacalcin, Zemplar, Hectorol, Zometa, Pamidronate, and Ganite

A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility or in a member’s home.

**BISPHOSPHONATES**

(oral)

This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

**BLOOD PRODUCTS**

FDA approved indications if given in the member’s home or in a long-term care facility:

- Plasma protein fraction; shock due to burns, trauma, surgery; hypoproteinemia; adult respiratory distress syndrome; cardiopulmonary bypass; liver failure; renal dialysis; or hemophilia.

**BOTULINUM TOXIN**

Botox, Myobloc, Xeomin, Dysport

If given in the member’s home or in a long-term care facility.

- *Cervical or Facial Dystonia*

*Not approved for Cosmetic Purposes*

**BRAND NAME MEDICATIONS**

Only brand name drugs that have a generically equivalent drug (as determined by the FDA) require a prior authorization. Exceptions to the rule include:

- The brand name drug has been exempted (see the list below)
- When the reimbursement for a brand-name drug is less expensive than the cost of the generic equivalent
- The physician is of an opinion that a transition to the generic equivalent of a brand-name drug would be unacceptably disruptive to the patient’s stabilized drug regimen
- The patient is started on a generic drug but is unable to continue treatment on the generic drug as determined by the patient’s physician

The following list of drug classes is exempt from the generic mandate rule (no PA is required). Medications used for the treatment of:

- Biologically based mental illness defined in 10-16-104 (5.5) C.R.S.
- Cancer
- Epilepsy

---

**Revision Date:** 3/1/2017  **Effective:** 4/1/2017
<table>
<thead>
<tr>
<th>Medicated Product</th>
<th>Criteria</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BUTALBITAL-CONTAINING PRODUCTS</strong></td>
<td>Effective August 1, 2014, products containing butalbital are limited to 180 units in 30 days. For members receiving more than 180 tablets in 30 days, these claims will be escalated to the Department for individual review. Please note that if more than one agent is used, the combined total utilization may not exceed 180 units in 30 days.</td>
<td>Case by case</td>
</tr>
<tr>
<td><strong>CERDELGA (eligulstat)</strong></td>
<td>Cerdela will be approved if all the following criteria are met:</td>
<td>One year</td>
</tr>
<tr>
<td></td>
<td>• Member has a diagnosis of Gaucher disease type 1 AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Documentation has been provided to the Department that the member is a CYP2D6 extensive, intermediate, or poor metabolizer as detected by an FDA cleared test AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Members who are CYP2D6 intermediate or poor metabolizers are not taking a strong CYP3A inhibitor (e.g., indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole,itraconazole, ketoconazole, nefazodone) AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Members who are CYP2D6 extensive or intermediate metabolizers are not receiving strong or moderate CYP2D6 inhibitors (e.g., sertraline, duloxetine, quinidine, paroxetine, fluoxetine, bupropion, terbinafine) AND a strong or moderate CYP3A inhibitor (e.g., indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole,itraconazole, ketoconazole, fluconazole, nefazodone, verapamil, diltiazem)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quantity Limits: Max 60 tablets/30 days</td>
<td></td>
</tr>
<tr>
<td><strong>CHOLBAM (cholic Acid)</strong></td>
<td>CHOLBAM® capsules will be approved for members who meet the following criteria:</td>
<td>One year</td>
</tr>
<tr>
<td></td>
<td>• Bile acid synthesis disorders:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member must be greater than 3 weeks old in age AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member has a diagnosis for bile acid synthesis disorder due to single enzyme defect (Single Enzyme-Defect Disorders: Defective sterol nucleus synthesis, 3β-hydroxy-Δ-ε27-steroid oxidoreductase deficiency, AKR1D1 deficiency, CYP7A1 deficiency, Defective side-chain synthesis, CYP27A1 deficiency (cerebrotendinous xanthomatosis), 2-methylacyl-CoA racemase deficiency (AMACR), 25-hydroxylation pathway (Smith–Lemli-Opitz).).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Peroxisomal disorder including Zellweger spectrum disorders:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member must be greater than 3 weeks old in age AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member has diagnosis of peroxisomal disorders (PDs) including Zellweger spectrum disorders AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Member has manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption.</td>
<td></td>
</tr>
<tr>
<td><strong>CIALIS (tadalafil)</strong></td>
<td>Cialis will be approved for members with a documented diagnosis of BPH who have failed a trial of finasteride (at least 3 months in duration) AND either a trial of a nonselective alpha blocker (therapeutic dose for at least two months) OR a trial of tamsulosin (therapeutic dose for at least one month). Documentation of BPH diagnosis will require BOTH of the following: 1. AUA Prostate Symptom Score ≥ 8 AND 2. Results of a digital rectal exam. Cialis will not be approved for any patient continuing alpha-blocker therapy as this combination is contraindicated in this population. Doses exceeding 5mg per day of Cialis will not be approved.</td>
<td>One year</td>
</tr>
</tbody>
</table>
CITALOPRAM (high dose) Prior authorization will be required for doses exceeding 40mg/day. Please see the FDA guidance at: http://fda.gov/Drugs/DrugSafety/ucm269086.htm for important safety information. One year

COLCRYS (colchicine) Quantity Limits:
- Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days
- Familial Mediterranean Fever: 120 tablets per 30 days One year

CONSTIPATION- OPIOID INDUCED MOVANTIK® (Naloxegol) will be approved for members who meet the following criteria:
- Member has diagnosis of constipation associated with chronic opioid use associated with non-cancer pain AND
- Opioid use must exceed 4 weeks of treatment AND
- Member must not be taking oral CYP3A4 inhibitors AND
- Member does not have diagnosis of GI obstruction AND
- Member has failed the following additive bowel regimens (failure is defined as lack of efficacy after 7 days of treatment with all four agents):
  ✓ Stimulant e.g. Senna
  ✓ Stool Softener e.g. Docusate Sodium
  ✓ Osmotic Agents e.g. Miralax® or Lactulose
  ✓ Nonphosphate Enema

RELISTOR® (Methylnaltrexone bromide) will be approved for members who meet the following criteria:
- Member has diagnosis of constipation associated with chronic opioid use associated with late-stage, advanced illness pain AND
- Member opioid use must exceed 4 weeks of treatment AND
- Member does not have diagnosis of GI obstruction AND
- If the member can take oral medications, the member has failed the following additive bowel regimens (failure is defined as lack of efficacy after 7 days of treatment with):
  ✓ Stimulant e.g. Senna
  ✓ Stool Softener e.g. Docusate Sodium
  ✓ Osmotic Agents e.g. Miralax® or Lactulose
  ✓ Nonphosphate Enema OR
- If the member cannot take oral medications, then the member has failed a 7-day trial of with a nonphosphate enema.

COUGH AND COLD (Rx) Member <21 years: covered benefit. A prior authorization is not needed. One year
Member ≥ 21 years must have diagnosis of a chronic condition such as COPD or asthma.

COX-2 INHIBITORS Celebrex (celecoxib) brand and generic PA is required for members who are 64 years of age and younger. Members over the age of 65 do not require a PA. A PA will be approved if the COX-2 is prescribed for a FDA approved indication. See chart

<table>
<thead>
<tr>
<th>FDA Approved Indication</th>
<th>Dose and Length of PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Pain</td>
<td>Up to 600mg day 1; 200mg BID for no more than 30 days</td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td>Up to 600mg day 1; 200mg BID. One year approval</td>
</tr>
<tr>
<td>Ankylosing spondylitis</td>
<td>200mg daily; after 6 weeks of 200mg daily dosing if member’s condition has been unresponsive,</td>
</tr>
<tr>
<td>Condition</td>
<td>Dosage/Approval</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>Familial Adenomatous Polyposis</td>
<td>400mg BID. Lifetime approval</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>200mg daily; 100mg BID. Lifetime approval</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>100-200mg BID. Lifetime approval</td>
</tr>
<tr>
<td>Juvenile Rheumatoid Arthritis</td>
<td>Up to 100mg BID. 6 month approval</td>
</tr>
</tbody>
</table>

**DALIRESP® (roflumilast)**

DALIRESP® tablets will be approved for members that meet the following criteria:

- Member has a diagnosis for severe COPD with history of COPD exacerbations (2 or more per year) and chronic bronchitis AND
- Member must be greater than 18 years of age AND
- Member must have failed a trial of two of the following: long-acting beta2 agonist, preferred anticholinergic/anticholinergic combination, or preferred inhaled anticholinergic/anticholinergic combinations due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction AND
- Member must not have moderate to severe liver disease (Child Pugh B or C).

