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-AND-

- An inadequate response or intolerance to a trial of at least two other covered alternatives (one if less than two available) within the same therapeutic class as the requested medication;

- An intolerance or allergy to one of the inactive ingredient(s) found in the generic version(s) of the medication (aripiprazole) that is not found in the brand name medication completed on a FDA Medwatch form.

References

1. Virginia Premier

ABUSE DETERRENT OPIOID (ARYMO, HYSINGLA, MORPHABOND, ZOHYDRO, EMBEDA, ROXYBOND)

Required

1) All long acting opioids
2) Any short-acting opioid prescribed for > 7 days or two (2) 7 day supplies is a 60 day period. The Virginia BOM regulations limit the treatment of acute pain with opioids to 7 days and post-op pain to no more than 14 days
3) Any cumulative opioid prescription exceeding 120 morphine milligram equivalents (MME) per day. Quantity limits apply to each drug

Long-Acting

- Prescriber attest that the member has intractable pain associated with active cancer, palliative care (treatment of symptoms associated with life limiting illnesses), or hospice care OR
- Member is in remission from cancer and prescriber is safely weaning member off opioids with a tapering plan OR
- Member is in a long-term care facility OR
- Diagnosis of Acute pain (less than 90 days), Post-operative pain, or Chronic pain AND
- The prescriber MUST check the Prescription Monitoring Program (PMP) on the date of this request to determine whether the patient is receiving opioid dosages or dangerous combinations (such as opioids and benzodiazepines) that put him or her at high risk for fatal overdose
- Prescriber must provide members active daily MME AND
- If member daily MME greater than 120, prescriber must attest that he/she will be managing the members’ opioid therapy long term has reviewed the Virginia BOM

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
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Regulations for Opioid Prescribing, has prescribed naloxone, and acknowledges the warnings associated with high dose opioid therapy including fatal overdose, and that therapy is medically necessary for this member AND

- Provider must provide last fill date from PMP for opioid and benzodiazepine prescription AND
- If benzodiazepine filled within the last 30 days, prescriber must attest that he/she has counseled the member on the FDA black box warning on the dangers of prescribing Opioids and Benzodiazepines including fatal overdose, has documented that the therapy is medically necessary, and has recorded a tapering plan to achieve the lowest possible effective doses of both opioids and benzodiazepines per the Board of Medicine Opioid Prescribing Regulations
- If member is a female between the ages of 18-45 prescriber must attest to discussing the risk of neonatal abstinence syndrome and provided counseling on contraceptive options
- For Chronic Pain the prescriber must order a UDS or serum medication level PRIOR to initiating treatment with short and/or long acting opioids

Renewal

- Prescriber must order and review UDS or serum medication level every three (3) months for the first year of treatment and every six (6) months thereafter to ensure medication adherence

Short Acting

- The prescriber MUST check the Prescription Monitoring Program (PMP) on the date of this request to determine whether the patient is receiving opioid dosages or dangerous combinations (such as opioids and benzodiazepines) that put him or her at high risk for fatal overdose
- Prescriber must provide members active daily MME AND
- If member daily MME greater than 120, prescriber must attest that he/she will be managing the members’ opioid therapy long term has reviewed the Virginia BOM Regulations for Opioid Prescribing, has prescribed naloxone, and acknowledges the warnings associated with high dose opioid therapy including fatal overdose, and that therapy is medically necessary for this member AND
- Provider must provide last fill date from PMP for opioid and benzodiazepine prescription AND
- If benzodiazepine filled within the last 30 days, prescriber must attest that he/she has counseled the member on the FDA black box warning on the dangers of prescribing Opioids and Benzodiazepines including fatal overdose, has documented that the therapy is medically necessary, and has recorded a tapering plan to achieve
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- ONE OF THE FOLLOWING:
  - FOR Long acting agent (Arymo ER, Hysingla ER, Morphabond ER, Zohydro): Member has had a trial and inadequate clinical response or intolerance to two preferred long-acting agents (Fentanyl patch, Morphine Sulfate ER, Oxycodone ER/Oxycontin); OR
  - FOR Short acting agent (Embeda, Roxybond): Member has had a trial and inadequate clinical response or intolerance to two preferred short acting agent (Oxycodone tablet, morphine sulfate tablet, oxycodone/apap, hydromorphone) corresponding to the formulation being requested; OR
  - Patient has a need for an abuse-deterrent formulation based upon a history of substance abuse disorder by dissolving in order to inject or snorting OR

Patient has a need for an abuse-deterrent formulation based upon household resident has active substance abuse disorder or a history of substance use disorder

**ACNE AGE LIMIT**

- Prescriptions for patients over the age of 18 years will require a prior authorization to determine diagnosis for treatment
- Products will only be covered for a diagnosis of acne vulgaris, cosmetic indications cannot be approved

**ACTEMRA (TOCILIZUMAB)**

- Prescribed by a Rheumatologist, AND
- Negative tuberculosis test or received treatment if tested positive, AND
- Absolute neutrophil count (ANC) > 2000/mm3, AND
- Platelet count must be > 100,000/ mm3, AND
- ALT and AST must not be 1.5 times the upper limit of normal, AND
- ≥18 years of age:
  - Moderately to severely active Rheumatoid Arthritis, AND
  - Tried/failed/intolerance to at least one DMARD, AND
  - Tried/failed/intolerance to methotrexate, AND
  - Tried/failed/intolerance to Enbrel and Humira, OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• ≥2 years of age:
  o Systemic Juvenile Idiopathic Arthritis (SJIA) or Polyarticular juvenile rheumatoid arthritis, AND
  o Tried/failed/intolerance to glucocorticoids or methotrexate

Reauthorization/Continuing treatment:
• Documentation of response to therapy using quantitative measures (e.g., reduction in ESR, CRP, and reduction in duration of morning stiffness and/or number of swollen/painful joints), AND
• Documentation of ALL of the following, along with date performed:
  o ANC at least 500/mm³
  o Platelet count at least 50,000/mm³ (50 x 10⁹/L, 5 x 10⁸/L 50,000/ml, 50 K/µL)
  o Transaminases (ALT, AST) not greater than 5x ULN

References


ACTIQ (FENTANYL CITRATE) LOZENGE
Criteria for use (bullet points below are all inclusive unless otherwise noted):
• The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
• Only approved for management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for underlying persistent cancer pain.
• Patients considered opioid-tolerant are those who are taking at least: 60 mg morphine/day or an equianalgesic dose of another opioid for a week or longer.
• Must be 18 years of age or older (16 or over for Actiq).
• Must be prescribed by oncologist or pain specialist.
• Must be able to comply with instructions to keep medication out of the reach of children and to discard open units properly.
• Maximum of a quantity of 4 units total for any combination of fentanyl oral products.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Must try and fail an adequate dose of a formulary immediate release narcotic for breakthrough pain.
• Must be on an adequate dose of a long-acting (maintenance, around-the-clock) opioid.

