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/pharmacy-resources
- 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/
- DME questions should be directed to DXC Technology (Formerly Hewlett Packard Enterprise) 1-844-235-2387. 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.
- Initiation of pharmaceutical product subject to Prior Authorization:
  - Please note that starting the requested drug, including a non-preferred drug, prior to a PA request being reviewed and approved, through either inpatient use, by using office "samples", or by any other means, does not necessitate Medicaid approval of the PA request.

<table>
<tr><th>Drug</th><th>Criteria</th><th>PAR Length</th></tr>
<tr><td>Drug classes that have been migrated to the Preferred Drug List (PDL)

https://www.colorado.gov/hcpf/pharmacy-resources</td><td>Anticoagulants (oral), Antidepressants, Antiemetics, Antiherpetics, Antihistamines with decongestants, Antihypertensives, Antiplatelets, Atypical Antipsychotics (oral), Bisphosphonates (oral), Constipation (opioid-induced), Diabetes Management Classes, Erythropoiesis Stimulating Agents, Fibromyalgia Agents, Filgrastim/Pegfilgrastim/Sargromastim/Filgrastim-SNDZ, Fluoroquinolones, Growth Hormones, Hepatitis C Virus Treatments, Insulin, Intranasal Corticosteroids, Leukotrienes, Multiple Sclerosis Agents, Neurocognitive Disorder Agents, Ophthalmic Allergy Products, Otezla (apremilast), Overactive Bladder Agents, Pancreatic Enzymes, Proton Pump Inhibitors, Pulmonary Arterial Hypertension Therapies, Respiratory Inhalants, Sedative Hypnotics, Skeletal Muscle Relaxants, Stimulants and other ADHD Agents, Targeted Immune Modulators (self-administered), Testosterone Products, Topical Immunomodulators, Triptans</td><td></td></tr>
<tr><td>ACETAMINOPHEN CONTAINING PRODUCT MAXIMUM DOSING</td><td>A prior authorization is required for dosages of acetaminophen exceeding 4000mg/day.

Doses over 4000mg/day are not qualified for emergency 3 day supply approval</td><td>N/A</td></tr>
<tr><td>ALBUMIN</td><td>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</td><td>One year</td></tr>
<tr><td>ALINIA (nitazoxanide)</td><td>Alinia® (nitazoxanide) may be approved for members meeting the following criteria:
Alinia® is being prescribed for diarrhea caused by Giardia lamblia or Cryptosporidium parvum AND
Member is 1 year of age or older AND
If Alinia® is being used to treat diarrhea due to C. parvum in members with Human Immunodeficiency Virus (HIV) infection, the member is receiving antiretroviral therapy AND
Prescription meets the following FDA-labeled dosing:
<table><tr><th>Age (years)</th><th>Dosage of Nitazoxanide</th><th>Duration</th></tr><tr><td>1-3</td><td>5 mL (100mg) oral suspension every 12 hours with food</td><td></td></tr><tr><td>4-11</td><td>10 mL (200mg) oral suspension every 12 hours with food</td><td>3 days</td></tr><tr><td>>11</td><td>500mg orally every 12 hours with food</td><td></td></tr></table>Note: The tablet product formulation is currently not reported as an active drug in the Medicaid Drug Rebate Program (MDRP) and will not be covered until such a time that there is change made to rebate status for this product.</td><td>One year</td></tr>
<tr><td>ALLERGY EXTRACT PRODUCTS (Oral)
Grastek, Oralair, Ragwitek</td><td>Grastek (Timothy grass pollen allergen extract)

Must be between 5 and 65 years old.
Must not be pregnant or nursing.
Must be prescribed by an allergist.</td><td>One year</td></tr>
</table>

Must have a documented diagnosis to ONLY timothy grass pollen allergen extract or the Pooideae 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 5 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, 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 • **Zemaira®**: Chronic augmentation and maintenance therapy in members with Alpha- 1 Proteinase Inhibitor deficiency with clinically evident emphysema	Lifetime
ANOREXIANTS	Weight loss medications are not a covered benefit. Adipex P (phentermine) Belviq (lorcaserin)	Weight loss drugs are not a

	Contrave (naltrexone/bupropion) Lomaira (phentermine) Qsymia (phentermine/topiramate ER) Phentermine Saxenda (liraglutide) Xenical (Orlistat)	covered benefit.
ANTI-ANEMIA MEDICATIONS	Oral prescription iron products may be approved for members with a diagnosis of iron deficient anemia (applies to products available by prescription only) Injectable anti-anemia agents (such as Infed, Ferrlecit, Venofer) may be approved for members meeting the following criteria: • Member has a diagnosis of iron deficient anemia **AND** • Oral preparations are ineffective or cannot be used **AND** • Medication is being administered in a long-term care facility or in the member's home by a home healthcare provider Note: For coverage criteria for OTC **f**errous sulfate and ferrous gluconate, refer to "OTC Products" section.	Lifetime
ATYPICAL ANTIPSYCHOTIC INJECTABLES Abilify Maintena, Aristada, Geodon injection, Invega Sustenna, Invega Trinza, Perseris ER, Risperdal Consta, Zyprexa Relprevv	A prior authorization may be approved for when the medication is administered in a long-term care facility or in a member's home by a healthcare professional. *Oral atypical antipsychotic criteria can be found on the preferred drug list.*	One year
BACTROBAN (mupirocin) Cream and Nasal Ointment	**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 cm^2 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.	Cream: One year Nasal Ointment: Lifetime
BARBITURATEs **Coverage for Medicare dual-eligible members**	<u>Dual-eligible Medicare-Medicaid Beneficiaries:</u> Beginning on January 1, 2013 Colorado Medicaid will no longer cover barbiturates for Medicare-Medicaid enrollees (dual-eligible members). For Medicaid 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	(3 months for neonatal narcotic abstinence syndrome)
BENLYSTA (belimumab)	**Benlysta®** 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.	One year
BENZODIAZEPINES Dual-eligible Medicare-Medicaid Beneficiaries	<u>Dual-eligible Medicare-Medicaid Beneficiaries:</u> Benzodiazepines will no longer be a Medicaid benefit for Medicare-Medicaid enrollees (dual-eligible members). The claims are no longer excluded from Medicare	One year

	part D coverage and therefore must be billed to Medicare part D. Colorado Medicaid will no longer cover these medications for these members beginning on January 1, 2013.	
BONE RESORPTION SUPPRESSION AND RELATED AGENTS (Injectable formulations) Boniva, Aredia, Miacalcin, Zemplar, Hectorol, Zometa, Reclast, Pamidronate, 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. **Prolia®** (denosumab) will be approved if the member Meets the following criteria: • Member is in a long term care facility or home health (this medication is required to be administered by a healthcare professional) AND • Member has one of the following diagnoses: o Postmenopausal osteoporosis with high fracture risk o Osteoporosis o Bone loss in men receiving androgen deprivation therapy in prostate cancer o Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer AND • Member has serum calcium greater than 8.5mg/dL AND • Member is taking calcium 1000 mg daily and at least 400 IU vitamin D daily AND • Has trial and failure of preferred bisphosphonate for one year AND (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) • Member meets ANY of the following criteria: o has a history of an osteoporotic vertebral or hip fracture o has a pre-treatment T-score of < -2.5 o has a pre-treatment T-score of < -1 but > -2.5 AND either of the following: • Pre-treatment FRAX score of > 20% for any major fracture • Pre-treatment FRAX score of > 3% for hip fracture Maximum dose of Prolia is 60mg every 6 months	One year
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.	Lifetime
BOTULINUM TOXIN Botox, Dysport, Myobloc, Xeomin	If given in the member's home or in a long-term care facility. • *Cervical or Facial Dystonia* ***Not approved for Cosmetic Purposes***	One year
BOWEL PREPERATION AGENTS	For the following Bowel Preparation Agents, members will require a prior authorization for quantities exceeding 2 units in 30 days. • Colyte • Gavilyte-C • Gavilyte-H • Gavilyte-N • Gialax • Golytely • Moviprep • Peg-Prep • Suprep • Trilyte	30 days