Note: this medication is not a bronchodilator and cannot be used for acute bronchospasms.

**DESI DRUGS**

DESI drugs (Drugs designated by the Food and Drug Administration as Less Than Effective Drug Efficacy Study Implementation medications) are not a covered benefit.

**DIABETES MANAGEMENT CLASSES**

This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

**DIFICID (fidoxomicin)**

Dificid will be approved if all the following criteria are met:

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records AND
- Prescriber must be a gastroenterologist or an infectious disease specialist AND
- Diagnosed with Clostridium difficile-associated diarrhea AND
- ≥ 18 years of age AND
- Failed at least a 10 day treatment course with oral metronidazole AND oral vancomycin OR
- Allergy and/or intolerance to both metronidazole and vancomycin

Quantity limits:

- Dificid: Max 20 tabs/30 days

**DUEXIS (famotidine/ibuprofen)**

Duexis will be approved for members that meet the following criteria:

- Member has a diagnosis of rheumatoid arthritis or osteoarthritis AND
- Member has failed a trial of an NSAID taken with three preferred proton pump inhibitors (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

**ELESTRIN GEL (estradiol)**

A prior authorization will only be approved if a member has tried and failed on generic oral estradiol therapy and diagnosed with moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

**EMVERM (mebendazole)**

Emverm will be approved for members that meet the following criteria:

- See Table
- Member is 2 years or older AND
- Member has a diagnosis of one of the following: Ancylostoma duodenale or Necator americanus (hookworm), Ascariasis (roundworm), Enterobiasis (pinworm), or Trichuriasis (whipworm) AND
- Member has failed a trial of albendazole for FDA approved indication and duration (Table 1) (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) AND
- For diagnoses other than pinworm, Emverm is being prescribed by an infectious disease specialist AND
- Female members have a negative pregnancy test AND
- Emverm Is being prescribed in accordance to FDA dosing and duration (Table 1)

Quantity limits will be based on indication (Table 1)

Table 1. Emverm FDA Approved Dosing and Duration in Adults and Children.

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Dose</th>
<th>Duration</th>
<th>Quantity Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ancylostoma duodenale or Necator</td>
<td>100 mg twice</td>
<td>3 consecutive days, may be repeated in 3 weeks</td>
<td>6 tablets/member</td>
</tr>
<tr>
<td>americanus (hookworm)</td>
<td>daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ascariasis (roundworm)</td>
<td>100 mg twice</td>
<td>3 consecutive days, may be repeated in 3 weeks</td>
<td>6 tablets/member</td>
</tr>
<tr>
<td></td>
<td>daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterobiasis (pinworm)</td>
<td>100 mg once</td>
<td>May give second dose in three weeks if needed.</td>
<td>2 tablets/member</td>
</tr>
<tr>
<td>Trichuriasis (whipworm)</td>
<td>100 mg twice</td>
<td>3 consecutive days, may be repeated in 3 weeks</td>
<td>6 tablets/member</td>
</tr>
<tr>
<td></td>
<td>daily</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ENTRESTO will be approved for members if the following criteria has been met:
- Member has a diagnosis of heart failure with reduced ejection fraction and NYHA Class II to IV AND
- Member is NOT currently on ACE-inhibitor or Angiotensin Receptor Blocking agent AND
- Member does not have history of angioedema related to previous ACE inhibitor or ARB therapy

One year

Epaned will be approved for members under the age of 5 years who cannot swallow a whole or crushed tablet.

One year

These drugs are not a covered benefit.

Not available
Not qualified for
Levitra  
Muse  
Viagra

Yohimbine: PAs can no longer be approved for erectile dysfunction. Any PAs for use as a mydriatic agent or a vasodilator (not related to erectile dysfunction) may be approved.

| ERYTHROPOIESIS STIMULATING AGENTS | This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products. | One year |

| ESBRIET (Pirenidone) | Esbriet will be approved if all the following criteria are met:  
- Member has been diagnosed with idiopathic pulmonary fibrosis AND  
- Is being prescribed by or in conjunction with a pulmonologist AND  
- Member is 18 years or older AND  
- Member has baseline ALT, AST, and bilirubin prior to starting therapy AND  
- Member does not have severe (Child Pugh C) hepatic impairment, severe renal impairment (CrCl<30 ml/min), or end stage renal disease requiring dialysis AND  
- Female members of reproductive potential must have been counseled regarding risk to the fetus AND  
- Member is not receiving a strong CYP1A2 inducer (e.g, carbamazepine, phenytoin, rifampin) | One year |

| FENTANYL PREPARATIONS | Actiq, Fentora, Onsolis and Subsys: Approval will be granted for members experiencing breakthrough cancer pain and those that have already received and are tolerant to opioid drugs for the cancer pain AND are currently being treated with a long-acting opioid drug. The PA may be granted for up to 4 doses per day.  
Duragesic Transdermal System: A PA is required for doses of more than 1 Patch/2 Days.  
For all Fentanyl preparations: If the patient is in hospice or palliative care, the PA will be automatically granted regardless of the number of doses prescribed. | One year |

| FIBROMYALGIA AGENTS | This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products. | One year |

| FILGRASTIM/PEGFILGRASTIM/SARGRAMOSTIM/FILGRASTIM-SNDZ | Prior authorization is required for therapy with filgrastim, pegfilgrastim or sargramostim.  
**Prior authorizations for PEGFILGRASTIM will be approved for the following indication if the criterion is met:**  
**Indication:** To decrease the incidence of infection due to neutropenia in members receiving myelosuppressive anti-cancer therapy.  
- **Criterion 1.** CBC and platelet count obtained before chemotherapy is administered.  
**Prior authorizations will be approved for FILGRASTIM AND SARGRAMOSTIM for the following indications if the applicable criteria are met:**  
**Indication:** To decrease the incidence of infection due to severe neutropenia caused by myelosuppressive anti-cancer therapy.  
- **Criterion 1.** Either the post nadir ANC is less than 10,000 cells/mm³ or the risk of neutropenia for the member is calculated to be greater than 20%  
- **Criterion 2.** Routine CBC and platelet counts twice weekly | One year |
| **FLECTOR 1.3% PATCH** (diclofenac) | A prior authorization will only be approved if a member has tried and failed on Voltaren Gel. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) | One year |
| **FLUORIDE PREPARATIONS** | A prior authorization will not be needed for members less than 21 years of age. For members 21 years old or older, approval will be granted if using well water or otherwise living in an under fluorinated area according to the CDC at: [https://nced.cdc.gov/DOH_MWF/Default/CountyList.aspx?state=Colorado&stateid=8&stateabbr=CO&reportLevel=2](https://nced.cdc.gov/DOH_MWF/Default/CountyList.aspx?state=Colorado&stateid=8&stateabbr=CO&reportLevel=2). Other situations will require a letter of necessity and will be individually reviewed. | One year |
| **FLUOROQUINOLONES** | This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products. | One year |
| **FUZEON (enfuvirtide)** | If administered in the physician’s office or delivered to physician’s office, physician must bill as a medical claim on the 1500 claim form (no PA required). If administered in the member’s home or in a long-term care facility, a prior authorization is required and must meet the criteria below for approval. Based on clinical trial data, ENF should be used as part of an optimized background regimen for treatment-experienced members:  
  - For treatment-experienced members with evidence of HIV-1 replication, treatment should include at least one antiretroviral agent with demonstrated HIV-1 susceptibility on the basis of genotypic/phenotypic resistance assays, and two “active” antiretroviral agents.  
    - Members must have limited treatment options among currently commercially available agents.  
  - Members must be 18 years of age or older with advanced HIV-1 infection, and not responding to approved antiretroviral therapy. | Six months |
Members must have a CD4 lymphocyte count less than 100 cells/mm$^3$ and a viral load greater than 10,000 copies/ml (measurement within the last 90 days).