REFERENCES
3. Virginia Premier

ACTHAR HP (REPOSITORY CORTICOTROPIN)

Infantile Spasms
• Prescribed by a Pediatric Neurologist, AND
• Infantile Spasm In Infants and children under TWO YEARS of AGE.
• Authorization is for maximum of 30 days
• FOR ALL OTHER INDICTIONS, Virginia Premier to review.
  o ***Partially approve the EOC and submit to the PA Hub External queue. Send an e-mail to Adam @ aharbert@envisionrx.com noting the EOC # and requested indication for use. Adam will forward the supporting documentation to the medical team at VPHP for final coverage determination.***

ACZONE (DAPSONE)

Criteria for use (bullet points below are all inclusive unless otherwise noted):

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Patient must be 12 years of age or older.
• Patient must be clinically diagnosed with acne vulgaris.
• Must be prescribed by a dermatologist.
• Must have tried and failed at least two other topical antimicrobial agents alone or in combination with benzoyl peroxide.
• Must have tried and failed tretinoin cream or gel.

**ADEMPAS (RIOCIGUAT)**
Criteria for use (bullet points below are all inclusive unless otherwise noted):

• Clinically diagnosed with pulmonary arterial hypertension (WHO Group 1). The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records;
• Patients with NYHA class II-IV
• Prescribed by a pulmonologist, cardiologist or a physician specializing in pulmonary arterial hypertension or chronic thromboembolic pulmonary hypertension
• Patient is not smoking cigarettes
• Must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test.
• Must have tried and failed sildenafil
• Must have tried and failed ambrisentan or bosentan
• QL of 90/30; OR

• Clinically diagnosed with persistent/recurrent chronic thromboembolic pulmonary hypertension (WHO Group 4) after surgical treatment or inoperable chronic thromboembolic pulmonary hypertension
• Patients with NYHA class II-IV
• Must have tried and failed bosentan
• QL of 90/30; AND
• No Contraindications:
  o Pregnancy
  o Use with nitrates or nitric oxide donors in any form
  o Use with phosphodiesterase (PDE) inhibitors

Criteria for continuation of therapy:

• Patient responding to treatment as demonstrated by improvement in six-minute walking test, improvement in functional class, a decrease in pulmonary artery pressure, or an increase in cardiac index
• Patient is tolerating and responding to medication and there continues to be a medical need for the medication
• QL of 90/30
• No Contraindications:
  o Pregnancy

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

References:


ADHD AGE LIMIT

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- For children < 4 years of age:
  - Medication is being prescribed by, or in consultation with, a Pediatric Psychiatrist, Pediatric Neurologist, or Developmental/Behavioral Pediatrician; OR
- For 18 years of age and older:
  Initial
  - Clinically diagnosed with ADD, ADHD or other FDA approved indication
  - Prescriber used the DSM V and determined that criteria have been met (including documentation of impairment in more than 1 major setting) to make diagnosis of ADHD, AND
  - Prescriber has reviewed the Virginia Prescription Monitoring Program on the date of this request, AND
  - Prescriber has ordered and reviewed a urine drug screen (UDS) prior to initiating treatment with the requested stimulant within 30 days of this request and the drug screen is submitted with the request (checking for THC, benzodiazepines, amphetamine/methamphetamine, cocaine, heroin, and other prescription opiates) AND
  RENEWAL
  - The prescriber has checked the prescription monitoring program at least every three (3) months after the start of treatment (and date of most recent check is provided), AND
  - Prescriber has ordered and reviewed a random urine drug screen at least every six (6) months (date of most recent check provided), AND
  - Prescriber has regularly evaluated the patient for stimulant and/or other substance use disorder, and, if present, initiated specific treatment, consulted with appropriate health care provider, or referred the patient for evaluation for treatment if needed.

Authorization: 12 months

AEMCOLO (RIFAMYCIN)

CRITERIA FOR USE

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• The indicated diagnosis must be for the treatment of Traveler’s Diarrhea 
   AND
• Patient must be 18 years of age or greater 
   AND
• An inadequate response, intolerance, contraindication or history of resistance to ciprofloxacin and azithromycin 
   AND
• An inadequate response, intolerance, contraindication to Xifaxan

Not approved if:
• Does not meet above criteria
• Any contraindication to treatment

Approval Duration: One treatment course (12 tablets/days) per year

Quantity Limit: 12 tablets/28 days; 1 treatment course per year

References
1. Aemcolo™ (rifamycin) product package insert, Aries Pharmaceuticals, INC. San Diego, CA 92121 November 2018

AFINITOR (EVEROLIMUS)
Afinitor (everolimus) may be approved for patients who meet the following criteria:
• Patient has a diagnosis of renal angiomyolipomas and tuberous sclerosis complex (TSC) and does not require immediate surgery, OR
• Patient has a diagnosis of Renal Cell Carcinoma (kidney cancer); AND
• Patient has failed treatment with one of the following:
  o Sutent (sunitinib); OR
  o Nexavar (sorafenib), OR
• Patient has a diagnosis of Waldenstrom’s macroglobulinemia (lymphoplasmacytic lymphoma) (NCCN), OR
• Patient has a diagnosis of Subependymal Giant Cell Astrocytoma (SEGA) associated with Tuberous Sclerosis (TS), OR
• Patient has a diagnosis of progressive neuroendocrine tumors of pancreatic origin that is unresectable, locally advanced, or metastatic, OR
• Patient has a diagnosis of lung neuroendocrine tumors. (NCCN), OR
• Patient has a diagnosis of hormone receptor-positive, HER2-negative metastatic breast cancer and prior therapy with a nonsteroidal aromatase inhibitor (e.g. Femara (letrozole), Arimidex (anastrozole)) (NCCN); AND
• Patient will be using Afinitor (everolimus) in combination with Aromasin ( exemestane)(NCCN)

References
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

ALFERON N (INTERFERON ALFA-N3)

- ≥18 years of age, AND
- External condylomata 19ysteine19 (venereal or genital warts or perianal warts), AND
- Tried/failed a minimum of 16 weeks of or intolerance to imiquimod cream, AND
- Non-allergic to egg protein, albumin, mouse immunoglobulin or neomycin.

Reauthorization/Continuing treatment:
- Patient must not initiate therapy until 3 months after the initial course of therapy, unless the warts enlarge or new warts appear.