BRAND NAME MEDICATIONS and GENERIC MANDATE	Brand Name Medications and Generic Mandate: • Brand name drug products that have a therapeutically equivalent generic drug product (as determined by the FDA) will require prior authorization for brand product coverage and will be covered without a prior authorization if meeting one of the following exceptions: o The brand name drug is prescribed for the treatment of (and the prescriber has indicated dispense as written on the brand name prescription): ▪ Biologically based mental illness defined in 10-16-104 (5.5) C.R.S. ▪ Cancer ▪ Epilepsy ▪ HIV/AIDS o The Department has determined that the brand name product is lower cost than the therapeutically equivalent generic • Prior authorization for use of a brand name drug product that has a therapeutically equivalent generic (and does not meet exceptions above) may also be approved if: o The prescriber is of the opinion that a transition to the generic equivalent of the brand name drug would be unacceptably disruptive to the patient's stabilized drug regimen o The patient is started on the generic equivalent drug but is unable to continue treatment on the generic drug as determined by the prescriber	One year
BUPRENORPHINE-CONTAINING PRODUCTS (used for opioid use disorder/opioid dependency*)	**Bunavail®** (buprenorphine/naloxone) buccal film will be approved for members who meet all of the following criteria: • 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 contraindication to generic buprenorphine/naloxone SL tablets or Suboxone films. **Sublocade®** (buprenorphine extended-release) injection will be approved for members who meet all of the following criteria: • Sublocade is being administered in a long-term care facility or in a member's home by a home healthcare provider (all other claims must be submitted through the medical benefit) AND • Sublocade is being dispensed directly to the home healthcare professional (medication should not be dispensed directly to the member) AND • Provider attests to member's enrollment in a complete treatment program including counseling and psychosocial support AND • Member must have documented diagnosis of moderate to severe opioid use disorder AND • Member must have initiated therapy with a transmucosal buprenorphine-containing product, and had dose adjustment for a minimum of 7 days AND • Maximum dose is 300 mg injection every month **Suboxone®** (buprenorphine/naloxone) sublingual film will be approved if the all of following criteria are met:	

	• The prescriber is authorized to prescribe Suboxone AND • The member has an opioid dependency AND • The member is not currently receiving an opioid or opioid combination product unless the physician attests the member is no longer using opioids AND • Will not be approved for the treatment of pain AND • Opioid claims will not be allowed for members with a claim for Suboxone in the preceding 30 days AND • Will not be approved for more than 24mg of buprenorphine /day **Subutex®** (buprenorphine) sublingual tablet will be approved if all of the following criteria are met: • The prescriber is authorized to prescribe Subutex AND • The member has an opioid dependency AND • The member is pregnant or the member is allergic to Naloxone AND • Subutex will not be approved for the treatment of pain AND • Subutex will not be approved for more than 24mg/day **Zubsolv®** (buprenorphine/naloxone) sublingual tablet will be approved if all of the following criteria are met: • 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. **Buprenorphine products indicated for treating pain are located on the preferred drug list (PDL)*	
CERDELGA (eligulstat)	**Cerdelga®** may be approved if all the following criteria are met: • Member has a diagnosis of Gaucher disease type 1 **AND** • 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** • 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** • Members who are CYP2D6 extensive or intermediate metabolizers are not receiving strong or moderate CYP2D6 inhibitors (e.g, sertraline, duloxetine, quinidine, paroxetine, fluoxetine, buproprion, 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) Quantity Limits: Max 60 tablets/30 days	One year
CIALIS (tadalafil)	**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:	One year

	• AUA Prostate Symptom Score ≥ 8 AND • 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.	
CONTRACEPTIVE TWELVE-MONTH SUPPLY	Prescription Contraceptive Products (oral and topical): Initial fills may be dispensed for up to a three-month supply to establish tolerance (lack of adverse events). If the prescribed medication is tolerated for at least three months of therapy, subsequent fills of that medication will be eligible to be filled for up to a twelve-month supply. *Depot and IUD formulations are billed through the medical benefit.*	One year
COUGH AND COLD (prescription products)	Member <21 years: covered benefit. A prior authorization is not needed. Member ≥ 21 years must have diagnosis of a chronic condition such as COPD or asthma. *Note: For OTC cough and cold product coverage, see "OTC Products" section.*	One year
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	One year
DARAPRIM (pyrimethamine)	**Daraprim®** will be approved if all the following criteria are met: • Member is being treated for toxoplasmic encephalitis or congenital toxoplasmosis or receiving prophylaxis for congenital toxoplasmosis AND • Daraprim is prescribed in conjunction with an infectious disease specialist AND • Member does not have megaloblastic anemia due to folate deficiency AND • For prophylaxis, member has experienced intolerance to prior treatment with trimethoprim-sulfamethoxazole (TMP-SMX) meeting one of the following: o Member has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate o Member has evidence of life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome) OR • Member is being treated for acute malaria due to susceptible strains of plasmodia AND • Member has tried and had an inadequate response or intolerant to two other malaria treatment regimens (such as but not limited to atovaquone/proguanil, Coartem, chloroquine, hydroxychloroquine, chloroquine plus Primaquine, quinine plus clindamycin, quinidine plus doxycycline) AND • Daraprim is prescribed in conjunction with an infectious disease specialist with travel/tropical medicine expertise AND • Member does not have megaloblastic anemia due to folate deficiency Note: The Center for Disease Control does not recommend Daraprim for the prevention or the treatment of malaria	8 weeks

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.	
DIFICID (fidoxomicin)	**Dificid®** (fidoxomicin) will be approved if all the following criteria are met: • Member is 18 years of age or older **AND** • Member has a documented diagnosis (including any applicable labs and/or tests) for Clostridium difficile-associated diarrhea **AND** • Prescribed by or in conjunction with a gastroenterologist or an infectious disease specialist **AND** • Member has failed at least a 10 day treatment course of oral vancomycin. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **Dificid®** maximum quantity: 20 tablets per 30 days	1 month
DIHYDROERGOTAMINE PRODUCTS Migranal	**Migranal®** and dihydroergotamine product formulations will be approved if member meets ALL of the following criteria: • Member is not currently taking a potent CYP 3A4 inhibitor (for example, protease inhibitor, macrolide antibiotic) AND • Member does not have uncontrolled hypertension or ischemic heart disease AND • Product is being prescribed for cluster headache (vial only) or acute migraine treatment (vial and nasal spray) AND • Intranasal dihydroergotamine generic and Migranal® will be approved with adequate trial and/or failure of dihydroergotamine vial (Failure is defined as: lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions) AND • If dihydroergotamine product is being prescribed for acute migraine treatment, member has adequate trial and/or failure of 2 triptan agents (for example sumatriptan, naratriptan)and 1 NSAID medication. Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions. OR • If dihydroergotamine product is being prescribed for cluster headaches, member has adequate trial and/or failure of 2 triptan agents. Failure is defined as: lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions. <u>Grandfathering:</u> Members currently utilizing Migranal® or a dihydroergotamine formulation (based on recent claims history) may receive one year approval to continue therapy with that medication. <u>Maximum Dosing:</u> Dihydroergotamine nasal spray and Migranal®: 16mg per 28 days Dihydroergotamine vial: 24mg per 28 days	One year
DUPIXENT (dupilumab)	**Dupixent®** (dupilumab) may be approved if the following criteria are met: <u>Atopic Dermatitis:</u> • Member is 18 years and older **AND**	One Year

	• Member has a diagnosis of severe chronic atopic dermatitis **AND**
	• Member has a history of failure, contraindication, or intolerance to both of the following:
	  • One medium potency to very-high potency topical corticosteroid [Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)] **AND**
	  • One topical calcineurin inhibitor [Elidel (pimecrolimus), Protopic (tacrolimus)] **AND**
	• For members under 18 years of age, must be prescribed by or in conjunction with a dermatologist
	
	<u>Asthma:</u>
	May be approved if meeting FDA-labeled indication, dosing, age, and role in therapy per package labeling
	
	Dupixent® quantity limit: 2 syringes every 28 days after initial 14 days of therapy (first dose is twice the regular scheduled dose)	

EGRIFTA (tesamorelin acetate)	**Egrifta®** will be approved if all the following is met:
	• Must be prescribed in consultation with a physician who specializes in HIV/AIDS AND
	• Member is 18 years of age or older AND
	• Member has a diagnosis of HIV-related lipodystrophy with excess abdominal fat meeting the following criteria:
	  o Male member must have a waist circumference of at least 95cm (37.4in) and a waist to hip ratio of at least 0.94 OR
	  o Female member must have a waist circumference of at least 94cm (37in) and a waist to hip ratio of at least 0.88 AND
	  o Baseline waist circumference and waist to hip ratio must be provided
	• Member is currently receiving highly active antiretroviral therapy including protease inhibitors, nucleoside reverse transcriptase inhibitor, or non-nucleoside reverse transcriptase inhibitors AND
	• Member does not have a diagnosis of hypophysectomy, hypopituitarism, pituitary surgery, head irradiation or head trauma AND
	• Member does not have any active malignancy or history of malignancy AND
	• For women of childbearing potential, member must have a negative pregnancy test within one month of therapy initiation
		6 months

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)	One year
EMFLAZA (deflazacort)	**Emflaza®** may be approved if all the following criteria are met: • Member is at least 5 years of age or older AND • Member has diagnosis of Duchenne muscular dystrophy and a documented mutation in the dystrophin gene AND • Member must have documented (per claims history or provider notes) adequate trial and/or failure to prednisone therapy, adequate trial duration is at least three month. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) AND • The medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders. AND • Serum creatinine kinase activity at least 10 times the upper limit of normal at some stage in their illness AND • Absence of active infection including tuberculosis and hepatitis B virus	One year

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- Maximum dose of 0.9mg/kg daily for tablets and suspension, may be rounded up to nearest ml

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<tr><td>EMVERM (mebendazole)</td><td>

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

<table>
<tr><th>Diagnosis</th><th>Dose</th><th>Duration</th><th>Quantity Limits</th></tr>
<tr><td>Ancylostoma duodenale or Necator americanus (hookworm)</td><td>100 mg twice daily</td><td>3 consecutive days, may be repeated in 3 weeks in needed.</td><td>6 tablets/member</td></tr>
<tr><td>Ascariasis (roundworm)</td><td>100 mg twice daily</td><td>3 consecutive days, may be repeated in 3 weeks if needed.</td><td>6 tablets/member</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 daily</td><td>3 consecutive days, may be repeated in 3 weeks in needed.</td><td>6 tablets/member</td></tr>
</table>

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

- 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)

<u>Quantity limits</u>: Based on indication (Table 1)

</td><td>See Table</td></tr>
<tr><td>ENTRESTO (sacubitril/valsartan)</td><td>

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

</td><td>One year</td></tr>
<tr><td>ERECTILE DYSFUNCTION OR SEXUAL DYSFUNCTION PRODUCTS</td><td>

These drugs are not a covered benefit for SD/ED indications.