Past adherence must be demonstrated based on:
- Attendance at scheduled appointments, and/or
- Prior antiretroviral regimen adherence, and/or
- Utilization data from pharmacy showing member’s use of medications as prescribed
- Ability to reconstitute and self-administer ENF therapy.

At 24 weeks, members must experience at least $\geq 1$ log$_{10}$ decrease in HIV RNA or have HIV RNA below quantifiable limits to continue treatment with ENF.

Members are not eligible if antiretroviral treatment-naive and/or infected with HIV-2.

Pre-approval is necessary

Practitioner must either be Board Certified in Infectious Disease, or be an HIV experienced practitioner. Verification must be produced with the prior approval documents.

**These guidelines may be modified on the basis of other payer formularies and/or the emergence of new data.**

<table>
<thead>
<tr>
<th>GATTEX (teduglutide)</th>
<th>Prior authorization will be approved if all of the following criteria are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Member is 18 years of age or older;</td>
</tr>
<tr>
<td></td>
<td>- Member has documented short bowel syndrome;</td>
</tr>
<tr>
<td></td>
<td>- Member is dependent on parenteral nutrition for twelve consecutive months;</td>
</tr>
<tr>
<td></td>
<td>- The prescribing physician is a gastroenterologist;</td>
</tr>
<tr>
<td></td>
<td>- Medical necessity documentation has been received and approved by</td>
</tr>
<tr>
<td></td>
<td>Colorado Medicaid clinical staff (please fax to 303-866-3590 attn: Clinical Pharmacy Staff)</td>
</tr>
<tr>
<td></td>
<td>- The initial prior authorization will be limited to a two month supply.</td>
</tr>
</tbody>
</table>

Two months initially; may be approved by State for up to one year

<table>
<thead>
<tr>
<th>GROWTH HORMONES</th>
<th>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</th>
</tr>
</thead>
</table>

One year

<table>
<thead>
<tr>
<th>H2 BLOCKERS</th>
<th>Generic H2 Blockers do not require a PA except for ranitidine capsules and liquid.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranitidine capsules and liquid</td>
<td>Ranitidine capsules: Require the prescribing provider to certify that capsules are “medically necessary” and that the member cannot use the tablets.</td>
</tr>
<tr>
<td></td>
<td>Ranitidine liquid: A prior authorization will be granted for members with a feeding tube or who have difficulty swallowing. A prior authorization is not required for children under 12 years of age.</td>
</tr>
</tbody>
</table>

One year

<table>
<thead>
<tr>
<th>HEPATITIS C VIRUS TREATMENTS</th>
<th>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</th>
</tr>
</thead>
</table>

One year

<table>
<thead>
<tr>
<th>HETLIOZ (tasimelteon)</th>
<th>HETLIOZ® will be approved for members who meet the following criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Have a documented diagnosis of non-24-hour sleep wake disorder (non-24 or N24) by a sleep specialist AND</td>
</tr>
<tr>
<td></td>
<td>- Member is completely blind</td>
</tr>
</tbody>
</table>

One year

<table>
<thead>
<tr>
<th>Homozygous Familial Hypercholesterolemia (HoFH)</th>
<th>Juxtapid (lomitapide) Prior authorization will be approved if all of the following criteria are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Member is 18 years of age or older;</td>
</tr>
<tr>
<td></td>
<td>- Member has documented diagnosis of homozygous familial hypercholesterolemia (HoFH);</td>
</tr>
<tr>
<td></td>
<td>- Member has failed therapy with high dose statin therapy (e.g. atorvastatin 40mg or higher, Crestor 20mg or higher)</td>
</tr>
</tbody>
</table>
The prescribing physician is enrolled in the Juxtapid REMS program.

**Kynamro ( mipomersen)** will be approved for members meeting all of the following criteria:
- Confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by either a or b
  - Laboratory tests confirming diagnosis of HoFH: LDLR DNA Sequence Analysis OR LDLR Deletion/Duplication Analysis for large gene rearrangement testing---only if the Sequence Analysis is negative OR APOB and PCSK9 testing if both of the above tests are negative but a strong clinical picture exists.
  - Documentation is received confirming a clinical or laboratory diagnosis of HoFH
- Has a history of therapeutic failure, contraindication, or intolerance to high dose statin therapy or cholesterol absorption inhibitor (ezetimibe or bile acid resin) AND
- Is being prescribed by a physician specializing in metabolic lipid disorders AND
- The prescriber is enrolled in the REMS program AND
- Is not being used as monotherapy AND
- Has baseline liver function (AST, ALT, ALK, and total bilirubin) AND
- Does not have moderate or severe hepatic impairment or active liver disease.

**HORIZANT (gabapentin enacarbil)**

**HORIZANT®** will be approved for members who have a diagnosis of Restless Leg Syndrome and who meet the following criteria:
- Member has failed a one month trial of Mirapex® (pramipexole) and Requip® (ropinorole) AND
- Member has had a positive therapeutic response to generic gabapentin but incomplete response due to duration of action.

Max quantity: 30 tablets/30 days

**HORIZANT®** will be approved for members who have a diagnosis of Post Herpetic Neuralgia and who meet the following criteria:
- Member has failed a one month trial of tricyclic antidepressant, pregabalin and gabapentin

Max quantity: 60 tablets / 30 days

**HORMONE THERAPY**

**Depo Provera (medroxyprogesterone)/Lunelle (estradiol cipionate/medroxyprogesterone)**

FDA approved indication if given in a long-term care facility or in the members home:
- Females: Contraception, uterine bleeding, amenorrhea, endometrial cancer
- Males: Sexual aggression / Pedophilia – Only Depo-Provera will be approved
- Not approved for administration in the physician’s office – these must be billed through medical.

**Implanon ( etonogestrel)**

See PHYSICIAN ADMINISTERED DRUGS. Not a covered pharmacy benefit when implanted in the clinic or hospital outpatient center.

**Nexplanon ( etonogestrel)**
- See PHYSICIAN ADMINISTERED DRUGS. Not a covered pharmacy benefit when implanted in the clinic or hospital outpatient center.

---

**Revision Date:** 3/1/2017  **Effective:** 4/1/2017
HP ACTHAR (corticotropin)

HP Acthar will be approved for members that meet the following criteria:
- Member has a diagnosis of Infantile Spasms (West Syndrome) and meets all the criteria below:
  - Member is < 2 years of age
  - Member has electroencephalogram documenting diagnosis
  - Acthar is being used as monotherapy
  - Member does not have suspected congenital infection
  - Prescribed by or in consultation with a neurologist or epileptologist
  - Member does not have concomitant primary adrenocortical insufficiency or adrenocortical hyperfunction
  - Member is not receiving concomitant live or live attenuated vaccines
  - Member does not have one of the following concomitant diagnoses:
    - Scleroderma, osteoporosis, systemic fungal infections, ocular, herpes simplex, recent surgery, history of or the presence of a peptic ulcer, heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin.
  - HP Acthar will be approved based on the following FDA recommended doses. (see Table 1)

Table 1. FDA Recommended Dosing for HP Acthar

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infantile Spasms under Age of 2 years</td>
<td>75 units/m² IM twice daily for two weeks; After two weeks, dose should be tapered according to the following schedule: 30 U/m² IM in the morning for 3 days; 15 units/m² IM in the morning for 3 days; 10 units/m² IM in the morning for 3 days; and 10 units/m² IM every other morning for 6 days (3 doses).</td>
</tr>
</tbody>
</table>

Quantity Limits: 4 week supply

INSULIN

This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

One year

INTRANASAL CORTICOSTEROIDS

This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

One year

IVIG

Members must have one of the following conditions:
- **Immunodeficiency disorders:**
  1. Common Variable Immunodeficiency (CVID)
  2. Severe Combined Immunodeficiency (SCID)
  3. X-Linked Agammaglobulinemia
  4. X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency
  5. Wiskott-Aldrich Syndrome
  6. Pediatric Human Immunodeficiency Virus (HIV):
    - Members are less than 13 years of age and CD-4 Count is > 200/mm³
- **Neurological disorders:**
  1. Guillain-Barre Syndrome
  2. Relapsing-Remitting Multiple Sclerosis
  3. Chronic Inflammatory Demyelinating Polynueropathy
  4. Myasthenia Gravis
  5. Polymyositis and Dermatomyositis
  6. Chronic Lymphocytic Leukemia (CLL)