References


ALOXI (PALONOSETRON)

- Prevention of nausea and vomiting associated with moderately or highly emetogenic cancer chemotherapy, OR
- Prevention of postoperative nausea and vomiting (PONV)

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


AMITIZA (LUBIPROSTONE)

- 18 years of age or older, AND
- Diagnosis of Idiopathic Constipation with treatment failure of at least ONE (1) preferred product from TWO (2) of the following classes:
  - 1) Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol), OR,
  - 2) Bulk Forming Laxatives (examples: Metamucil® (psyllium), Citrucel®, fiber), OR
  - 3) Stimulant Laxatives (examples: bisacodyl, senna). OR
- Diagnosis of Constipation predominant irritable bowel syndrome (IBS-C), AND patient is female, AND treatment failure of at least ONE (1) preferred product from TWO (2) of the following classes:
  - 1) Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol), OR,
  - 2) Bulk Forming Laxatives (examples: Metamucil® (psyllium), Citrucel®, fiber), OR
  - 3) Stimulant Laxatives (examples: bisacodyl, senna). OR
- Diagnosis of Opioid Induced Constipation in chronic NON-cancer pain, AND patient has tried and failed both PEG (i.e. Miralax) AND Lactulose.

Authorization: 6 months

AMPYRA (DALFAMPRIDINE)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial therapy (all of the following is required)
1. Indication of walking difficulty with a diagnosis of MS.
2. Prescribed by a neurologist.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
3. Medical records from neurology consultation documenting the deterioration of walking ability confirmed by gait assessment (e.g. MS Walking Scale 12 (MSWS-12), Timed 25-foot Walk (T25FW), 6-minute Walk Test, Expanded Disability Status Scale (EDSS).
4. Documentation of past or current physical therapy
5. History of or current treatment with immune modulating therapies for MS
6. No history of seizure and no diagnosis of moderate to severe renal impairment.

Continuation of Therapy
1. Medical records from neurology consultation documenting the improvement of walking ability confirmed by gait assessment.

EXCLUSIONS

Ampyra will not be covered in patients with any of the following exclusion criteria:
1. The patient has a seizure disorder, OR
2. The patient has moderate renal impairment (defined as a creatinine clearance (CrCl) of 30–50 ml/min) or severe renal impairment (defined as a CrCl ≤50 ml/min), OR
3. The patient is unable to walk 25 feet in 8–60 seconds with walking aids if needed, OR
4. The patient has minimal or no impairment of ambulation (corresponding to an EDSS of less than 4.5*), OR
5. The patient has severe impairment of ambulation and is essentially restricted to a wheelchair (corresponding to an EDSS of 7* or higher) OR
6. Contraindications to prescribing.

*The Expanded Disability Status Score (EDSS) quantifies disability in eight functional systems: pyramidal, cerebellar, brainstem, sensory, bowel and bladder, visual, cerebral, and other. EDSS scores 1.0 to 4.5 refer to people with multiple sclerosis who are fully ambulatory. EDSS scores 5.0 to 9.5 are defined by increasing impairment to ambulation.

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
11. Ampyra™, Symptomatic Medicine Approved by FDA to Improve Walking for People with All Types of MS. Available at www. Nationalmssociety.org

ANTIMIGRAINE (AIMOVIG, EMGALITY, AJOVY)

Initial

- Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria AND
- Member is age 18 or older AND
- Member does NOT have medication overuse headache AND
- Women of childbearing age have had a pregnancy test at baseline AND
- Member has experienced ≥ 4 migraines per month for at least 3 months AND
- Member is utilizing prophylactic intervention modalities (e.g. behavioral therapies, physical therapy, or life-style modifications) AND
- Member has tried and failed ≥ 1 month trial of any 2 of the following oral medications; Antidepressants (e.g. amitriptyline, venlafaxine), Beta-Blockers (propranolol, metoprolol, timolol, atenolol); Anti-epileptics (e.g. valproate, topiramate); ACE-Inhibitors/Angiotensin II receptor blockers AND
- If requesting a product other than Emgality, Member has tried and failed preferred anti-cgrp medication, Emgality

Continuation

- Member demonstrates significant decrease in the number, frequency, and/or intensity of headaches AND
- Member exhibits an overall improvement in function with therapy AND
- Member continues to utilize prophylactic intervention modalities (e.g., behavioral therapy, physical therapy, life-style modification) AND
- Women of childbearing age continue to be monitored for pregnancy status

Approval Duration:

Initial: 6 months
Continuation: 12 months

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

ANTIPSYCHOTICS < 18 YEARS OF AGE

For patients less than 18 y.o.:
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Medication is prescribed by or documented consultation with a psychiatrist, neurologist, or developmental/behavior pediatrician, AND
- Patient is participating in a behavioral management program (NOTE: Not applicable if a Psychiatrist), AND
- Patient has received a developmentally-appropriate, comprehensive psychiatric assessment with diagnoses, impairments, treatment target, and treatment plan clearly identified and documented (NOTE: Not applicable if a Psychiatrist), AND
- Patient has had inadequate response to at least 12 weeks of psychosocial treatment and psychosocial treatment will continue with parent/guardian involvement for the duration of medication therapy (NOTE: Not applicable if a Psychiatrist).

Authorization: 6 months

References

1. Virginia Premier

ANZEMET (DOLASETORN MESYLATE) VIAL
- Prevention and treatment of postoperative nausea and vomiting (PONV), OR
- Prevention of radiation-induced nausea and vomiting.
- Chemotherapy-induced nausea and vomiting; Prophylaxis

References


ARCALYST (RILONACEPT)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Prescribed by a Rheumatologist or Immunologist, AND
• ≥ 12 years of age, AND
• Cryopyrin-Associated Periodic Syndromes (CAPS) disorder:
  o Familial Cold Autoinflammatory Syndrome, OR
  o Muckle-Wells Syndrome.

Note: Must NOT be the following CAPS disorders:
• Neonatal-Onset Multisystem Inflammatory Disease (NOMID), OR
• Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA).

References


AREDIA (PAMIDRONATE DISODIUM)

• Hypercalcemia and patient’s hypercalcemia must be associated with malignancy or immobilization and lab reports verify high calcium levels, OR
• Osteolytic metastases and the patient is also diagnosed with multiple myeloma, OR
• Severe osteogenesis imperfecta with bone pain and repeated fractures, OR
• History of osteoporotic fracture or low trauma fracture, OR,
• Osteoporosis, with BMD T-score: < -2.5 SD from the mean, OR,
• BMD T-score between: -1 and -2.5 SD with the presence of one or more of the following:
  o Age > 50 years old
  o Postmenopausal status in women
  o Hypogonadal status in men
  o Currently taking certain medications that can decrease BMD:
    • Glucocorticoids (equivalent of >5mg/day of prednisone for > 3 months),
    • Cyclosporine, chemotherapy, anticonvulsants, aluminum salts,
    • Gonadotropin-releasing hormone agonists, heparin, lithium, high doses of thyroxine
  o Concurrent disease state that increases the risk of osteoporosis:
    • Hypogonadal diseases, endocrine disorders, nutritional and gastrointestinal disorders, rheumatic disorders, hematologic/oncologic disorders, organ transplantation, selected inherited disorders, chronic obstructive pulmonary disease, pregnancy and lactation, scoliosis,
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Other risk factors:
  - Vitamin D or calcium deficiency, alcohol intake (3 or more drinks per day), parental history of hip fracture, small frame or stature, early menopause, and low body mass index (BMI in kg/m²; BMI for healthy weight is between 18.5 to 24.9 kg/m², current smoking.
  - Tried/failed/intolerance to alendronate.
  - Paget's disease of bone with elevations in serum alkaline phosphatase (ALP) of ≥2 x ULN of the age-specific normal reference range with:
    - Symptomatic disease (bone pain, hearing loss, bone deformities, fractures, arthritis), AND
    - At risk of complications from Paget's disease (e.g., osteoarthritis, heart failure, kidney stones, broken bones), AND
    - Concomitant treatment with calcium and vitamin D, AND
  - Tried/failed/intolerance to alendronate.