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.

</td><td>Not available
Not qualified for</td></tr>
</table>

Caverject, Cialis, Edex, Imvexxy, Levitra, Muse, Viagra, Addyi, Premarin Cream, Sildenafil, Tadalafil (generic Cialis), Staxyn, Stendra, Xiaflex, Yohimbine	Sildenafil may be approved for off-label use in Reynaud's	emergency 3 day supply
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
EUCRISA (crisaborole)	**Eucrisa®** will be approved if all the following criteria are met: • Member is at least 2 years of age and older AND • Member has a diagnosis of mild to moderate atopic dermatitis AND • Member has a history of failure, contraindication, or intolerance to at least two medium- to high-potency topical corticosteroid for a minimum of 2 weeks, or is not a candidate for topical corticosteroids AND • Member must have trialed and/or failed pimecrolimus and tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions. AND • Must be prescribed by or in conjunction with a dermatologist	One year
EXJADE (deferasirox)	Please see "Jadenu and Exjade"	
FASENRA (benrelizumab)	**Fasenra®** prior authorization may be approved for member's meeting all of the following criteria: • Fasenra® is being administered by a healthcare professional in the member's home or in a long-term care facility (all other claims are billed through the Health First Colorado medical benefit) AND • Member is 12 years of age or older AND • Member has diagnosis of severe asthma with eosinophilic phenotype AND • Member has eosinophil count of at least 300 cells/µl AND • Fasenra is being prescribed as add-on therapy (not monotherapy) AND • Member is taking a high dose inhaled corticosteroids and a long-acting beta agonist AND • Member has had at least 2 asthma exacerbations requiring systemic corticosteroid therapy in the past 12 months Maximum dose: 30mg subcutaneous injection every 4 weeks for 3 doses, then every 8 weeks thereafter	One year
FERRIPROX (Deferiprone)	**Ferriprox®** will be approved if all the following is met: • Must be prescribed in conjunction with a hematologist or oncologist AND • Member's weight must be provided AND • Member has a diagnosis of transfusion-related iron overload due to thalassemia syndrome or sickle cell disease AND	One year

	• Member has an absolute neutrophil count > 1.5 x 109 AND • Member has failed or has had an inadequate response to Desferal (deferoxamine) AND Exjade (deferasirox) as defined by serum ferritin >2,500mcg/L before treatment with Ferriprox OR member has been intolerant to or experienced clinically significant adverse effects to Desferal (deferoxamine) or Exjade (deferasirox) such as evidence of cardiac iron overload or iron-induced cardiac dysfunction. Maximum dose of Ferriprox® is 99mg/kg/day	
FLUORIDE PRODUCTS	Prescription fluoride products: • Prescription fluoride products will be approved for members less than 21 years of age without a prior authorization. • For members 21 years of age or older approval will be granted if using well water or living in an under-fluoridated area designated by the CDC*. • Approval for members not meeting these criteria will require a letter of necessity and will be individually reviewed. OTC fluoride products: • The following OTC fluoride products are eligible for prior authorization approval for all members using well water or living in an under-fluoridated area designated by the CDC*: fluoride chewable tablets, ludent fluoride chewable tablets, sodium fluoride 0.5mg/mL drops • Approval for members not meeting these criteria will require a letter of necessity and will be individually reviewed. *Information and reports regarding water fluoridation can be found on the CDC website at: https://nccd.cdc.gov/DOH_MWF/Default/CountyList.aspx?state=Coloradateid=8&stateabbr=CO&reportLevel=2.	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. • Members must have a CD4 lymphocyte count less than 100 cells/mm3 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.	Six months

	At 24 weeks, members must experience at least ≥ 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.**	
GATTEX (teduglutide)	**Gattex®** will be approved if all of the following criteria are met: • Member is 18 years of age or older AND • Member has documented short bowel syndrome AND • Member is dependent on parenteral nutrition for twelve consecutive months AND • The prescribing physician is a gastroenterologist AND • Medical necessity documentation has been received and approved by Colorado Medicaid clinical staff (please fax to 303-866-3590 attn: Clinical Pharmacy Staff) • The initial prior authorization will be limited to a two month supply.	Two months initially; may be approved by State for up to one year
H2 BLOCKERS	Prescription H2 Blockers (generic products) do not require a prior authorization except for ranitidine capsules and liquid. Ranitidine capsules: Require the prescribing provider to certify that capsules are medically necessary and that the member cannot use the tablets. Ranitidine liquid: A prior authorization will be approved for members with a feeding tube or who have difficulty swallowing. A prior authorization is not required for children under 12 years of age.	One year
HETLIOZ (tasimelteon)	**Hetlioz®** will be approved for members who meet the following criteria: • Have a documented diagnosis of non-24-hour sleep wake disorder (non-24 or N24) by a sleep specialist AND • Member is completely blind	One year
Homozygous Familial Hypercholesterolemia (HoFH)	**Juxtapid® (lomitapide)** Prior authorization will be approved if all of the following criteria are met: • Member is 18 years of age or older; • Member has documented diagnosis of homozygous familial hypercholesterolemia (HoFH); • Member has failed therapy with high dose statin therapy (e.g. atorvastatin 40mg or higher, Crestor 20mg or higher) • 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 a. 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 dPCSK9 testing if both of the above tests are negative but a strong clinical picture exists.	One year

	b. 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 (gabapentil 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	One year
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.	One year
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: o Member is < 2 years of age o Member has electroencephalogram documenting diagnosis o Acthar is being used as monotherapy o Member does not have suspected congenital infection o Prescribed by or in consultation with a neurologist or epileptologist **OR** • Member has diagnosis of multiple sclerosis and is experiencing an acute exacerbation **AND** • Member does not have concomitant primary adrenocortical insufficiency or adrenocortical hyperfunction **AND**	4 week supply

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Member has trialed and failed corticosteroid therapy prescribed to treat acute exacerbation due to multiple sclerosis. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
Member is not receiving concomitant live or live attenuated vaccines AND
Member does not have one of the following concomitant diagnoses:

Scleroderma, osteoporosis, systemic fungal infections, ocular, herpes simplex, recent surgery, history of peptic ulcer disease, heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin. AND

HP Acthar will be approved based on the following FDA recommended doses. (see Table 1)

Table 1. FDA Recommended Dosing for HP Acthar
<table>
<tr><th>Diagnosis</th><th>Dose</th></tr>
<tr><td>Infantile Spasms under Age of 2 years</td><td>75 units/m^2 IM twice daily for two weeks; After two weeks, dose should be tapered according to the following schedule: 30 U/m^2 IM in the morning for 3 days; 15 units/m^2 IM in the morning for 3 days; 10 units/m^2 IM in the morning for 3 days; and 10 units/m^2 IM every other morning for 6 days (3 doses).</td></tr>
<tr><td>Acute Exacerbation of Multiple Sclerosis</td><td>80-120 units IM or SQ daily for 2-3 weeks</td></tr>
</table>
Quantity Limits: 4 week supply
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<tr>
<td>HUNTINGTON’S CHOREA / TARDIVE DYSKINESIA AGENTS
Austedo, Ingrezza, Tetrabenazine, Xenazine</td>
<td>
Austedo® (deutetrabenazine) will be approved if all the following criteria have been met:

Member is 18 years and older with chorea secondary to Huntington’s Disease OR Tardive Dyskinesia AND

For chorea secondary to Huntington’s Disease: member must have trialed and/or failed tetrabenazine, adequate trial duration is 1 month (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) OR
For tardive dyskinesia a baseline AIMS AND 12 week AIMS are required. If the 12 week AIMS does not show improvement from baseline, the prior authorization will no longer be approved

Member does not have untreated depression, suicidal thoughts, or a history of suicide attempt AND
Member has been informed of the risks of depression and suicidality AND
Member does not have severe hepatic impairment
Maximum dose 48mg/day, 120 tablets per month