One year

CLL: One year

AN: 6 months
<table>
<thead>
<tr>
<th>Condition</th>
<th>Criteria</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autoimmune Neutropenia (AN)</td>
<td>1. Absolute neutrophil count is less than 800 mm And 2. Has recurrent bacterial infections</td>
<td>AHA: 5 weeks</td>
</tr>
<tr>
<td>Autoimmune Hemolytic Anemia (AHA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver or Intestinal Transplant</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Idiopathic Thrombocytopenic Purpura (ITP) | 1. Preoperatively for members undergoing elective splenectomy with platelet count < 20,000  
2. Members with active bleeding & platelet count < 30,000.  
3. Pregnant women with platelet counts < 10,000 in the third trimester.  
4. Pregnant women with platelet count 10,000 to 30,000 who are bleeding. | ITP: 5 days      |

**KALYDECO (ivacaftor)**

Kalydeco will only be approved if all of the following criteria are met:
1. Member has been diagnosed with cystic fibrosis AND
2. Member is an adult or pediatric patient 2 years of age or older AND
3. Documentation has been provided to indicate one of the following gene mutation: in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, R117H * AND
4. Documentation has been provided that baseline ALT and AST have been accessed and are within 2x normal limits (AST and ALT should be examined every 3 months for the first year and annually after that).

* If the member’s genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bidirectional sequencing when recommended by the mutation test instructions for use.

Kalydeco will only be approved at doses no more than 150 mg twice daily. Prior Authorizations need to be obtained yearly.

Kalydeco will not be approved for members who are concurrently receiving rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John’s Wort.

**LEUKOTRIENES**

This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

**LHRH/GnRH**

Luteinizing Hormone Releasing Hormone/Gonadotropin Releasing Hormone

Must be given in the member’s home or in a long-term care facility.

Prior authorization will be granted for FDA Approved Indications Only:

- **Eligard**: Palliative treatment of Advanced Prostate Cancer
- **Lupron (leuprolide)**: Prostate Cancer, Endometriosis, Uterine Leiomyomata (fibroids), Precocious Puberty

Lupron will be approved for Gender Identity Dysphoria based on the following criteria:

- The member has a diagnosis of Gender Identity Dysphoria which is made by a mental health professional with experience in treating gender dysphoria. Where available, the mental health professional should ideally have training in child and adolescent developmental psychology AND
- The member should have at least 6 months of counseling and psychometric testing for gender identity prior to initiation of Lupron AND
- The prescribing provider has training in puberty suppression using a gonadotropin releasing hormone agonist AND
- Lupron may not be started until girls and boys exhibit physical changes of puberty (confirmed by levels of estradiol and testosterone, respectively) and no earlier than Tanner stages 2-3 (bilateral breast budding or doubling to tripling testicular size to 4-8 cc).

<table>
<thead>
<tr>
<th>Prior Authorization</th>
<th>Duration</th>
<th>16 years of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lupron (leuprolide)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Duration of treatment:
Lupron will be covered to a maximum of 16 years of age for Gender Identity Dysphoria.
- **Trelstar:** Palliative treatment of Advanced Prostate Cancer
- **Viadur:** Palliative treatment of Advanced Prostate Cancer
- **Vantas:** Palliative treatment of Advanced Prostate Cancer
- **Zoladex:** Breast Cancer, Endometriosis, Endometrial Thinning, Prostate Cancer

### LIPIDS/AMINO ACIDS/PLASMA PROTEINS
Approval will be given if administered in the member’s home or in a long-term care facility. If given in the hospital or physician’s office, the claim must be billed as a medical expense.

| MAKENA  
Hydroxyprogesterone caproate injection | Makena will be approved for members that meet the following criteria |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• The drug is being administered in the home or in long-term care setting;</td>
</tr>
<tr>
<td></td>
<td>• Member has a Singleton pregnancy and a history of singleton spontaneous preterm birth;</td>
</tr>
<tr>
<td></td>
<td>• Therapy is being initiated between 16 weeks gestation and 20 weeks, 6 days gestation.</td>
</tr>
<tr>
<td></td>
<td>• Continue through 36 weeks 6 days gestation or delivery; whichever occurs first.</td>
</tr>
<tr>
<td></td>
<td>• Dose is administered by a healthcare professional.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MOXATAG (amoxicillin)</th>
<th>A prior authorization will only be approved if a member is allergic to inactive ingredients in immediate release amoxicillin.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>MULTIPLE SCLEROSIS AGENTS</th>
<th>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quantity limit</strong></td>
<td>for Copaxone 20mg: 30 units per 30 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NEUROCOGNITIVE DISORDER AGENTS</th>
<th>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>NEWLY APPROVED PRODUCTS</th>
<th>Newly marketed drugs may be subject to prior authorization for a minimum of nine months following FDA marketing approval. Initial approval criteria will include non-preferred criteria (for drugs within a reviewed PDL class); or FDA approved indications, dose, age and place in therapy. For drugs in PDL classes, the next class annual review will include the new agent. For non-PDL drugs, criteria shall be reviewed at the quarterly DUR meeting closest to the nine month minimum.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>NUCALA (mepolizumab)</th>
<th>A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility. Medications administered in a physician’s office must be billed as a medical expense. Because this medication has a Black Box warning requiring the administration under the supervision of a physician, a PA will not be approved if administered in a member’s home.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>OFEV (Nintedanib)</th>
<th>Ofev will be approved if all the following criteria are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Member has been diagnosed with idiopathic pulmonary fibrosis AND</td>
</tr>
<tr>
<td></td>
<td>• Is being prescribed by or in conjunction with a pulmonologist AND</td>
</tr>
<tr>
<td></td>
<td>• Member is 18 years or older AND</td>
</tr>
<tr>
<td></td>
<td>• Member has baseline ALT, AST, and bilirubin prior to starting therapy AND</td>
</tr>
<tr>
<td></td>
<td>• Member does not have moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment AND</td>
</tr>
<tr>
<td></td>
<td>• Female members of reproductive potential must have been counseled regarding risk to the fetus and to avoid becoming pregnant while receiving treatment with Ofev and to use adequate contraception during treatment and at least 3 months after the last dose of Ofev AND</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Lifetime</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>See criteria</td>
</tr>
<tr>
<td></td>
<td>One year</td>
</tr>
<tr>
<td></td>
<td>One year</td>
</tr>
<tr>
<td></td>
<td>One year</td>
</tr>
<tr>
<td></td>
<td>One year</td>
</tr>
<tr>
<td></td>
<td>One year</td>
</tr>
<tr>
<td>OMEGA-3 ETHYL ESTERS</td>
<td>Omega-3-acid ethyl esters will be approved for members that have confirmed diagnosis of hypertriglyceridemia defined as TG ≥ 500 mg/dL</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Quantity Limits: 60 tablets/30 days</td>
<td></td>
</tr>
<tr>
<td>ONFI (clobazam)</td>
<td>ONFI® will be approved for members who meet the following criteria:</td>
</tr>
<tr>
<td>• Member is &gt; 2 years of age AND</td>
<td></td>
</tr>
<tr>
<td>• Has a documented diagnosis of seizure AND</td>
<td></td>
</tr>
<tr>
<td>• Is being prescribed by or in conjunction with a neurologist AND</td>
<td></td>
</tr>
<tr>
<td>• Has failed a one month trial with three anticonvulsants (Failure is defined as: lack of efficacy, allergy, intolerable side effects contraindication to, or significant drug-drug interactions).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>OPIOID AGONIST/ANTAGONIST</td>
<td>Revia (naltrexone) - A PA is not required.</td>
</tr>
<tr>
<td></td>
<td><strong>Naloxone vial or prefilled syringe</strong> – a prior authorization is not required.</td>
</tr>
<tr>
<td></td>
<td>The atomizer device for use with naloxone can be obtained by the pharmacy billing as a DME claim code A4210.  The unit limit is 1 atomizer per vial/syringe dispensed up to a total of 15 per year.  A prior authorization is not required.</td>
</tr>
<tr>
<td></td>
<td><strong>Bunavail® (buprenorphine/naloxone) buccal film</strong> will be approved for members who meet the following criteria:</td>
</tr>
<tr>
<td>• Approval will be granted if the prescriber meets the qualification criteria under the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescribe Subutex® or Suboxone® AND</td>
<td></td>
</tr>
<tr>
<td>• The member has a diagnosis of opioid dependence AND</td>
<td></td>
</tr>
<tr>
<td>• The member is 16 years of age or older AND</td>
<td></td>
</tr>
<tr>
<td>• No claims data show concomitant use of opiates in the preceding 30 days unless the physician attests the member is no longer using opioids AND</td>
<td></td>
</tr>
<tr>
<td>• The member must have tried and failed, intolerant to, or has contraindication to generic buprenorphine/naloxone SL tablets or Suboxone films.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Evzio (naloxone)</strong> will be approved if nasal route of administration (via nasal atomizer) cannot be used.</td>
</tr>
<tr>
<td></td>
<td><strong>Narcan (naloxone)</strong> will be approved if nasal route of administration (via nasal atomizer) cannot be used.</td>
</tr>
<tr>
<td></td>
<td><strong>Suboxone (buprenorphine/naloxone)</strong> will be approved if the following criteria are met:</td>
</tr>
<tr>
<td>• The prescriber is authorized by the manufacturer to prescribe Suboxone</td>
<td></td>
</tr>
<tr>
<td>• The member has an opioid dependency</td>
<td></td>
</tr>
<tr>
<td>• The member is not currently receiving an opioid or opioid combination product unless the physician attests the member is no longer using opioids.</td>
<td></td>
</tr>
<tr>
<td>• Will not be approved for the treatment of pain.</td>
<td></td>
</tr>
<tr>
<td>• Opioid claims will not be allowed for members with a claim for Suboxone in the preceding 30 days.</td>
<td></td>
</tr>
</tbody>
</table>
Subutex (buprenorphine) will be approved if all of the following criteria are met:

- The prescriber is authorized by the manufacturer to prescribe Subutex
- The member has an opioid dependency
- The member is pregnant or the member is allergic to Naloxone
- Subutex will not be approved for the treatment of pain.
- Subutex will not be approved for more than 24mg/day

Vivitrol (naltrexone)

- Approval will be given if administered in the member’s home or in a long-term care facility. If given in the hospital or physician’s office, the claim must be billed as a medical expense.

Zubsolv (buprenorphine/naloxone)

- Approval will be granted if the prescriber meets the qualification criteria under the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescribe Subutex or Suboxone AND
- The member has a diagnosis of opioid dependence AND
- The member is 16 years of age or older AND
- No claims data show concomitant use of opiates in the preceding 30 days unless the physician attests the member is no longer using opioids AND
- The member must have tried and failed, intolerant to, or has a contraindication to generic buprenorphine/naloxone SL tablets or Suboxone films.

OPHTHALMIC ALLERGY PRODUCTS

This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

OPIOD MEDICATIONS

The total daily limit of milligrams of morphine equivalents will be 300mg effective 2/17/2016. This includes opioid-containing products where conversion calculations are applied. Prescriptions that cause the member’s drug regimen to exceed the maximum daily limit of 300 milligrams of morphine equivalents (MME) will be denied. This does not currently include methadone prescriptions.

- Prior authorizations will be granted to allow for tapering.
- Diagnosis of sickle cell anemia will receive a preemptive PA for lifetime.
- A one year PA will be granted for admission to or diagnosis of hospice or end of life care.
- A one year PA will be granted for pain associated with cancer.
- Medicaid provides guidance on the treatment of pain, including tapering, on our website Pain Management Resources and Opioid Use at [www.Colorado.gov/hcpf](http://www.Colorado.gov/hcpf) then search Pain Management.
- Only one long-acting oral opioid agent (including different strengths) and one short-acting opioid agent (including different strengths) will be considered for a prior authorization.

Long-acting opioids are a part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

OPIODS- ORAL SHORT ACTING

Short acting opioids will be limited to a total of 120 tablets per 30 days per member. Exceptions will be made for members with a diagnosis of a terminal illness (hospice or palliative care) or sickle cell anemia. For members who are receiving more than

Chronic pain: 6 months to
120 tablets currently and who do not have a qualifying exemption diagnosis, a 6 month prior authorization can be granted via the prior authorization process for providers to taper members. Please note that if more than one agent is used, the combined total utilization may not exceed 120 units in 30 days. Information regarding tapering, morphine equivalents, other therapies and other resources can be found on the Department website at: https://www.colorado.gov/hcpf/provider-forms.

Acute Pain: If a member has an acute pain situation, and is prescribed more than 4 tablets per day, the pharmacy may enter diagnosis code G89.1 on the claim to receive an immediate override. Please note that the override will be available for acute pain indications only. Prior authorization will still be required for more than 120 tablets per 30 days. The Department will monitor the utilization of the diagnosis code to assure it is being used to override daily limits for cases of acute pain indications only. The pharmacy or prescriber may also still call 1-800-365-4944 and request a prior authorization for acute pain. Examples of acute pain situations are post-operative surgery (including dental), fractures, shingles, and a car accident. This is not an all-inclusive list.

ORACEA (doxycycline)
A prior authorization will only be approved if all of the following criteria are met:

- member has taken generic doxycycline for a minimum of three months and failed therapy in the last 6 months (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions),
- member has been diagnosed with rosacea with inflammatory lesions, and
- member is 18 years of age or older

ORKAMBI (lumacaftor/ivacaftor)
ORKAMBI® will be approved for members if the following criteria has been met:

- Member must have diagnosis of cystic fibrosis with genetic testing performed to confirm that member is homozygous for the F508del mutation in the CFTR gene AND
- Member is 6 years of age or older AND
- Member is being treated by a pulmonologist AND
- Member has < 5 times upper limit of normal (ULN) AST/ALT or < 3 times ULN AST/ALT if concurrently has > 2 times ULN bilirubin at time of initiation AND
- Member has serum transaminase and bilirubin measured before initiation and every 3 months during the first year of treatment

OTC PRODUCTS
Medical Necessity

- Aspirin, Insulin and Plan B are covered without a PA
- Prilosec OTC: See Proton Pump Inhibitor’s section
- Guaifenesin 600mg LA is covered for members having an abnormal amount of sputum
- Quinine Sulfate is no longer covered for leg cramps
- Herbal products are not a benefit except for cranberry tablets, which are covered for urinary tract infections
- Diabetic needles and supplies are not a prescription benefit and should be billed as supply
- Broncho saline is not covered- refer to Sodium Chloride section
- Cough and Cold Products must have a diagnosis of a chronic respiratory condition for which these medications may be prescribed or otherwise be medically necessary
- Antihistamine (w/ decongestant) must have a diagnosis of seasonal or perennial allergic rhinitis or chronic sinusitis or otherwise be medically necessary
- Nicomide is approved for acne

Nursing Facilities: Please provide OTC floor stock list.
*Members with Erythema Bullosum (EB) can receive any OTC medication with a prior authorization.*

<table>
<thead>
<tr>
<th>Drug/Class</th>
<th>Description</th>
<th>Effective Date</th>
<th>Prior Authorization Requirements</th>
</tr>
</thead>
</table>
| **OTEZLA (apremilast)** | This drug is part of the Preferred Drug List (PDL). Please refer to the PDL posted at https://www.colorado.gov/hcpf/provider-forms | 4/1/2017 | Approval will be granted for members who meet the following criteria:  
- Member has diagnosis for rheumatoid arthritis AND  
- Member cannot take methotrexate by mouth due to intolerable gastrointestinal side effects AND  
- Member cannot take an injection due to limited functional ability. |
| **OTREXUP (methotrexate)** | METHOTREXATE AUTOINJECTOR authorization will be approved for members who meet the following criteria: | 4/1/2017 | One year |
| **OVERACTIVE BLADDER AGENTS** | This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at https://www.colorado.gov/hcpf/provider-forms for the Preferred Products. | 4/1/2017 | One year |
| **OXSORALEN (methoxsalen)** | Approval will be granted with diagnosis of: Myosis; Fungoides; Psoriasis or Vitiligo | 4/1/2017 | One year |
| **PANCREATIC ENZYMES** | This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at https://www.colorado.gov/hcpf/provider-forms for the Preferred Products. | 4/1/2017 | One year |
| **PCSK9 INHIBITORS** | PCSK9 injections will be approved for members that meet the following criteria:  
- Member has the below diagnosis for each agent below:  
  - Praluent: heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease  
  - Repatha: heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease AND  
- PCSK9 is prescribed by one of the following providers: AND  
  - Cardiologist  
  - Lipid Specialist  
  - Endocrinologist AND  
- Member is concurrently adherent (>80% of the past 180 days) on maximum doses (see table below) of statin therapy (must include atorvastatin and rosuvastatin). If member is intolerant to statins due to side effects, must have documented three-month trial and failure of pravastatin and one other statin at lower doses and/or every other day treatment. For members with a past or current incidence of rhabdomyolysis, three-month failure is not required AND  
- The member has not achieved 50% reduction in LDL-C from baseline while > 80% adherent for the past 180 days on maximally tolerated statin, diet and adjunct lipid lowering therapies AND  
- Prescribing provider attests to providing appropriate counseling to advise a diet with sufficient fruits and vegetables, fiber, and omega-3 fatty acids AND  
- Member must be concurrently treated (in addition to statin) with one of the following unless contraindicated or significant safety concern exists: ezetimibe, niacin, and bile acid sequestrate AND  
- LDL-C levels must be > 250 AND | 4/1/2017 | Max - One year |