References


ARIKAYCE

CRITERIA FOR USE

- Patient must have a diagnosis of Mycobacterium Avium Complex (MAC) lung disease, refractory AND
- MAC must be confirmed by any of the following; chest radiography or high resolution computed tomography (HCRT) scan; At least 2 positive serum cultures AND
- Other conditions such as tuberculosis and lung malignancy have been ruled out AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Patient is 18 years of age or older  
  AND  
• Patient has failed a multi-drug regimen with a macrolide (clarithromycin or azithromycin) rifampin and ethambutol (Failure defined as continual positive sputum cultures for MAC while adhering to a multi-drug treatment regimen for a minimum duration of 6 months)  
  AND  
• Patient had a documented failure or intolerance to aerosolized administration of amikacin solution for injection, including pretreatment with a bronchodilator

**ATRIPLA (EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE)**

**Duplicate therapy:**
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

**References**

1. Virginia Premier

**AUBAGIO (TERIFLUNOMIDE)**

**Criteria for use (bullet points below are all inclusive unless otherwise noted):**

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Must be clinically diagnosed with relapsing remitting multiple sclerosis
- Must be 18 years of age or older
- Failed/intolerant to Copaxone (glatiramer acetate)
- Intolerant to both Avonex (IFN Beta-1a) and Betaseron (IFN Beta-1b)

**OR**

- Failure with Avonex (IFN Beta-1a) or Betaseron (IFN Beta-1b)
- Patient must have been compliant with treatment
- Patient must meet at least one of the following conditions:
  - Two disabling relapses within a 12-month period
  - Secondary progression with an observable increase in disability over a six-month period
  - Loss of ability to walk for a period longer than six months

**Criteria for continuation of therapy:**
- Continued response – decrease in number of, or no relapses

**Contraindication:**
- Severe hepatic impairment

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
- Pregnancy
- Current leflunomide treatment

Not approved if:
- Does not meet the above stated criteria.
- Have any contraindications to the use of teriflunomide.

References
1.) Virginia Premier

AURYXIA (FERRIC CITRATE)

CRITERIA FOR USE
- Patient must have a diagnosis of Hyperphosphatemia
  AND
- Patient must have chronic kidney disease on dialysis
  AND
- Patient is 18 years of age or older
  AND
- Patient has tried/failed or intolerant to Calcium Acetate Capsules (667mg)
  AND
- Patient has tried/failed or intolerant to Sevelamer

Criteria for Renewal
- Patient continues to meet initial criteria
  AND
- Prescriber attests patient has had a positive response to therapy

Not approved if:
- Does not meet above criteria
- Any contraindication to treatment

Approval Duration: Initial – 6 months; Renewal – 12 months

AUSTEDO (DEUTETRABENAZINE)

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- Member is 18 years of age or older, AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Member has a diagnosis of Chorea associated with Huntington’s Disease OR
• Member has a diagnosis of Tardive Dyskinesia, AND
• Medication is prescribed by, or in consultation with, a Neurologist or Psychiatrist, AND
• Member has attempted an alternative method to manage the condition such as dose reduction, tapering, discontinuation of the offending agent, switching to an alternative agent AND
• For diagnosis of Chorea associated with Huntington’s Disease: Member has an intolerance or treatment failure of tetrabenazine AND
• Member is not receiving concurrent therapy with MAOI or VMAT2 inhibitors AND
• Member does not have any suicidal thoughts/behaviors or untreated or inadequately treated depression

FOR RENEWAL:
• Documentation of positive clinical response to Austedo and improvement in AIMS score AND
• Absence of toxicity from the drug AND
• Must not be taking other MAOI or VMAT2 inhibitors

DURATION:
Initial – 3 months, Renewal 12 months

**AUVI-Q (EPINEPHRINE)**

Criteria for use for (bullet points below are all inclusive unless otherwise noted):
• Must be used for treatment of anaphylaxis
• Must have clinical trial and failure of all of the following:
  o Epinephrine Auto-Injector (generic EpiPen)
  o Epinephrine Injection (generic AdrenaClick)
  o AdrenaClick
  o EpiPen (requires Prior authorization and trial and failure of all previously listed) OR
  o Patient has visual or hearing deficits requiring the need for an auto-injector with visual cues for self-administration (chart notes/medical record documenting visual/hearing deficit required)
• Patient weighs 7.5kg (16.5 lbs.) or more
• Not approved for convenience of use

**References**
Virginia Premier

**AVASTIN (BEVACIZUMAB)**
• Metastatic colorectal cancer, in combination with oxaliplatin and capecitabine, OR
• Metastatic carcinoma of the colon or rectum and used in combination with a 5-fluorouracil-based chemotherapy regimen, OR
• Metastatic carcinoma of the colon or rectum and used in combination with irinotecan, OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
- Non-squamous, non-small cell lung carcinoma (NSCLC) and used in combination with platinum-based systemic chemotherapy (e.g. cisplatin, carboplatin) and paclitaxel, OR
- Ovarian cancer and tried/failed/intolerance to two chemotherapy regimens, OR
- Relapsed or medically unresectable stage IV clear cell renal carcinoma and used in combination with interferon alfa-2a, OR
- Neovascular (Wet) Age-Related Macular Degeneration confirmed by an ophthalmologist, OR
- Recurrence or salvage therapy of Glioblastoma Multiforme, Anaplastic Astrocytoma or Anaplastic Oligodendroglioma, AND
  - Received radiation therapy and tried/failed/intolerance to systemic chemotherapy (e.g. temozolomide, carmustine, or an agent that has activity against the primary tumor), OR
- Neovascular Glaucoma and tried/failed/intolerance to maximal doses of one antiglaucoma medication, OR
- Proliferative diabetic retinopathy, AND
  - Will be undergoing vitrectomy, OR
- Diabetic macular edema, OR
- Soft tissue sarcoma, AND
  - Angiosarcoma, OR
  - Solitary fibrous tumor/hemangiopericytoma, OR
- Retinopathy of prematurity, OR
- Metastatic breast cancer, HER2-negative, OR
- Metastatic breast cancer, In combination with capecitabine in patients previously treated with an anthracycline and a taxane.