Xenazine® (tetrabenazine) will be approved if all the following criteria have been met:

Member is 18 years and older with chorea secondary to Huntington’s Disease AND
Member does not have a history of suicide or untreated depression AND
Member has been informed of the risks of depression and suicidality AND
Member does not have severe hepatic impairment

</td>
<td>One year unless AIMS follow-up required</td>
</tr>
</table>

	• Maximum dose 50mg/day, 60 tablets per month **Ingrezza® (valbenazine)** will be approved if all the following criteria have been met: • Member is 18 years or older AND • Member has been diagnosed with tardive dyskinesia clinically AND • Has a baseline Abnormal Involuntary Movement Scale (AIMS) AND • If there is no improvement at 6 weeks of therapy per AIMS, the medication will be discontinued • Quantity limit of 60 capsules per 30 days	
IVIG	Members must have one of the following conditions: • <u>Immunodeficiency disorders:</u> o Common Variable Immunodeficiency (CVID) o Severe Combined Immunodeficiency (SCID) o X-Linked Agammaglobulinemia o X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency o Wiskott-Aldrich Syndrome o Pediatric Human Immunodeficiency Virus (HIV): ▪ Members are less than 13 years of age and CD-4 Count is > 200/mm3 • <u>Neurological disorders:</u> o Guillain-Barre' Syndrome o Relapsing-Remitting Multiple Sclerosis o Chronic Inflammatory Demyelinating Polyneuropathy o Myasthenia Gravis o Polymyositis and Dermatomyositis • <u>Chronic Lymphocytic Leukemia (CLL)</u> • <u>Autoimmune Neutropenia (AN):</u> o Absolute neutrophil count is less than 800 mm AND o Has recurrent bacterial infections • <u>Autoimmune Hemolytic Anemia (AHA)</u> • <u>Liver or Intestinal Transplant</u> • <u>Idiopathic Thrombocytopenic Purpura (ITP):</u> o Preoperatively for members undergoing elective splenectomy with platelet count < 20,000 o Members with active bleeding & platelet count <30,000. o Pregnant women with platelet counts <10,000 in the third trimester. o Pregnant women with platelet count 10,000 to 30,000 who are bleeding.	One year One year CLL: One year AN: 6 months AHA: 5 weeks ITP: 5 days
JADENU and EXJADE (Deferasirox)	**Jadenu®** and **Exjade®** will be approved for members that meet the following criteria: • Must be prescribed in conjunction with a hematologist or oncologist AND • Member's weight must be provided AND • Member has a diagnosis for chronic iron overload due to blood transfusion AND • Member is 2 years of age or older AND • Member has consistently high serum ferritin levels > 1000 mcg/L (demonstrated by at least 2 values in the prior three months OR • Member has a diagnosis for chronic iron overload due to non-transfusion dependent thalassemia syndromes AND	One Year

	• Member is 10 years of age or older AND • Member has liver iron levels > 5 mg iron per gram of dry weight and serum ferritin levels > 300 mcg/L document in the prior three months Members must also meet the following additional criteria for all Jadenu and Exjade approvals: • Member does not have advanced malignancies and/or high-risk myelodysplastic syndromes AND • Member has a creatinine clearance > 40 ml/min AND • Member has a platelet count > 50 x 10^9/L Maximum Dosing: Maximum dose of Jadenu® is 28mg/kg/day Maximum dose of Exjade® is 40mg/kg/day	
KALYDECO (ivacaftor)	**Kalydeco®** will only be approved if all of the following criteria are met: • Member has been diagnosed with cystic fibrosis AND • Member is an adult or pediatric patient 2 years of age or older AND • 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, S549R or another FDA approved gene mutation.* AND • 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 bi-directional 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.	One year
KUVAN (sapropterin dihydrochloride)	**Kuvan®** will be approved if all the following criteria are met: • Member is > 1 month old AND • Member has been diagnosed with hyperphenylalaninemia due to tetrahydrobiopterin responsive phenylketonuria AND • Prescriber is a metabolic specialist AND • Phenylalanine levels must be greater than 6 mg/dL for neonates through 12 years of age OR • Phenylalanine levels must be greater than 10 mg/dL for members between 13 to 17 OR • Phenylalanine levels must be greater than 15 mg/dL for members 18 years and older AND • Must be in conjunction with dietary restriction of phenylalanine • Initial approval will be for 1 month. Authorization may be extended if: o Members on the 10mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month of treatment should increase to 20mg/kg/day. These members will be approved for another 1 month trial at the higher dose.	Initial approval one month

	○ Members on the 20mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month are considered non-responders, and treatment will be discontinued. ○ Members responding to therapy receive additional authorization at 1-year intervals.	
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®:** 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). ○ 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	One year 16 years of age
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.	Lifetime
LUCEMYRA (lofexidine)	**Lucemyra®** may receive prior authorization approval for members meeting ALL of the following criteria: • Member is 18 years of age or older **AND** • Lucemyra® is prescribed for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation **AND** • Member is not pregnant or nursing **AND** • Member is not experiencing withdrawal symptoms from substances other than opioids **AND** • Member is not currently taking monoamine oxidase inhibitors or allergic to imidazole drugs **AND** • Member does not have an abnormal cardiovascular exam prior to treatment: ○ Clinically significant abnormal ECG (e.g., second or third degree heart block, uncontrolled arrhythmia, or QTc interval > 450 msec for males, and > 470 msec for females) ○ Heart rate less than 45 bpm or symptomatic bradycardia ○ Systolic blood pressure < 90 mm Hg or symptomatic hypotension (diastolic blood pressure < 60 mm Hg) ○ Blood pressure > 160/100 mm Hg	14 days

	○ Prior history of myocardial infarction **AND** • Member has two-day trial and failed clonidine IR for opioid withdrawal symptoms. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Approval for Lucemyra® will be 14 days	
MAKENA (hydroxyprogesterone caproate) vial and autoinjector	**Makena®** will be approved for members that meet the following criteria: • The drug is being administered in the home or in long-term care setting • Member has a Singleton pregnancy and a history of singleton spontaneous preterm birth • Therapy is being initiated between 16 weeks gestation and 20 weeks 6 days gestation and continued through 36 weeks 6 days gestation or delivery (whichever occurs first) • Dose is administered by a healthcare professional. <u>Maximum Dosing:</u> Makena vial: 250mg IM once weekly Makena autoinjector: 275mg SubQ once weekly	See criteria
MOXATAG (amoxicillin)	A prior authorization will only be approved if a member has an allergic/intolerance to inactive ingredients in immediate release amoxicillin.	One year
MYALEPT (metreleptin)	**Myalept®** will be approved if all of the following criteria are met: • Prescriber is an endocrinologist who is enrolled in the Myalept REMS program AND • Member has a diagnosis of congenital or acquired generalized lipodystrophy AND • Member does not have HIV-related lipodystrophy AND • Member has a diagnosis of leptin deficiency AND • Member has been diagnosed with poorly controlled diabetes (HgA1c > 7) and/or hypertriglyceridemia (> 500 mg/dl) AND • Member has tried and failed two standard therapies for diabetes and/or hypertriglyceridemia	Six Months
NALOXONE and **NALTREXONE**	**Narcan®** (naloxone) intranasal <u>does not</u> require prior authorization. **Revia®** (naltrexone) tablet <u>does not</u> require prior authorization. **Naloxone** vial/prefilled syringe: • <u>does not</u> require prior authorization. • 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. **Vivitrol®** (naltrexone ER) injection: • Prior authorization for claims submitted under the pharmacy benefit may be approved when Vivitrol is administered by a healthcare professional in the member's home or in a long-term care facility. All other Vivitrol claims must be billed through the medical benefit. • Effective 01/01/2019, pharmacies that have entered into a collaborative practice agreement with one or more physicians for administration of Vivitrol may receive reimbursement for enrolled pharmacists to administer Vivitrol with appropriate claim submission through the Health First Colorado medical benefit (claims for pharmacist administration of Vivitrol are not covered under the pharmacy benefit). Additional information regarding pharmacist enrollment and	