| Statin | | |
|-------|------------------|
| Atorvastatin 80mg | |
| Fluvastatin 80 mg | |
| Lovastatin 80 mg | |
| Pravastatin 80 mg | |
| Rosuvastatin 40 mg | |
| Simvastatin 40 mg (80 mg not used in practice) | |
**PHENOBARBITAL**

For Medicaid primary members, barbiturates (phenobarbital) will be approved for use in epilepsy, cancer, chronic mental health disorder, sedation, treatment of insomnia, tension headache, muscle contraction headache and treatment of raised intracranial pressure. All other uses will require manual review.

Phenobarbital will be approved for neonatal narcotic abstinence syndrome based on the following criteria:

- The member has a diagnosis of non-opiate or polysubstance abuse OR
- The member has first failed methadone for the diagnosis of opiate withdrawal AND
- Serum phenobarbital levels are being monitored.

Max duration: 3 months

**PHYSICIAN ADMINISTERED DRUGS**

Medications given in a hospital, doctor’s office or dialysis unit are only to be billed directly by those facilities as a medical item. IV Fluids, meds, etc. may be billed by the pharmacy when given in a long-term care facility or by home infusion following prior authorization approval. Prior authorizations will be approved based upon documentation of the location for administration.

**PROCYSBI (cysteamine)**

Approval will be granted if the member is 2 years of age or older AND

- Has a diagnosis of nephropathic cystinosis AND documentation is provided to the Department that treatment with cysteamine IR (Cystagon®) was ineffective, not tolerated, or is contraindicated.

Max duration: 1 year otherwise

**PROMACTA (eltrombopag)**

Promacta will be approved for members with **Chronic Immune Thrombocytopenia Purpura (ITP)** if the following criteria is met:

- Confirmed diagnosis of chronic (> 3 months) immune idiopathic thrombocytopenia purpura AND
- Must be prescribed by a hematologist AND
- Member is at risk (documented) of spontaneous bleed as demonstrated by the following labs: AND
  - Platelet count less than 20,000/mm3 or
  - Platelet count less than 30,000/mm3 accompanied by signs and symptoms of bleeding
- In the past 6 months, member has tried and failed (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) systemic corticosteroids (e.g. prednisone 1 to 2 mg/kg for 2 to 4 weeks, or pulse dexamethasone 40 mg daily for 4 days), immunoglobulin replacement, or splenectomy.

Promacta will be approved for members with **Thrombocytopenia associated with Hepatitis C** if the following criteria is met:

- Member must have confirmed diagnosis of chronic hepatitis C associated thrombocytopenia AND
- Must be prescribed by a gastroenterologist, infectious disease specialist, transplant specialist or hematologist AND
- Member has clinically documented thrombocytopenia defined as platelets < 60,000 microL AND

Max duration: 1 year
- Patients’ degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy.

Promacta will be approved for members with **Severe Aplastic Anemia** if the following criteria is met:

- Member must have confirmed diagnosis of Severe Aplastic Anemia AND
- Must be prescribed by a hematologist AND
- Member must have had a documented insufficient response to immunosuppressive therapy (antithymocyte globulin (ATG) alone or in combination with cyclosporine and/or a corticosteroid

*Prior authorizations will be granted for 12 months. Further approvals for a maximum of 6 months require lab results and documentation for efficacy.

### PROMETHAZINE

A Prior authorization is required for all routes of administration for members under the age of two. Children under the age of two should not use Promethazine. Promethazine is contraindicated in such patients because of the potential for fatal respiratory depression.

### PROPECIA (finasteride)

*Not covered for hair loss*

### PROTON PUMP INHIBITORS

This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

### PULMONARY ARTERIAL HYPERTENSION THERAPIES

This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

### PULMOZYME (dornase alfa)

Pulmozyme will be approved for members that meet the following criteria:

- Member has a diagnosis of cystic fibrosis AND
- Member is five years of age or older
  - For children < 5 years of age, Pulmozyme will be approved if the member has severe lung disease as documented by bronchoscopy or CT scan

Pulmozyme twice daily will only be approved if patient has tried and failed an adequate trial of once daily dosing for one month.

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon documentation from the prescriber that the member continues to benefit from Pulmozyme therapy.
<table>
<thead>
<tr>
<th><strong>Quantity Limits:</strong> 30 ampules (2.5 mg/2.5 ml) per month</th>
<th></th>
</tr>
</thead>
</table>
| **RASUVO (methotrexate) Auto-Injector** | Rasuvo will be approved for members who meet the following criteria:  
- Member has diagnosis for rheumatoid arthritis AND  
- Member cannot take methotrexate by mouth due to intolerable gastrointestinal side effects AND  
- Member cannot take a methotrexate injection via syringe due to limited functional ability | One year |
| **RAVICTI (glycerol phenylbutyrate)** | Ravicti will only be approved for members meeting the following criteria:  
- Member must be 2 years of age or older  
- Member must have a documented diagnosis of urea cycle disorder (UCD)  
- Member must be on a dietary protein restriction (verified by supporting documentation)  
- Member must have tried and failed Buphenyl as evidenced by uncontrolled hyperammonia over the past 365 days  
- Medication must be prescribed by a physician experienced in the management of UCD (e.g., geneticist) | One year |
| **REBATE DISPUTE DRUGS** | Medical necessity. | Not qualified for emergency 3 day supply PA |
| **REQUIP XL (pramipexole)** | A prior authorization will only be approved if a member has tried and failed on generic immediate release ropinirole for a period of 3 or more months in the last 6 months and the member has a diagnosis of Parkinson’s disease. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) | One year |
| **REVIA (naltrexone)** | Please see opioid agonist/antagonist. | N/A |
| **RESPIRATORY INHALANTS** | This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products. | One year |
| **SANDOSTATIN (octreotide)** | Approved for: acromegaly; carcinoid tumors; and vasoactive intestinal peptide tumors. | Lifetime |
| **SEDATIVE/HYPNOTICS** | This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products. | One year |
| **SILENOR (doxepin)** | A prior authorization will be approved if a member meets one of the following criteria:  
- Contraindication to preferred oral sedative hypnotics (Lunesta, zaleplon and zolpidem)  
- Medical necessity for doxepin dose < 10 mg  
- Age greater than 65 years old or hepatic impairment (3 mg dose will be approved if this criteria is met) | One year |
| **SIMVASTATIN 80mg** | Simvastatin 80mg dose products will only be covered for members who have been stable for more than 12 months at that dose. Providers should consider alternate preferred statins in members who have not met cholesterol goals on simvastatin at | One year |
### SKELETAL MUSCLE RELAXANTS
This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

### SODIUM CHLORIDE
For inhalation use

Broncho Saline is **not** covered as a drug benefit.

Inhaled NaCl is now classified as a supply and can only be billed as medical.

All requests for sodium chloride (inhalation use) must be billed through medical.

### SOLARAZE 3% GEL (diclofenac sodium)
A prior authorization will only be approved if the member has a diagnosis of Actinic Keratoses (AK).