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

BANZEL (RUFINAMIDE)

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- Must be clinically diagnosed with seizures associated with Lennox-Gastaut syndrome.
- Patient must be refractory to at least 2 of the following:
  i. Felbamate (Felbatol)
  ii. Lamotrigine (Lamictal)
  iii. Topiramate (Topamax)
  iv. Valproic acid (Depakene)
  v. Divalproex sodium (Depakote)
- Must be 4 years of age or older.
- Patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.
- Not approved for Patients with familial short QT syndrome (contraindication).

Not approved if:
- Does not meet the above stated criteria
- Patient has any contraindications to the use of rufinamide

References
1. Virginia Premier

BELBUCA (BUPRENOPRHINE FILM)

Generic name: Buprenorphine buccal film
Brand name: Belbuca
Medication class: Analgesic; partial opioid agonist
FDA-approved uses: Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
Available dosage forms: 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg buccal film

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Usual dose: One film twice daily

Criteria for use for Belbuca (bullet points below are all inclusive unless otherwise noted):

- Must have moderate to severe chronic cancer pain, which requires management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. APPROVE for 6 months.

OR

- Moderate to severe chronic non-cancer pain which requires management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time.
- Prescriber has checked state Prescription Monitoring Program for other controlled substance use.
- Patient has clear treatment goals
- Quantity Limits: must be prescribed with the FDA labeling: Belbuca: 60 films per 30 days
- Trial and failure or was intolerant to at least 2 non-opioid therapies such as:
  - APAP/NSAIDs/Cox-2 agent- e.g. celecoxib, ibuprofen
  - Anticonvulsants- e.g. Gabapentin
  - Muscle relaxants- e.g. Baclofen, tizanidine,
  - Antidepressants- Duloxetine, amitriptyline, nortriptyline, desipramine, imipramine, venlafaxine
  - Topical analgesics- Lidocaine Patches, diclofenac 1% gel

Criteria for continuation of therapy:

- Patient’s pain has been recently re-assessed and there continues to be a medical need for the medication.
- Patient is tolerating and responding to medication.
- Patient has improved functioning and is meeting treatment goals.
- Patient is not exhibiting addictive behaviors and is not being treated for substance abuse.

Cautions:

- Can cause QT prolongation.
- Drug interactions with Class 1A or Class III antiarrhythmic.

Contraindication:

- patients who have significant respiratory depression,
- patients with severe bronchial asthma,
- patients who have or are suspected of having paralytic ileus,
- Patients with known hypersensitivity to any of the product’s ingredients.
- Management of acute pain, postoperative pain, mild pain, and intermittent pain, and in patients who require short-term opioid analgesic therapy.

Not approved if:

- Being used for treatment of opioid dependence
- Has any contraindications to the use of Belbuca
- Does not meet the above stated criteria.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Patient is being treated for substance abuse (including treatment with buprenorphine or buprenorphine-naloxone).

References

1. Virginia Premier

BONIVA (IBANDRONATE) SYRINGE

• Osteoporosis or high risk of osteoporosis with any ONE of the following:
  o BMD T-score worse than -2.5 SD (DEXA [Dual Energy X-ray Absorptionmetry] measured T-scores), OR
  o History of osteoporotic fractures (i.e. vertebral, hip, compression fractures), OR
  o BMD T-score between: -1 and -2.5 SD with the presence of one or more of the following:
    ▪ Age > 50 years old
    ▪ Postmenopausal status in women
    ▪ Hypogonadal status in men
    ▪ Currently taking certain medications that can decrease BMD:
      ▪ Glucocorticoids (equivalent of >5mg/day of prednisone for > 3 months), cyclosporine, chemotherapy, anticonvulsants, aluminum salts, gonadotropin-releasing hormone agonists, heparin, lithium, high doses of thyroxine
    ▪ Concurrent disease state that increases the risk of osteoporosis:
      ▪ Hypogonadal diseases, endocrine disorders, nutritional and gastrointestinal disorders, rheumatic disorders, hematologic/oncologic disorders, organ transplantation, selected inherited disorders, chronic obstructive pulmonary disease, pregnancy and lactation, scoliosis, multiple sclerosis, sarcoidosis, amyloidosis, acromegaly, diabetes mellitus type 1, chronic liver disease, or states of immobilization.
    ▪ Other risk factors:
      ▪ Vitamin D or calcium deficiency, alcohol intake (3 or more drinks per day), parental history of hip fracture, small frame or stature, early menopause, and low body mass index (BMI in kg/m2; BMI for healthy weight is between 18.5 to 24.9 kg/m2, current smoking, AND

• Tried/failed/intolerance to alendronate.

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


**BOTOX (ONABOTULINUMTOXINA)**

- Dystonia, Spasticities, and Neuro-ophtalmological conditions, including:
  - Focal Dystonias:
    - Treatment of blepharospasm, OR
    - Cervical dystonia, including spasmodic torticollis, OR
    - Focal hand dystonia (e.g. writer’s cramp), OR
    - Jaw-closing oromandibular dystonia causing any one of the following:
      - Persistent pain
      - Interference with nutritional intake
      - Significant speech impairment/interference with the ability to communicate, OR
  - Meigne’s syndrome/cranial dystonia (i.e., blepharospasm with jaw-closing oromandibular cervical dystonia causing any one of the following:
    - Persistent pain
    - Interference with nutritional intake
    - Significant speech impairment/interference with the ability to communicate, OR
  - Meigne’s syndrome/cranial dystonia (i.e., blepharospasm with jaw-closing oromandibular cervical dystonia causing any one of the following:
    - Persistent pain
    - Interference with nutritional intake
    - Significant speech impairment/interference with the ability to communicate, OR

- Spastic conditions:
  - Cerebral palsy (including spastic equines foot deformities), OR
  - Cerebrovascular accident, OR
  - Localized adductor muscle spasticity in multiple sclerosis, OR
  - Spinal cord injury, OR
  - Traumatic brain injury, OR
  - Muscle spasms unresponsive to at least 2 traditional therapies (i.e. muscle relaxants), OR

- Hemifacial spasms/Seventh cranial nerve palsy causing persistent pain or vision impairment, OR