	medical claims billing can be found at https://www.colorado.gov/hcpf/otc-immunizations . **Evzio®** (naloxone) autoinjector – Product is not Medicaid rebate eligible per current status in Medicaid Drug Rebate Program (MDRP); product excluded *For buprenorphine/naloxone products, see "Buprenorphine-containing Products" section	
NEWLY APPROVED PRODUCTS	Newly marketed medications may be subject to prior authorization following FDA marketing approval. New medications that fall within a PDL drug class will be subject to non-preferred prior authorization criteria for the drug class and will be included as part of the next scheduled P&T Committee review for that class. New medications that fall within a drug category on appendix P (such as "Blood Products" or "Injectable Antipsychotic Injectables") will be subject to prior authorization criteria listed for medications in that category on Appendix P. New medications that are not in a PDL drug class or Appendix P drug category may be subject to prior authorization criteria and notice will be given for criteria to be reviewed as part of the agenda for the next scheduled public DUR Board quarterly meeting.	
NON-PREFERRED MEDICATIONS WHERE BRAND IS FAVORED OVER GENERIC	The Department designates certain brand name medications to be favored for coverage over the generic equivalent in cases where both the brand name and the generic equivalent are non-preferred in the same PDL drug class. These products include the following: • **Emend Tripack®** (aprepitant) • **Kapvay®** (clonidine ER) tablet (removed 1/28/19) • **Lotronex®** (alosetron) tablet • **Ritalin LA®** (methylphenidate ER) capsule • **Treximet®** (sumatriptan/naproxen) 85/500 mg tablet • **Zyflo CR®** (zileuton ER) tablet	
NORTHERA (droxidopa)	**Northera®** (droxidopa) will be approved if all the following is met: • Member has a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) as defined by one of the following when an upright position is assumed or when using a head-up tilt table testing at an angle of at least 60 degrees. o At least a 20 mmHg fall is systolic pressure o At least a 10 mmHg fall in diastolic pressure AND • NOH caused by one of the following: o Primary autonomic failure (e.g, Parkinson's disease, multiple system atrophy, and pure autonomic failure o Dopamine beta-hydroxylase deficiency o Non-diabetic autonomic neuropathy AND • Member does not have orthostatic hypotension due to other causes (e.g, heart failure, fluid restriction, malignanacy) AND • Members has tried at least three of the following non-pharmacological interventions: o Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates, excluding SL symptom treatment formulations), alpha-adrenergic antagonists, and antidepressants] o Raising the head of the bed 10 to 20 degrees o Compression stockings o Increased salt and water intake, if appropriate	3 months

	○ Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing) AND • NORTHERA is being prescribed by either a cardiologist, neurologist, or nephrologist AND • Member has failed a 30 day trail, has a contraindication, or intolerance to both Florinef (fludrocortisone) and ProAmatine (midodrine).	
NUCALA (mepolizumab)	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 FDA-labeled boxed warning requiring the administration under the supervision of a physician, a prior authorization will not be approved if administered in a member's home.	One year
NUEDEXTA (dextromethorphan /quinidine)	**Nuedexta®** (dextromethorphan/quinidine) will be approved for members who meet the following criteria: • Nuedexta® is being prescribed for diagnosis of pseudobulbar affect caused by structural neurologic condition (i.e. MS or ALS) AND • Member has a Center for Neurologic Study-Lability Scale (CNS-LS) score of 13 or higher AND • Member has at least 10 episodes of inappropriate laughing or crying per day before therapy AND • Member has a baseline electrocardiogram (ECG) with no significant abnormalities and no history of QT prolongation syndrome AND • Nuedexta® is prescribed by a neurologist or in conjunction with a neurologist AND Member has trailed and failed one tricyclic antidepressant and one selective serotonin reuptake inhibitor within the past year (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) Initial approval will be given for 3 months and continued approval for one year may be given if member has 50% reduction in daily episodes at 3 months of therapy Nuedexta® Max Dose: 2 capsules (dextromethorphan 20mg/quinidine 10mg) per day given every 12 hours Renewal: members currently stabilized on this medication may continue to receive it with a documented diagnosis of pseudobulbar affect and evidence of efficacy (documentation of decrease in pseudobulbar episodes by 50% from baseline)	Initial Approval: 3 months Continuation Approval: One year
OCREVUS (ocrelizumab)	**Ocrevus®** (ocrelizumab) will be approved if the following criteria are met: • Ocrevus is being administered in a LTCF or in the member's home **AND** • <u>If prescribed for Relapsing Forms of Multiple Sclerosis (MS)</u> ○ Member is 18 years of age or older **AND** ○ Member has a relapsing form of multiple sclerosis **AND** ○ Member has experienced one relapse within the prior year or two relapses within the prior two years **AND** ○ Member has trial and failure of three of the following agents: Avonex (interferon beta-1a), Rebif (interferon beta 1-a), Betaseron/Extavia (interferon beta-1b), Plegridy (peginterferon beta1a), Copaxone/Glatopa (glatiramer acetate), Aubagio (teriflunomide tablets), Gilenya (fingolimod capsules), Tecfidera (dimethyl fumarate delayed-release capsules), Tysabri (Natalizumab) or Lemtrada (alemtuzumab). Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy. Lack of efficacy will be defined as one of the following:	One year

	○ One of the following on MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy ○ On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer **AND** • Ocrevus is prescribed by a neurologist or is prescribed in conjunction with a neurologist **AND** • <u>If prescribed for Primary Progressive Multiple Sclerosis</u> ○ Member is 18 years of age or older **AND** ○ Member is not concomitantly taking: Avonex (interferon beta-1a), Rebif (interferon beta 1-a), Betaseron/Extavia (interferon beta-1b), Plegridy (peginterferon beta1a), Copaxone/Glatopa (glatiramer acetate), Aubagio (teriflunomide tablets), Gilenya (fingolimod capsules), Tecfidera (dimethyl fumarate delayed-release capsules), Tysabri (Natalizumab) or Lemtrada (alemtuzumab) **AND** • Member does not have active hepatitis B infection **AND** • Ocrevus is prescribed by a neurologist or is prescribed in conjunction with a neurologist Maximum maintenance dose: 600mg every 6 months	
OFEV (nintedanib)	**Ofev®** (nintedanib) 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 moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment AND • 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 • Member is not taking a P-gp or CYP3A4 inducer (e.g, rifampin, carbamazepine, phenytoin, St. John's Wort) Quantity Limits: 60 tablets/30 days	One year
ORILISSA (elagolix)	**Orilissa®** (elagolix) may be approved for members meeting the following criteria: • Member is a premenopausal woman 18-49 years of age **AND** • Orilissa® is not being prescribed for dyspareunia or any other sexual function related indication **AND** • Member has a definitive diagnosis of endometriosis as noted by surgical histology of lesions **AND** • Member has failed a 6-month trial of contraceptive agents (progestins, combined contraceptives, medroxyprogesterone acetate, levonorgestrel IUD). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • Member has failed a 1 month trial of NSAIDs. Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • Member has failed a 3 month trial with a GnRH agonist (such as leuprolide). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND**	One year 6 months for moderate hepatic impairment (Child Pugh Class B)

	• Member is not pregnant, breast feeding, planning a pregnancy within the next 24 months, or less than 6 months post-partum, post-abortion, or post-pregnancy **AND** • Member has been instructed that only non-hormonal contraceptives should be used during therapy and for at least 1 week following discontinuation **AND** • Member does not have osteoporosis or severe hepatic impairment (Child-Pugh Class C) **AND** • Member is not concomitantly taking a OATP 1B1 inhibitor (such as gemfibrozil, cyclosporine, ritonavir, rifampin). Orilissa® Maximum Dose: 150mg tablet daily, or 200mg tablet twice daily Orilissa® limited to a maximum treatment duration of 6 months for members with moderate hepatic impairment (Child-Pugh Class B)	
ORKAMBI (lumacaftor/ivacaftor)	**Orkambi®** (lumacaftor/ivacaftor) 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	One year
OTC PRODUCTS*	The following OTC products do not require a prior authorization for coverage: o Aspirin o OTC insulin (see PDL for coverage details) o Oral emergency contraceptive products o Polyethylene glycol powder laxatives o Docusate (oral and suppository) *Effective 03/01/19* o Bisocodyl (oral and suppository) *Effective 03/01/19* o Children's liquid and chewable acetaminophen for ages 2-11 years o Children's liquid and chewable ibuprofen for ages 6 months – 11 years o Children's dextromethorphan suspension for ages 4-11 years o Nicotine replacement therapies (OTC patch, gum, and lozenge) The following OTC products may be covered with a prior authorization: • L-methylfolate may be approved for members with depression who are currently taking an antidepressant and are partial or non-responders • Nicomide may be approved for the treatment of acne • Cranberry tablets may be approved for urinary tract infections • Cough and Cold Products may be approved for members with a diagnosis of a chronic respiratory condition for which these medications may be prescribed or based on medical necessity supported by clinical practice recommendations • Combination antihistamine/decongestant products may be approved for members with a diagnosis of seasonal or perennial allergic rhinitis or chronic sinusitis or based on medical necessity supported by clinical practice recommendations • Guaifenesin 600mg LA may be approved for members having an abnormal amount of sputum	One year