### STADOL (butorphanol) nasal spray
**Quantity limit:** 10mg/ml 2.5ml bottle limit of 4 bottles (10ml) per 30 days

### STATINS
This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

### STIMULANTS and OTHER ADHD AGENTS
This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products.

### SUBOXONE and SUBUTEX
Please refer to Opioid Agonist/Antagonist

### SYNAGIS (Palivizumab)
Pharmacy Prior Authorization requests for Synagis® must be submitted by fax or phone using the Synagis® Prior Authorization Form found at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms). Medical PAs must be submitted through eQHealth at [http://co.eqhs.org](http://co.eqhs.org). Synagis season will begin November 30, 2016 and end April 30, 2017. PARs may be requested beginning November 16, 2016.

**Key Points**

1. No more than 5 doses per season. 5 doses provide more than 6 months of protective serum concentration.
2. Synagis® is not recommended for controlling outbreaks of health care-associated disease.
4. Infants born later in the season may require less than 5 doses to complete therapy to the end of the season.
5. Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.
6. Synagis® is not recommended to prevent wheezing, nosocomial disease, or treatment of RSV
7. Synagis® is not routinely recommended for patients with a diagnosis of Down syndrome unless they also have a qualifying indication listed below.

8. **In the first year of life** Synagis® is recommended:
   a. For infants born before 29w 0d gestation.
   b. For infants born before 32w 0d **AND** with CLD of prematurity **AND** requirements of >21% oxygen for at least 28 days after birth.
   c. For infants with hemodynamically significant heart disease (cyanotic heart disease who are receiving medication to control CHF and will require cardiac surgical procedures **AND** infants with moderate to
severe pulmonary hypertension) **AND** born within 12 months of onset of the RSV season.

d. Children who undergo cardiac transplantation during the RSV season.

e. For infants with cyanotic heart defects **AND** in consultation with a pediatric cardiologist **AND** requirements of >21% oxygen for at least 28 days after birth **AND** continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy)

f. If an infant has neuromuscular disease or pulmonary abnormality **AND** is unable to clear secretions from the upper airways

g. A child who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy)

h. An infant with cystic fibrosis with clinical evidence of CLD **AND/OR** nutritional compromise

9. In the **second year of life** Synagis® is recommended for:

a. Infants born before 32w 0d **AND** with CLD of prematurity **AND** requirements of >21% oxygen for at least 28 days after birth **AND** continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy)

b. A child who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy)

c. Infants with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities of chest radiography or chest computed tomography that persist when stable) **OR** weight for length less than the 10th percentile.

d. Children who undergo cardiac transplantation during the RSV season.

<table>
<thead>
<tr>
<th>TARGETED IMMUNE MODULATORS (iv infused products)</th>
<th>Entyvio (vedolizumab) – On a case by case basis</th>
<th>One year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TARGETED IMMUNE MODULATORS (self-administered)</strong></td>
<td><strong>Orencia (abatacept)</strong> – will be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following:**</td>
<td><strong>Remicade (infliximab)</strong> will be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following:**</td>
</tr>
<tr>
<td><strong>Members with moderate to severe rheumatoid arthritis who have failed therapy with both Enbrel and Humira</strong></td>
<td><strong>members with ulcerative colitis</strong></td>
<td><strong>Members with moderate to severe juvenile idiopathic arthritis</strong></td>
</tr>
<tr>
<td><strong>Members with moderate to severe juvenile idiopathic arthritis</strong></td>
<td><strong>members with rheumatoid arthritis who have tried and failed therapy with both Enbrel and Humira</strong></td>
<td><strong>members with ankylosing spondylitis</strong></td>
</tr>
<tr>
<td><strong>Remicade (infliximab)</strong> will be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following:**</td>
<td><strong>members with psoriatic arthritis</strong></td>
<td><strong>members with juvenile idiopathic arthritis</strong></td>
</tr>
<tr>
<td><strong>members with plaque psoriasis</strong></td>
<td><strong>members with Crohn’s Disease</strong></td>
<td><strong>members with Chronic Lymphocytic Leukemia</strong></td>
</tr>
<tr>
<td><strong>members with Non-Hodgkins Lymphoma</strong></td>
<td><strong>Rituxan (rituximab)</strong> - will be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following:**</td>
<td><strong>Members with moderate to severe rheumatoid arthritis who have tried and failed both Enbrel and Humira</strong></td>
</tr>
<tr>
<td><strong>Members with Chronic Lymphocytic Leukemia</strong></td>
<td><strong>Members with Non-Hodgkins Lymphoma</strong></td>
<td><strong>Members with Chronic Lymphocytic Leukemia</strong></td>
</tr>
</tbody>
</table>

This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at [https://www.colorado.gov/hcpf/provider-forms](https://www.colorado.gov/hcpf/provider-forms) for the Preferred Products. One year
<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DESCRIPTION</th>
<th>REIMBURSEMENT</th>
<th>LIMITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>TESTOSTERONE PRODUCTS</td>
<td>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</td>
<td>One year</td>
<td></td>
</tr>
<tr>
<td>THROMBOLYTIC ENZYMES</td>
<td>Approved for IV Catheter Clearance or Occluded AV Cannula if given in member’s home or long term care facility.</td>
<td>One year</td>
<td></td>
</tr>
<tr>
<td>TOBACCO CESSATION (Rx &amp; OTC)</td>
<td>Prior authorization is required for all tobacco cessation medications except for the first fill of the gum/lozenge form of short-acting nicotine replacement therapy (NRT). Members can receive combination therapy with patch form of long-acting NRT and gum/lozenge short-acting NRT per 90 day benefit. Members should be referred to the QuitLine or another behavior modification program. The name of that program should be included on the prior authorization form. Medical Assistance Program will pay for multiple strengths of a product (patch, gum, or lozenge) or multiple products during the two 90-day paid benefit periods.</td>
<td>Two 90-day paid benefits per year</td>
<td>Not qualified for emergency 3 day supply PA</td>
</tr>
<tr>
<td>TOPICAL IMMUNOMODULATORS</td>
<td>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</td>
<td>One year</td>
<td></td>
</tr>
<tr>
<td>TORADOL (ketorolac)</td>
<td><strong>Quantity limit:</strong> 5 days of therapy for every 30 days = 20 tablets per 30 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TPN PRODUCTS</td>
<td>Approval will be given if administered in the member’s home or in a long-term care facility. If given in the hospital or physician’s office, the claim must be billed as a medical expense.</td>
<td>Lifetime</td>
<td></td>
</tr>
<tr>
<td>TRAMADOL</td>
<td>Tramadol is not approved for more than 400mg/day.</td>
<td>One year</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Rybox ODT</strong>&lt;br&gt; Rybox will be approved for members who are unable to swallow oral tablets or for members who are unable to absorb oral medications (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Ryzolt</strong>&lt;br&gt; A prior authorization will only be approved if a member has tried and failed on the maximum dose of tramadol (400mg per day) for a period of 3 or more months in the last six months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRIPTANS</td>
<td>This class is part of the Preferred Drug List (PDL). Please refer to the PDL posted at <a href="https://www.colorado.gov/hcpf/provider-forms">https://www.colorado.gov/hcpf/provider-forms</a> for the Preferred Products.</td>
<td>One year</td>
<td></td>
</tr>
<tr>
<td>TYBOST (Cobicistat)</td>
<td><strong>TYBOST®</strong> will be approved for members who meet the following criteria:&lt;br&gt; - Member has a diagnosis of HIV-1 AND&lt;br&gt; - Member is currently being treated with atazanavir or darunavir only AND&lt;br&gt; - Member is not taking cobicistat-containing drugs, or ritonavir-containing drugs AND&lt;br&gt; - Member has failed treatment with ritonavir (failure defined as intolerable side effect, allergy, or lack of efficacy).</td>
<td>One year</td>
<td></td>
</tr>
<tr>
<td>VACCINES</td>
<td>All other vaccines must be bill on Colorado 1500 form as a medical expense unless administered in long-term care facility. Any vaccine can be approved by prior authorization if a member is living in a long-term care facility. (Not a covered benefit for regular patients – only long-term care facilities).</td>
<td>One year</td>
<td>Not qualified for emergency 3 day supply PA</td>
</tr>
</tbody>
</table>
| VALCYTE (valganciclovir hydrochloride) | Valcyte will be approved for members with diagnosis of Cytomegalovirus (CMV) retinitis AND acquired immunodeficiency Syndrome (AIDS) per dosing guidelines below
For members that require prophylactic treatment for CMV post kidney, heart or kidney-pancreas transplant per dosing guidelines below
OR
For members ≤ 16 years of age that are at high risk of CMV infection and need prophylactic treatment post heart or kidney transplant per dosing guidelines below |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adult Dosage</strong></td>
<td><strong>Pediatric Dosage</strong></td>
</tr>
<tr>
<td><strong>Treatment of CMV retinitis</strong></td>
<td><strong>Prevention of CMV disease in kidney transplant patients 1 month to 16 years of age</strong></td>
</tr>
<tr>
<td>Induction: 900 mg (two 250 mg tablets) twice a day for 21 days</td>
<td>Dose once daily within 10 days of transplantation until 100 days post-transplantation</td>
</tr>
<tr>
<td>Maintenance: 900 mg once a day</td>
<td></td>
</tr>
<tr>
<td><strong>Prevention of CMV disease in heart or kidney-pancreas patients</strong></td>
<td><strong>Prevention of CMV disease in kidney transplant patients 4 month to 16 years of age</strong></td>
</tr>
<tr>
<td>900 mg once a day within 10 days of transplantation 100 days post-transplantation</td>
<td>Dose once daily within 10 days of transplantation until 200 days post-transplantation</td>
</tr>
<tr>
<td><strong>Prevention of CMV disease in kidney transplant patients</strong></td>
<td><strong>Prevention of CMV disease in heart transplant patients 1 month to 16 years of age</strong></td>
</tr>
<tr>
<td>900 mg once a day within 10 days of transplantation until 200 days post-transplantation</td>
<td>Dose once a day within 10 days of transplantation until 100 days post-transplantation</td>
</tr>
</tbody>
</table>