- Trigeminal Neuralgia/ Temporomandibular Joint Disorder (TMJ), OR

- Strabismus disorders in adults, when:
  - One of the following is present:
    - Horizontal strabismus up to 50 prism diopters
    - Vertical strabismus
    - Persistent sixth nerve palsy of one month or longer duration
    - AND
  - One of the following is present:
    - Diplopia
    - Impaired depth perception
    - Impaired peripheral vision
    - Impaired ability to maintain fusion, OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
- Gastrointestinal Conditions:
  - Primary Esophageal Achalasia with any of the following:
    - Patients who are considered poor surgical risks (e.g., patients with comorbidities such as elderly patients with decreased life expectancy
    - Patients who have a history or are at high risk for complications of myotomy or perforation caused by previous pneumatic dilatation
    - Epiphrenic diverticulum or hiatal hernia
    - Previous esophageal perforation
    - Sigmoid-shaped esophagus
    - Tried/failed/intolerance to isosorbide dinitrate, nifedipine, or verapamil, OR
- Hyperhidrosis
  - Treatment of primary and secondary axillary OR palmar hyperhidrosis OR gustatory sweating (Frey' syndrome) when the condition is refractory to conventional topical treatment (e.g., prescription strength topical aluminum chloride, Drysol), AND:
    - Interfering with patients activities of daily living, OR
    - Causing persistent or chronic cutaneous conditions such as skin maceration, dermatitis, fungal infections, and secondary microbial conditions, AND
    - Episodes occur at least once per week, AND
    - Age of onset was less than 25 years, AND
    - Focal sweating stops during sleep, OR
- Voiding dysfunction associated with any of the following:
  - Intracranial lesions or cerebrovascular accident-induced voiding difficulty
  - Detrusor sphincter dyssynergia due to spinal cord injury
  - Tried/failed/intolerance to oral therapy:
    - Urinary antispasmodic (e.g., oxybutynin), OR
    - Tricyclic antidepressant (e.g., amitriptyline), AND
    - Muscle relaxant (e.g., baclofen), OR
- Headache – Migraine or Intractable Daily Headache:
  - Prescribed by a Neurologist or Headache Specialist, AND
  - Chronic daily headache - patients experiencing more than 15 days of headache per month either migraine or tension-type features, AND
  - Headaches at least twice per month causing disability lasting three or more days or more per month, AND
  - Standard abortive medication required more than twice per week or is contraindicated/ineffective/not tolerated, AND
  - Tried/failed/intolerance to 3 of the following preventive therapies:
    - ACEIs/ARBs
    - Beta-blockers,
    - Calcium channel blockers,
    - Anticonvulsants,
    - Antidepressants,
    - NSAIDs, OR
- Backache:
  - Tried/failed/intolerance to oral therapy:
    - Muscle relaxant (e.g., baclofen), OR
    - NSAIDs, OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Benign prostatic hyperplasia:
  o Tried/failed/intolerance to oral therapy:
    ▪ Alpha-blocker, AND
    ▪ 5-alpha-reductase inhibitor, OR
• Excessive salivation (Sialorrhea):
  o Tried/failed/intolerance to oral therapy:
    ▪ Glycopyrrolate, OR
• Epicondylitis, OR
• Fibromyalgia:
  o Tried/failed/intolerance to oral therapy:
    ▪ Gabapentin, OR
    ▪ Lyrica, AND
    ▪ Cymbalta, OR
• Tourette Syndrome, OR
• Tardive dyskinesia, OR
• Whiplash injury to neck

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at
least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Clinically diagnosed with opioid dependence
  - FDA approved indication is for treatment of opioid dependence only, **NOT** pain management.
- Must be 16 years of age or older
- Due to a higher risk of fatal overdose with concomitant use of these drugs, the prescriber shall only co-prescribe (benzodiazepines, opioids, sedative hypnotics, tramadol, carisoprodol) when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medication. Prescriber has a documented tapering plan.
- Prescriber must have reviewed the Virginia Controlled Substance Database Prescription Monitoring Program (PMP) **before the initiation of therapy** ([https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx](https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx))

  Once the diagnosis of opioid dependence has been confirmed, authorization will be given for a 180 day period. A maximum dose of 24/6 mg buprenorphine/naloxone per day is allowed for the first 60 days of therapy. A quantity limit is in place after the 60 days of therapy (2 per day). The prescriber must reduce dose to 16/4 mg buprenorphine/naloxone per day. If the physician believes the patient cannot reduce the dose, a 1x authorization for 30 days of the 24/6 mg/day dose is allowed. Dosing must be 16/4mg or below for future fills after the 1x authorization. Requests are to be denied and the member/prescriber may appeal if dosing cannot be reduced to 16/4 mg/day, after the 1x authorization. Renewal authorizations up to the 16/4 mg/day dosage will be for a 180 day period, pending drug screen results

**Maintenance**

- Clinically diagnosed with opioid dependence
  - FDA approved indication is for treatment of opioid dependence only, **NOT** pain management.
- Must be 16 years of age or older
- Prescriber must review the PMP Web Site **on the date of the request for maintenance therapy**

  A quantity limit is in place after the 60 days of therapy (2 per day). The prescriber must reduce dose to 16/4 mg buprenorphine/naloxone per day. If the physician believes the patient cannot reduce the dose, a 1x authorization for 30 days of the 24/6 mg/day dose is allowed. Dosing must be 16/4mg or below for future fills after the 1x authorization. Requests are to be denied and the member/prescriber may appeal if dosing cannot be reduced to 16/4 mg/day, after the 1x authorization. Renewal authorizations up to the 16/4 mg/day dosage will be for a 180 day period, pending drug screen results

**Quantity Limits**

- Bunavail 2.1-0.3 mg – 1/day
- Bunavail 4.2-0.7 mg – 2/day

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Bunavail 6.3-1mg – 2/day
- Buprenorphine/Naloxone Tablet 2-0.5mg – 3/day
- Buprenorphine/Naloxone Tablet 8-2 mg – 2/day
- Zubsolv 1.4-0.36mg – 2/day
- Zubsolv 2.9-0.71mg – 2/day
- Zubsolv 5.17-1.4mg – 2/day
- Zubsolv 8.6-2.1 mg – 2/day
- Zubsolv 11.4-2.9mg – 2/day

**BUPRENORPHINE (GENERIC BUPREX, GENERIC SUBUTEX)**

**Subutex generic:**

- Diagnosis of opioid use disorder, patient is female between ages of 16 and 44 and patient is pregnant; **OR**

**Initial**

- Clinically diagnosed with opioid dependence
- Must be 16 years of age or older
- Prescriber must have reviewed the Virginia Controlled Substance Database Prescription Monitoring Program (PMP) **before the initiation of therapy** ([https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx](https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx))
- Due to a higher risk of fatal overdose with concomitant use of these drugs, the prescriber shall only co-prescribe (benzodiazepines, opioids, sedative hypnotics, tramadol, carisoprodol) when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medication. Prescriber has a documented tapering plan.