	• Bisacodyl enema may be approved following adequate trial and/or failure with a bisocodyl oral formulation and bisocodyl suppository (Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects, or significant drug-drug interactions). *Effective 03/01/19* • Docusate enema may be approved following adequate trial and/or failure with a docusate oral formulation and docusate suppository (Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects, or significant drug-drug interactions). *Effective 03/01/19* • Ferrous sulfate and ferrous gluconate may be approved with diagnosis iron deficient anemia OR iron deficiency verified by low serum ferritin. *Effective 03/01/19* • Members with erythema bullosum (EB) may be approved to receive OTC medications (any Medicaid rebate-eligible OTC medications) Other OTC product coverage information: • Diabetic needles and supplies are covered under the DME benefit • Broncho saline: *See Sodium Chloride section* • Fluoride supplements: *See Fluoride Products section* • OTC Proton Pump Inhibitors: *See PDL Proton Pump Inhibitor section* • Long Term Care Facilities (LTCFs): Various OTC drugs and supplies for LTCF residents shall be furnished by the facility, within the per diem rate, at no charge to the resident pursuant to 10 CCR 2505-10 Skilled Nursing Facility: 8.440 NURSING FACILITY BENEFITS. These OTC drugs and supplies, known as products on a "floor stock list", are not covered or eligible for prior authorization under the pharmacy benefit for LTCF members. ** Coverage criteria outlined in this section apply to prescriptions written by non-pharmacist prescribers. For coverage relating to pharmacist prescribers please see "Pharmacist Prescriptions" section.*	
OTREXUP (methotrexate)	**Otrexup®** (methotrexate) authorization 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 administer generic methotrexate by injection due to limited functional ability.	One year
OXSORALEN (methoxsalen)	**Oxsoralen®** (methoxsalen) pproval may be granted with diagnosis of: Myosis; Fungoides; Psoriasis or Vitiligo	One year

PHARMACIST PRESCRIPTIONS	The following OTC products will be covered with a written prescription by a pharmacist:
	• Oral emergency contraceptive products
	• Nicotine replacement therapy products including:
	  o Nicotine gum (up to 200 units/fill)
	  o Nicotine patch (up to 30 patches/30days)
	  o Nicotine lozenge (up to 288 units/fill)
	• Children's dextromethorphan suspension for members age 4-11 years (up to 150 ml per 30 days)
	• Children's liquid and chewable acetaminophen for members age 2-11 years (up to 240 ml per 30 days)
	• Children's liquid and chewable ibuprofen for members age 6 months – 11 years (up to 240 mL per 30 days)	

PCSK9 INHIBITORS Praluent, Repatha	PCSK9 inhibitors will be approved for members that meet the following criteria: • Medication is prescribed for one of the following diagnoses: o PRALUENT: heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease	Initial Approval: 3 months

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<tr>
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REPATHA: heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (defined below)

<table>
<tr><th>Conditions Which Define Clinical Atherosclerotic Cardiovascular Disease</th></tr>
<tr><td>• Acute Coronary Syndrome
• History of Myocardial Infarction
• Stable or Unstable Angina
• Coronary or other Arterial Revascularization
• Stroke
• Transient Ischemic Attach
• Peripheral Arterial Disease of Atherosclerotic Origin</td></tr>
</table>

PCSK9 inhibitor therapy is prescribed by, or in consultation with, one of the following providers:

Cardiologist
Certified Lipid Specialist
Endocrinologist AND

Member is concurrently adherent (>80% of the past 180 days) on maximally tolerated dose (see table below) of statin therapy (must include atorvastatin and rosuvastatin). If intolerant to a statin due to side effects, member must have a one month documented trial with at least two other statins. For members with a past or current incidence of rhabdomyolysis, one month failure is not required AND
Member must be concurrently treated (in addition to maximally tolerated statin) with ezetimibe AND have a treated LDL $\geq$ 70 mg/dl for a clinical history of ASCVD or LDL $\geq$ 100 mg/dl if familial hypercholesterolemia AND
PA will be granted for 3 months initially. Additional one year approval for continuation will be granted with provider attestation of safety and efficacy with initial medication therapy

<table>
<tr><td>Atorvastatin 80mg</td></tr>
<tr><td>Fluvastatin 80 mg</td></tr>
<tr><td>Lovastatin 80 mg</td></tr>
<tr><td>Pravastatin 80 mg</td></tr>
<tr><td>Rosuvastatin 40 mg</td></tr>
<tr><td>Simvastatin 40 mg (80 mg not used in practice)</td></tr>
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<td>Continuation Approval: One year</td>
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<tr>
<td>PHYSICIAN ADMINISTERED DRUGS</td>
<td>Medications given in a hospital, doctor’s office or clinic, or dialysis unit are only to be billed by those facilities through the Health First Colorado medical benefit. Medications administered intravenously or medication formulations requiring administration by a healthcare professional may only be billed through the pharmacy benefit when given in a long-term care facility or when administered in the member’s home by a healthcare professional or home infusion service. Prior authorization for pharmacy dispensing of these medications may be approved based upon documentation of one of the aforementioned locations for medication administration.</td>
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<tr>
<td>PREVYMIS (letermovir)</td>
<td>Prevymis® (letermovir) will be approved for members that meet the following criteria:

Member is a CMV-seropositive transplant recipient and meets ALL of the following: AND

Member is 18 years or older.
Member has received an allogeneic hematopoietic stem cell transplant.
Member does not have severe hepatic impairment (Child-Pugh Class C).
Member is not receiving pitavastatin or simvastatin co-administered with cyclosporine.

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<td>100 days</td>
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	○ Member is not receiving pimozide or ergot alkaloids. • Prevymis® is being prescribed by or in consultation with an oncologist, hematologist, infectious disease specialist, or transplant specialist. AND • Provider agrees to monitor for CMV reactivation. AND • Prevymis® dose does not exceed 480 mg orally or dose does not exceed 240mg if co-administered with cyclosporine. AND • If request is for IV injectable Prevymis®, must provide medical justification why the patient cannot use oral therapy. AND • If request is for IV injectable Prevymis®, must be administered in a long-term care facility or in a member's home by a home healthcare provider Length of Approval: Prevymis® will only be approved for 100 days Renewal: Authorization may be reviewed every 100 days to confirm that current medical necessity criteria are met and that the medication is effective (e.g. no evidence of CMV viremia).	
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.	One year
PROMACTA (eltrombopag)	**Promacta®** (eltrombopag) prior authorization will be approved for members meeting criteria for the following diagnoses: <u>Chronic immune idiopathic thrombocytopenia purpura:</u> • 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. <u>Thrombocytopenia associated with hepatitis C:</u> • 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 • Patients' degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy <u>Severe aplastic anemia:</u> • Member must have confirmed diagnosis of severe aplastic anemia AND	One year*

	• 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 *All initial prior authorization approvals 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. Not qualified for emergency 3 day supply PA	One year
PROPECIA (finasteride)	***Not covered for hair loss*** *Not qualified for emergency 3 day supply PA*	One year
PULMOZYME (dornase alfa)	**Pulmozyme®** (dornase alfa) 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 o 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. Quantity Limits: 30 ampules (2.5 mg/2.5 ml) per month	

RADICAVA (edaravone)	**Radicava®** (edaravone) will be approved for members that meet the following criteria:
	• RADICAVA is being administered in a long-term care facility or in a member's home by a home healthcare provider AND
	• Member has a "definite" or "probable" diagnosis of amyotrophic lateral sclerosis (ALS) based on medical history and diagnostic testing which may include imaging and nerve conduction conditions studies AND
	• Member meets ALL of the following:
	  o Member has a diagnosis of ALS for 2 or less years (for new starts only).
	  o Diagnosis has been established by or with the assistance of a neurologist with expertise in ALS using El Escorial or Airlie House diagnostic criteria (ALSFRS-R).
	  o Member has normal respiratory function as defined as having a percent-predicated forced vital capacity of greater than or equal to 80%.
	  o The ALSFRS-R score is greater than or equal to 2 for all items in the criteria.
		6 months

	○ Member does not have severe renal impairment (CrCl< 30 ml/min) or end stage renal disease ○ Member does not have moderate or severe hepatic impairment (Child-Pugh Class C) AND • RADICAVA is prescribed by or in consultation with a neurologist. Length of Approval: 6 months. Quantity Limits: For patients initiating therapy, approval will include 28 bags per 28 days (initial dose) for the first month and 20 bags per 28 days for the remainder of the 6 months. Renewal: Authorization may be reviewed every six months to confirm that current medical necessity criteria are met and that the medication is effective per improvement in ALSFRS-R score.	
RASUVO (methotrexate)	**Rasuvo®** (methotrexate) 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®** (glycerol phenylbutyrate) 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	One year
SANDOSTATIN (octreotide)	Approved for acromegaly; carcinoid tumors; and vasoactive intestinal peptide tumors.	Lifetime
SIVEXTRO (tedizolid)	**Sivextro®** may be approved for adults if all of the following criteria are met: • Member has diagnosis of acute bacterial skin and skin structure infection (ABSSSI) caused by one of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus* Group (including *Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus*), and *Enterococcus faecalis.* AND • Member has adequate trial and/or failure of linezolid 600mg twice daily for 10 days. Failure is defined as: lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions Maximum dosing: 200mg daily for 6 days total duration	Six months
SODIUM CHLORIDE (inhalation)	Broncho Saline is not covered under the pharmacy benefit.	N/A