| VELTASSA (patiromer) | A prior authorization will be approved for members that meet the following criteria:
- Documented diagnosis of hyperkalemia (serum potassium > 5 mEq/L) AND
- Veltassa is not being used for emergent hyperkalemia AND
- Member does not have severe gastrointestinal motility dysfunction AND
- Member does not have hypomagnesemia (serum magnesium < 1.4 mg/dL) |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VERIPRED (prednisolone)</th>
<th>A prior authorization will only be approved if a member has tried and failed on a generic prednisolone product (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One year</td>
</tr>
</tbody>
</table>

| VERSED (Midazolam) | Approved if given in the member’s home or in a long-term care facility and given for:
- Preoperative sedation or anesthesia
- Terminally ill members with Cancer
- Member with Erythema Bullosum (EB) – approval for one year |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One month</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VERSED</th>
<th>Midazolam injection used as nasal spray</th>
</tr>
</thead>
</table>
| Midazolam injection used as a nasal inhalation will be approved for members who meet the following criteria:
1. Member is > 6 months of age AND
2. Has a diagnosis of seizure disorder AND
3. Is prescribed by or in conjunction with a Neurologist AND
4. Treatment dose does not exceed 10mg |
| | One year |

<table>
<thead>
<tr>
<th>Dosing Limits:</th>
<th>Only MIDAZOLAM 5mg/ml (for doses ≤ 5mg) and 10mg/2ml (for doses &gt; 5 mg) will be covered.</th>
</tr>
</thead>
</table>
The atomizer device for use with midazolam can be obtained by the pharmacy billing as a DME claim code A4210. The atomizer dispensed limit is up to a total of 15 per year. A prior authorization is not required.

### VIBERZI (eluxadoline)

A prior authorization will be approved for members that meet the following criteria:
- Documented diagnosis of Irritable Bowel Syndrome (IBS) with diarrhea AND
- Member does not have severe (Child-Pugh C) hepatic impairment, history of severe constipation, known mechanical gastrointestinal obstruction, biliary duct obstruction, history of pancreatitis or structural disease of the pancreas AND
- Member does not drink more than 3 alcoholic drinks per day AND
- Member has tried and failed a 10 day treatment with both loperamide AND dicyclomine OR hyoscamine

### VIMOVO (naproxen/esomeprazole magnesium)

Approved if member has failed treatment with two Preferred Proton Pump Inhibitors within the last 24 months, and has one of the following diagnoses:
- Ankylosing spondylitis in patients at increased risk of developing NSAID induced ulcers;
- Osteoarthritis in patients at increased risk of developing NSAID induced ulcers;
- Rheumatoid arthritis in patients at increased risk of developing NSAID induced ulcers.

### VITAMINS (Rx)

**Prescription Vitamins (except for prenatals) will be authorized for:**
- ESRD, CRF, renal insufficiency, diabetic neuropathy or renal transplant
- Members under the age of 21 with a diagnosis disease that prohibits the nutrition absorption process as a secondary effect of the disease.
- Members with Erythema Bullosum (EB)

Hydroxocobalamin Injections
In addition to the above general vitamin criteria, approval can also be given for methylmalonic academia (MMA).

Cyanocobalamin Injections
In addition to the above general vitamin criteria, approval can also be given for vitamin B12 deficiency.

Folic Acid Vitamins (exceptions exist for Folic Acid 1mg, see below)
In addition to the above general vitamin criteria, approval can also be given for folic acid vitamins if one of the following criteria is met:
- Currently taking Methotrexate or Alimta
- A diagnosis of folic acid deficiency (megaloblastic and macrocytic anemia are the most common). Some drugs or other conditions may cause deficiency -- Approval will be granted for these indications IF the member has current folic acid deficiency and documented by the provider.
- For Female Members: Approval will be granted for the prevention of a neural tube defect pregnancy and for the prevention of miscarriages.
- Homocysteinemia
- Sickle cell disease

Cyanocobalamin/Folic Acid/Pyridoxine
In addition to the above general vitamin criteria, approval can also be given for members:
- with Homocysteinemia or Homocystinuria
- on dialysis
- with or at risk for cardiovascular disease

---

Revision Date: 3/1/2017 Effective 4/1/2017 | Page A-29
**L-methylfolate** approved for depressed members who are currently taking antidepressants and are partial or non-responders

**Metanx** approved for members with non-healing diabetic wounds

**Prenatal Vitamins** are a regular benefit for all female members. Prenatal vitamins are not covered for male members.

**Folic Acid 1mg** does not require a prior authorization for female members.

**Prescription Vitamin D and Vitamin K products** do not require a prior authorization.

**VIVITROL**  
Please refer to Opioid Agonist/Antagonist

**VUSION OINTMENT**  
(miconazole/zinc oxide/white petrolatum)  
A prior authorization will only be approved if a member has failed on an OTC antifungal and a generic prescription antifungal. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)  
One year

**XERESE**  
(acyclovir/hydrocortisone)  
A prior authorization will be approved for members that meet the following criteria:  
- Documented diagnosis of recurrent herpes labialis AND  
- Member is immunocompetent AND  
- Member has failed treatment of at least 10 days with acyclovir (please refer to the Anti-Herpetic Agents segment of the PDL for dose recommendations). Failure will be defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects) AND  
- Member has failed treatment of at least one day with famciclovir 1500 mg OR valacyclovir 2 GM twice daily (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects)  
One year

**XOLAIR** (omalizumab)  
A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility. Medications administered in a physician’s office must be billed as a medical expense. Because this medication has a Black Box warning requiring the administration under the supervision of a physician, a PA will not be approved if administered in a member’s home.  
One year

**YOSPRALA**  
(aspirin/omeprazole)  
Delayed release tablets  
Yosprala will be approved for members who meet the following criteria:  
- Member requires aspirin for secondary prevention of cardiovascular or cerebrovascular events AND  
- Member is at risk of developing aspirin associated gastric ulcers (member is ≥ 55 years of age or has documented history of gastric ulcers) AND  
- Member has failed treatment with three preferred proton pump inhibitors in the last 6 months (Failure is defined as: lack of efficacy of a seven-day trial, allergy, intolerable side effects, or significant drug-drug interaction.)  
One year

**ZUBSOLV**  
Please refer to Opioid Agonist/Antagonist