- Patients that cannot tolerate naloxone or Suboxone (buprenorphine/naloxone). Intolerance to Suboxone or naltrexone must be accompanied by documentation of the intolerance from the submission of a FDA Medwatch form to the FDA. Request must include a completed FDA Medwatch form.

**Maintenance**

- Clinically diagnosed with opioid dependence
  - FDA approved indication is for treatment of opioid dependence only, **NOT** pain management.
- Must be 16 years of age or older
- Prescriber must review the PMP Web Site **on the date of the request for maintenance therapy**
- Due to a higher risk of fatal overdose with concomitant use of these drugs, the prescriber shall only co-prescribe (benzodiazepines, opioids, sedative hypnotics, tramadol, carisoprodol) when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medication. Prescriber has a documented tapering plan.
- Prescriber must check random urine drug screens

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Urinary drug screens must check for buprenorphine, norbuprenorphine, methadone, oxycodone, benzodiazepines, amphetamine/methamphetamine, cocaine, heroin, and other prescription opiates.

- A quantity limit is in place of 24mg/day of buprenorphine. Doses over 24mg per day cannot be approved.

**Quantity Limits**
- Buprenorphine SL Tab 2 mg – 12 tabs per day
- Buprenorphine SL Tab 8 mg – 3 tabs per day

**Authorization Dates**
- Pregnancy – 1 time 10 month authorization only
- Allergy to Film/Naloxone – Initial 3 months, Renewal 6 months

**Buprenex inj (generic)**
- Moderate to severe pain, OR
- Postoperative pain

**References**
1. Virginia Premier

**BUTORPHANOL (GENERIC STADOL)**

Migraine Headaches (bullet points below are all inclusive unless otherwise noted)
- Failed / intolerant to VPHP-preferred Triptans
- Failed / intolerant to Fioricet
- Prophylactic therapy is currently being used at a sufficient dose.
  - Or
  - Prophylaxis with at least two different therapy classes was either ineffective or not tolerated.

Criteria for Use: Pain (bullet points below are all inclusive unless otherwise noted)
- Evaluation of chronic pain has been documented.
- Failed other opioid pain management regimens including but not limited to: morphine extended release and Duragesic patches.
- Patient is NPO.
- Criteria for use for greater than 2 canisters per month:
  - Clinical documentation and/or treatment plan to support the need for greater than 2 canisters per month.

**References**
1. Virginia Premier

**CABLIVI (CAPLACIZUMAB-yhdp)**

**CRITERIA FOR USE**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
The prescription must be written by a hematologist AND

member must be at least 18 years of age or older AND

Must have a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) AND

Must be used in combination with plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or rituximab)

Continuation Criteria

Provider must submit documentation of remaining signs of persistent underlying disease (such as suppressed ADAMTS13 activity levels) Ceprotin - Protein C Concentrate,

Auth Duration: 3 months

CALQUENCE (ACALABRUTINIB)

Patient is diagnosed with mantle cell lymphoma

Patient has received at least 1 prior therapy

Patient is 18 years of age or older

Prescribed by an Oncologist

Medication is being used as a single agent

Warnings, Precautions, and other Clinical Information:

Calquence (acalabrutinib) has not been evaluated in patients with severe hepatic impairment (Child-Pugh Class C or total bilirubin between 3-10x ULN and any AST)

Monitor for bleeding and manage appropriately

Monitor patients for signs and symptoms of infection and treat as needed, consider prophylaxis in patients at risk for opportunistic infections

Infections due to hepatitis B virus reactivation and progressive multifocal leukoencephalopathy (PML) have occurred

Monitor complete blood counts monthly for thrombocytopenia and neutropenia

Secondary primary malignancy can occur, especially skin cancer, advise patients to use sun protection

Interrupt and reduce Calquence dose with third occurrence of an adverse effect

Discontinue Calquence with fourth occurrence of an adverse reaction

Avoid use with strong CYP3A inhibitor, if inhibitor use is to be < 7 days, interrupt dose of Calquence

With moderate CYP3A inhibitor use, reduce Calquence dose to 100 mg once daily

Avoid use with strong CYP3A inducers, if unable to avoid, adjust dose of Calquence to 200 mg twice daily

Avoid use with proton pump inhibitors, separation of doses does not eliminate the interaction

Stagger dosing with H2-receptor antagonists and antacids

Woman who is breast feeding an infant or child should stop breast feeding

The mean absolute bioavailability of Calquence (acalabrutinib) is 25%, solubility decreases with increasing pH

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Pretreatment platelet count < 30,000/mm³ (30 x 10⁹/L or 30,000/ml) or a platelet count < 50,000/mm³ (50 x 10⁹/L or 50,000/ml) with significant mucous membrane bleeding or risk factors for bleeding, AND
- Tried/failed/intolerance to corticosteroids or splenectomy.

Reauthorization/continuing treatment:
- Platelet count of at least 50,000/mm³), OR
- Increase in platelet count over baseline to a level sufficient to avoid clinically important bleeding.

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Diagnosis of ACUTE, painful musculoskeletal condition, AND
Trial and failure of at least two (2) formulary preferred alternative skeletal muscle relaxants (i.e. baclofen tablet, tizanidine tablet, cyclobenzaprine tablet, methocarbamol) AND
16 years of age or older

Authorization Date
1 month (Renewal requests will NOT be granted for at least 6 months following last day of previous course of therapy.)

Quantity Limit
4 tablets per day

References
1. Virginia Premier

CHENODAL (CHENODIOL)

Cerebrotendinous xanthomatosis (CTX), OR
Radiolucent Gallstone with the following:
  - Tried/failed/intolerance to ursodiol.

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

CIALIS (TADALAFIL) 5MG ONLY

- Prescribed by a Urologist, AND
- Benign Prostatic Hypertrophy, AND
  - Tried/failed/intolerance to:
    - Doxazosin or terazosin, AND
    - Tamsulosin, AND
    - Finasteride

References

1. Virginia Premier

CIMZIA (CERTOLIZUMAB PEGOL)

- Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Crohn's Disease/Fistulizing Crohn's disease
  - Clinically diagnosed with Crohn’s disease.
  - Prescribed by a GI specialist.
  - Failed/intolerant to at least one corticosteroid.
  - Failed/intolerant to Humira.
  - Failed/intolerant to at least one of the following:
    - sulfasalazine (Azulfidine)
    - mesalazine (Asacol, Pentasa).
- Rheumatoid Arthritis:
  - Prescribed by a rheumatologist
  - Clinically diagnosed rheumatoid arthritis.
  - Failed/intolerant to Enbrel and Humira.
  - Failed/intolerant to at least one of the following:
    - azathioprine (Imuran)
    - 6-mercaptopurine (Purinethol)
    - Methotrexate.
- Ankylosing Spondylitis (AS)
  - Individual is 18 years of age or older with active AS; AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Individual has failed to respond to, is intolerant of, or has medical contraindication to conventional therapy (such as NSAIDs or non-biologic DMARDs); **AND**
- Individual has had an inadequate response to TWO preferred biologic therapies in the previous 180 days. (Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab))

**Psoriatic Arthritis (PsA) when the following are met:**
- Individual is 18 years of age or older with active PsA; **AND**
- Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as non-biologic DMARDs); **AND**
- Individual has had an inadequate response to TWO preferred biologic therapies in the previous 180 days. (Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab))

**Criteria for continuation of therapy:**
- Achievement of clinical response

**Cimzia** (certolizumab pegol) **may NOT be approved** for individuals with any of the following:
- Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections; **or**
- Individuals who have not had a tuberculin skin (TST), or a CDC-recommended equivalent, to evaluate for latent tuberculosis; **or**
- Using in combination with other TNF antagonists; **or**
- Using in combination with the following non-TNF immunomodulatory drugs: abatacept (Orencia), anakinra (Kineret), natalizumab (Tysabri), or rituximab (Rituxan).