	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).	One year
SOLOSEC (secnidazole)	**Solosec®** (secnidazole) may be approved for members meeting the following criteria: • Solosec® is being prescribed for bacterial vaginosis in an adult female member **AND** • Member has adequately trialed and failed an oral OR topical formulation of metronidazole (Failure is defined as lack of efficacy of a 7 day trial, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy) **AND** • Member has adequately trialed and failed an oral OR topical formulation of clindamycin (Failure is defined as lack of efficacy of a 7 day trial, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy) Solosec® Maximum Quantity: 1 packet of 2 grams per 30 days	One year
STRENSIQ (asfotase alfa)	**Strensiq®** (asfotase alfa) will be approved if all the following is met: Member has a diagnosis of either perinatal/infantile- OR juvenile-onset hypophosphatasia (HPP) based on all of the following a. Member was ≤ 18 years of age at onset b. Member has/had clinical manifestations consistent with hypophosphatasia at the age of onset prior to age 18 (e.g. vitamin B6-dependent seizures, skeletal abnormalities: such as rachitic chest deformity leading to respiratory problems or bowed arms/legs, "failure to thrive"). c. Member has/had radiographic imaging to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g. infantile rickets, alveolar bone loss, craniosynostosis) d. Member has one of the following: elevated urine concentration of phosphoethanolamine (PEA), elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test, or elevated urinary inorganic pyrophosphate (PPi) AND e. Molecular genetic test has been completed confirming mutations in the ALPL gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP) within 30 days of initiation. If genetic test is negative, approval will not be granted past 30 days. f. Prescriber is a specialist in the area of the members disease (e.g, endocrinologist)	Six months
SYMDEKO (tezacaftor/ivacaftor and ivacaftor)	**Symdeko®** (tezacaftor/ivacaftor and ivacaftor) will be approved for members that meet the following criteria: • The member has a diagnosis of cystic fibrosis AND • The member is 12 years of age or older AND • The member has one of the following mutations: o Homozygous for the F508del mutation in the CFTR gene 2 OR o Heterozygous for the F508del mutation in the CFTR gene and one of the following mutations: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D1270N, D579G, 711+3A-G, E831X, S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, 3272-26A-G, 2789+5G-A, 3849-10kbC-T AND	One year

	• Member has ALT, AST, and bilirubin at baseline and tested every 3 months for the first year AND • Member has a baseline ophthalmological examination and periodic follow-up exams for cataracts AND • Must be prescribed by or in consultation with a pulmonologist or gastroenterologist AND • Member is not receiving dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator AND • Member has had 2 negative respiratory cultures for any of the following organisms: *Burkholeria cenocepacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus* in the past 12 months.	
SYNAGIS (palivizumab)	**Pharmacy Prior Authorization requests for Synagis® must be submitted by fax using the Synagis® Prior Authorization Form found at** https://www.colorado.gov/hcpf/provider-forms. **Medical PAs must be submitted at** http://coloradopar.com/. **Synagis® season will begin November 26, 2018 and end April 30, 2019. PARs may be requested beginning November 12, 2018.** **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. 3. Synagis® is not recommend for prevention of health care-associated RSV 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 (acyanotic heart disease who are receiving medication to control CHF and will require cardiac surgical procedures or 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:	Maximum of 5 doses per season

	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.	
SYPRINE (trientine)	**Syprine**® (trientine) will be approved if all the following criteria are met: • Must be prescribed in conjunction with a gastroenterologist, hepatologist, or liver transplant specialist. **AND** • Member has a diagnosis of Wilson's Disease meeting at least one of the following criteria: o Hepatic parenchymal copper content of ≥250µg/g dry weight o Presence of Kayser-Fleischer Ring in cornea o Serum ceruloplasmin level <50mg/L o Basal 24-hour urinary excretion of copper >100µg (1.6 µmoles) o Genetic testing results indicating mutation in ATP7B gene **AND** • Member has failed a three-month trial or is intolerant to penicillamine. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions **AND** • Member has failed a three-month trial or is intolerant to generic trientine. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.	One year
TAMIFLU (oseltamivir) capsules	Effective 1/18/2019: Brand and generic Tamiflu capsules are both payable. Effective 11/15/18 (until above change on 1/18/19): Brand Tamiflu capsules are covered as a favored product and claims for brand Tamiflu capsules will pay with submission of DAW code 0, 1, or 9. Generic oseltamivir capsules will require prior authorization and may be approved based on prescriber verification that there is clinical necessity of use of the generic product. Tamiflu (oseltamivir) suspension is not affected by this change. Brand and generic oseltamivir suspension products will continue to be subject to coverage criteria outlined in the generic mandate (see section "Brand Name Medications and Generic Mandate").	
TARGETED IMMUNE MODULATORS (IV and physician-administered products)	**Entyvio®** (vedolizumab) may be approved for members who are receiving infusion in their home or in a long-term care facility and who meet the following criteria: • Medication is being used in an adult member with ulcerative colitis or Crohn's disease AND • For diagnosis of **Crohn's disease**, have trialed and failed Humira and Cimzia OR for a diagnosis of **ulcerative colitis**, have trialed and failed Humira and Simponi. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction ANDHas had an inadequate response with, intolerance to, or demonstrated a dependence on corticosteroids AND • Member is not receiving Entyvio in combination with Humira, Simponi, or Tysabri AND	One year

	• Medication is initiated and titrated per FDA-labeled dosing for Crohn's Disease and Ulcerative Colitis up to a maximum of 300mg IV infusion every 8 weeks **Orencia®** (abatacept) – may be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following: • Members with moderate to severe rheumatoid arthritis who have failed therapy with both Enbrel and Humira • Members with moderate to severe juvenile idiopathic arthritis **Remicade®** (infliximab) will be approved for members who are receiving the infusion in their home or in a long-term care facility and who meet one of the following: • members with ulcerative colitis • members with rheumatoid arthritis who have tried and failed therapy with both Enbrel and Humira • members with psoriatic arthritis • members with ankylosing spondylitis • members with juvenile idiopathic arthritis • members with plaque psoriasis • members with Crohn's Disease **Rituxan®** (rituximab) IV and subcutaneous - will be approved for administration in a long-term care facility or in a member's home by a home healthcare provider AND for members who meet one of the following: • Members with moderate to severe rheumatoid arthritis who have tried and failed both Enbrel and Humira • Members with Chronic Lymphocytic Leukemia • Members with Non-Hodgkins Lymphoma Prior Authorizations for biosimilars **Inflectra®** and **Renflexis®** may be approved on a case by case basis.	
THROMBOLYTIC ENZYMES	Approved for **IV Catheter Clearance or Occluded AV Cannula** if given in member's home or long term care facility.	One year
TOBACCO CESSATION	Effective 11/01/18 prior authorization will not be required for tobacco cessation medications including nicotine gum, nicotine patch, nicotine lozenge, nicotine inhaler (Nicotrol®), varenicline (Chantix®), and bupropion SR (Zyban®). Smoking and tobacco cessation resources are available at no charge to members or providers through the Colorado QuitLine found at coquitline.org or by calling 1-800-QUIT-NOW.	
TPN PRODUCTS	Approval will be given if administered in the member's home or in a long-term care facility by a home healthcare provider. If given in the hospital or physician's office, the claim must be billed as a medical expense.	Lifetime
TYBOST (cobicistat)	**Tybost®** will be approved for members who meet the following criteria: • Member has a diagnosis of HIV-1 AND • Member is currently being treated with atazanavir or darunavir only AND • Member is not taking cobicistat-containing drugs, or ritonavir-containing drugs AND • Member has failed treatment with ritonavir (failure defined as intolerable side effect, allergy, or lack of efficacy).	One year
TYSABRI (natalizumab)	Tysabri (natalizumab) will be approved for initial therapy if the following criteria are met:	One year

	• Tysabri is being administered in a long-term care facility or in home-health setting **AND** • Medication is not currently being used in combination with immunosuppresants (azathioprine, 6-mercaptopurine, methotrexate) or TNF-alpha inhibitors (adalimumab, certolizumab pegol, infliximab) **AND** <u>If prescribed for induction of remission of moderate to severe Crohn's disease</u> • The patient is ≥ 18 years of age **AND** • Member has tried and failed Aminosalicylates **AND** • Member has tried and failed Corticosteroids **AND** • Member has tried and failed immunomodulators **AND** • Member has tried and failed two TNF-alpha inhibitors (e.g. adalimumab, • certolizumab pegol, infliximab) **AND** • Tysabri is prescribed by or in consultation with a gastroenterologist. <u>If prescribed for relapsing remitting multiple sclerosis (RRMS)</u> • The patient is ≥ 18 years of age; **AND** • Member has trial and failure of three of the following agents: Avonex (interferon beta-1a), Rebif (interferon beta 1-a), Betaseron/Extavia (interferon beta-1b), Plegridy (peginterferon beta1a), Copaxone/Glatopa (glatiramer acetate), Aubagio (teriflunomide tablets), Gilenya (fingolimod capsules), Tecfidera (dimethyl fumarate delayed-release capsules), Ocrevus (ocrelizumab) or Lemtrada (alemtuzumab). Failure will be defined as intolerable side effects, drug-drug interaction, or lack of efficacy indicated by one of the following: ○ One of the following on MRI: presence of any new spinal lesions, cerebellar or brain stem lesions, or change in brain atrophy ○ On clinical exam, signs and symptoms consistent with functional limitations that last one month or longer **AND** • Tysabri is prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis	
VACCINES	Effective 11/01/2018, pharmacies that have entered into a collaborative practice agreement with one or more physicians may receive reimbursement (with claim submission through the Health First Colorado <u>medical</u> benefit) for enrolled pharmacists to administer the following vaccines (claims for pharmacist administration of vaccines are not covered under the pharmacy benefit): • Shingles • Pneumococcal • Tdap • Td Additional information regarding pharmacist enrollment and vaccine medical claims billing can be found at https://www.colorado.gov/hcpf/otc-immunizations All other vaccines must be billed on Colorado 1500 form as a medical expense unless administered in a long-term care facility. Pharmacy claims for vaccines administered in a long-term care facility may receive prior authorization approval with verification that the member is residing in a long-term care facility. Not qualified for emergency 3 day supply PA	One year
VALCYTE (valganciclovir hydrochloride)	Effective 05/01/19: Brand Valcyte® solution is covered as a favored product and claims for brand Valcyte® solution will pay with submission of DAW code 0, 1, or 9. Generic valganciclovir solution will require prior authorization and may be approved	One year

<table>
<tr>
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<td>based on prescriber verification that there is clinical necessity of use of the generic product.
Valcyte® (valgancyclovir) tablets are not affected by this change. Brand and generic valganciclovir tablet products will continue to be subject to coverage criteria outlined in the generic mandate (see section “Brand Name Medications and Generic Mandate”).

Valcyte® will be approved for members with diagnosis of Cytomegalovirus (CMV) retinitis AND acquired immunodeficiency Syndrome (AIDS) per dosing guidelines below
OR
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>
<tr><th colspan="2">Adult Dosage</th></tr>
<tr><td>Treatment of CMV retinitis</td><td>Induction: 900 mg (two 250 mg tablets) twice a day for 21 days
Maintenance: 900 mg once a day</td></tr>
<tr><td>Prevention of CMV disease in heart or kidney-pancreas patients</td><td>900 mg once a day within 10 days of transplantation 100 days post-transplantation</td></tr>
<tr><td>Prevention of CMV disease in kidney transplant patients</td><td>900 mg once a day within 10 days of transplantation until 200 days post-transplantation</td></tr>
<tr><th colspan="2">Pediatric Dosage</th></tr>
<tr><td>Prevention of CMV disease in kidney transplant patients 4 month to 16 years of age</td><td>Dose once daily within 10 days of transplantation until 200 days post-transplantation</td></tr>
<tr><td>Prevention of CMV disease in heart transplant patients 1 month to 16 years of age</td><td>Dose once a day within 10 days of transplantation until 100 days post-transplantation</td></tr>
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<tr>
<td>VELTASSA (patiromer)</td>
<td>Veltassa® 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)</td>
<td>One year</td>
</tr>
<tr>
<td>VERIPRED (prednisolone)</td>
<td>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.)</td>
<td>One year</td>
</tr>
<tr>
<td>VERSED (midazolam) Injection</td>
<td>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</td>
<td>One month</td>
</tr>
<tr>
<td>VERSED (midazolam) Injectable Product for Intranasal Use</td>
<td>Midazolam injection used as for nasal inhalation will be approved for members who meet the following criteria:
• Member is ≥ 6 months of age AND
• Has a diagnosis of seizure disorder AND
• Is prescribed by or in conjunction with a Neurologist AND
• Treatment dose does not exceed 10mg</td>
<td>One year</td>
</tr>
</table>

	Dosing Limits: 10 vials or prefilled syringes/month Only MIDAZOLAM 5mg/ml (for doses ≤ 5mg) and 10mg/2ml (for doses > 5 mg) will be covered. 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.	
VITAMINS* (prescription vitamins)	**Coverage criteria outlined in this section apply to vitamin products available as prescription drugs. For over-the-counter product coverage, please see "OTC Products" section.* The following prescription vitamin products will be covered without prior authorization: • Vitamin D • Vitamin K **General prescription vitamin criteria: Prescription vitamin products will be approved for: • ESRD, CRF, renal insufficiency, diabetic neuropathy or renal transplant OR • Members under the age of 21 with a disease state or clinical diagnosis associated with prohibited nutritional absorption processes as a secondary effect OR • Members with Erythema Bullosum Hydroxocobalamin injection will be approved for: • Members meeting any general prescription vitamin criteria** OR • Methylmalonic acidemia (MMA) Cyanocobalamin will be approved for: • Members meeting any general prescription vitamin criteria** OR • Vitamin B12 deficiency Folic acid prescription products will be approved for: • Members meeting any general prescription vitamin criteria** OR • Folic acid 1mg will be approved for female members without a prior authorization OR • Members currently taking methotrexate or pemetrexed OR • Documented folic acid deficiency by the treating clinician (megaloblastic and macrocytic anemia are the most common. Some drugs or other conditions may cause deficiency as well) OR • Homocysteinemia OR • Sickle cell disease OR • Female members prescribed folic acid for the prevention of a neural tube defect during pregnancy or for the prevention of miscarriage Cyanocobalamin/folic acid/pyridoxine prescription products will be approved for: • Members meeting any general prescription vitamin criteria** ORMembers meeting any general prescription vitamin criteria* OR • Members with Homocysteinemia or Homocystinuria OR • Members on dialysis OR • Members with (or at risk for) cardiovascular disease For prescription iron-containing products see "Anti-anemia Medications"	One year

	Metanx will be approved for members with non-healing diabetic wounds	
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
XIFAXAN (rifaximin)	**Xifaxan®** prior authorization will be approved for members meeting the following criteria: • For members prescribed Xifaxan for prophylaxis of hepatic encephalopathy (HE) in adults: o Member must be concomitantly taking lactulose or other non-absorbable disaccharide AND o Member must not have undergone transjugular intrahepatic portosystemic shunt (TIPS) procedure within the last 3 months AND o Xifaxan is being prescribed for secondary prophylaxis of HE (member has experienced previous episode of HE) AND o Maximum dosing regimen is 550mg twice daily o Members meeting criteria will receive approval for one year • For members prescribed Xifaxan for irritable bowel syndrome with diarrhea (IBS-D): o Maximum dosing regimen is 550mg three times daily for 14 days AND o Approval is limited to <u>two</u> 14-day treatment courses per 14 week time period • For members prescribed Xifaxan for traveler's diarrhea: o Member must be ≥ 12 years of age AND o Maximum dosing regimen is 200mg three times daily for 3 days o Members meeting criteria will receive approval for one year	See Criteria
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 an FDA Boxed Warning requiring administration under the supervision of a physician, a PA will not be approved if administered in a member's home.	One year
XYREM (sodium oxybate)	**Xyrem®** may be approved for <u>adults and children 7 to 17 years of age</u> if all the following criteria are met: • Member has a diagnosis of cataplexy or excessive daytime sleepiness with narcolepsy (confirmed by one of the following): o Cataplexy episodes occurring three or more times per month OR o Hypocretin deficiency OR o Nocturnal sleep polysomnography showing rapid eye movement (REM) sleep latency less than or equal to 15 minutes, or a Multiple Sleep Latency Test (MSLT) showing a mean sleep latency less than or equal to 8 minutes and two or more sleep-onset REM periods AND • Baseline excessive daytime sleepiness is measured using the Epworth Sleepiness Scale or cataplexy episode count AND • Member has adequately trialed and/or failed therapy with 3 stimulants for narcolepsy (examples include methylphenidate and amphetamine	Initial Approval: 30 days Continuation Approval: One year

	salts) Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects, or significant drug-drug interactions. AND • Member must not have recent (within 1 year) history of substance abuse AND • Member is not taking opioids, benzodiazepines, sedative hypnotics (such as zolpidem, zaleplon, eszopiclone, chloral hydrate, etc.) or consuming alcohol concomitantly with Xyrem® AND • Prescriber is enrolled in Xyrem® REMS program AND • If member is an adult (age ≥ 18 years), they have had an adequate trial and/or failure of therapy with 3 sedative hypnotic medications (examples include zolpidem and eszopiclone). Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects or significant drug-drug interactions. <u>Initial and Continuation Prior Authorization Approval:</u> Initial prior authorization approval will be for 30 days. For continuation approval for one year, the following information must be provided: • Verification of Epworth Sleepiness Scale score reduction on follow-up OR • Verification of cataplexy episode count reduction on follow-up Maximum dose 9g/day	
YOSPRALA (aspirin/omeprazole)	**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