**Note:** Cimzia (certolizumab pegol) has a black box warning related to the increased risk of developing serious infections that could result in hospitalization or death. Individuals should be closely monitored for the development of infection during and after treatment with discontinuation of therapy if the individual develops a serious infection or sepsis. Reported infections include: Tuberculosis, invasive fungal infections (including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens (including Legionella and Listeria). The risks and benefits of treatment with Cimzia should be considered prior to initiating in individuals with chronic or recurrent infection. Cimzia is not indicated for the use in pediatric individuals due to reports of lymphoma and other malignancies developing in children and adolescents treated with tumor necrosis factor (TNF) blockers.

**References**

1. Virginia Premier
CINQAIR (RESLIZUMAB)

Cinqair (reslizumab) is indicated for add-on maintenance treatment of patients with severe asthma aged 18 years and older, and with an eosinophilic phenotype.

**Initial Authorization Criteria: Must meet all of the criteria listed below:**
- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist; **AND**
- Patient is at least 18 years of age or older; **AND**
- Clinical diagnosis of severe persistent asthma. **Chart documentation must be provided; AND**
- Must have an eosinophilic phenotype defined as the following
  - A blood eosinophil count of at least 400/mcl within 3 to 4 weeks of dosing. **Test date must be provided; AND**
- Asthma symptoms have not been adequately controlled despite adherence to an optimized medication therapy regimen, defined by one (1) of the following:
  - Hospitalization for asthma in the past year
  - Requirement for systemic (oral, parenteral) corticosteroids to control exacerbations of asthma on two (2) occurrences in the past year
  - On daily corticosteroid with inability to taper off
- Trial and failure of add-on maintenance treatment with a high dose inhaled corticosteroid and two (2) of the following:
  - Inhaled long-acting beta agonist
  - Inhaled long-acting muscarinic antagonist
  - Leukotriene receptor antagonist
  - Theophylline

**Reauthorization Criteria:**
- Prescriber attests that patient’s condition has improved while on therapy.
- Patient has experienced a reduction in one of the following:
  - Exacerbations
  - Hospitalizations
  - Emergency department visits
  - Requirement for oral corticosteroid therapy.

**Authorization**
- Initial – 6 months
- Renewal – 1 year

**References**

COMBIVIR (LAMIVUDINE/ZIDOVUDINE)

**Duplicate therapy:**
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, **AND**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

References

1. Virginia Premier.

COMPLERA (EMTRICITABINE/RILPIVIRINE/TENOFOVIR DISOPROXIL FUMARATE)

Duplicate therapy:
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

References

1. Virginia Premier.

COMPONDED MEDICATIONS

OVERVIEW

Compound prescription drug products are used for a variety of indications from treating pain to hormone replacement therapy. The compounded formulations can contain just one active drug in a base vehicle or they may contain a combination of active drugs. Compounded medications are not Food and Drug Administration (FDA) approved and the FDA has limited regulatory authority over compounding pharmacies, since they are licensed by their respective state board of pharmacy. Compounded medications also do not undergo the rigorous drug review process to demonstrate safe and effective use in patients that all commercially available prescription drugs must establish prior to widespread availability. Also, generally, compounded medications do not have standardized dosages and duration for use; likewise, there are no standardized protocols to prepare each compound. For these reasons compounded preparations are more likely to have batch-to-batch variability and their sterility/purity cannot be guaranteed relative to the commercially available products.

POLICY STATEMENT

Prior authorization is required for prescription benefit coverage of compound prescription drug products whose total prescription ingredient cost is more than $200.00 for members 21 years of age or younger. **For anyone >21 the dollar limit is $90 for a compound Prior Authorization.**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
AUTHORIZATION CRITERIA

Due to the lack of robust clinical efficacy data, or safety data or standardized dosages and formulations, approval is not provided for topical compounded formulations of ketamine, gabapentin, diclofenac, ketoprofen, and flurbiprofen (either alone or in combination with other medications) except as noted below.

Topical compounded product containing gabapentin as a single active-ingredient compound is covered for diagnosis of vulvodynia when the patient has previously tried two oral or topical agents for the treatment of vulvodynia.

NOTE: Bulk Powders & PCCA products are excluded from coverage. Compounds must be made from existing product formulations (i.e., tabs, caps, suspension, injectable, etc.)

Medical Necessity policy 5/1/14 (topical ketamine, NSAID, gabapentin NOT COVERED): approve lidocaine patches, voltaren gel in lieu of theses compounds.

Initial Authorization for compounds and bulk powders will only be approved based on all of the following criteria:

1. Similar commercially available product is not available; and
2. The requested drug component is a covered medication; and
3. The requested drug component is to be administered for an FDA-approved indication; and
4. If a drug included in the compound requires precertification, all precertification criteria must also be met; and
5. If chemical entity is no longer available commercially it must not have been withdrawn for safety reasons; and
6. One of the following:
   a. A unique vehicle is required for topically administered compounds; or
   b. A unique dosage form is required for a commercially available product due to patient’s age, weight or inability to take a solid dosage form

Coverage for compounds and bulk powders will NOT be approved for any of the following:

1. Requested compound contains any of the following ingredients which are available as over-the-counter products:
   a. Cetyl Myristoleate
   b. Coenzyme Q10
   c. Methylcobalamin
   d. Hyaluronic Acid
   e. Nicotinamide
   f. Methyltetrahydrofolate
   g. Ibuprofen
   h. Lipoic acid
   i. Beta Glucan
   j. Ubiquinol

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

OR

2. For topical compound preparations (e.g. creams, ointments, lotions or gels to be applied to the skin for transdermal, transcutaneous or any other topical route), requested compound contains any FDA approved ingredient that is not FDA approved for TOPICAL use, including but NOT LIMITED TO the following:

- a. Ketamine
- b. Gabapentin
- c. Flurbiprofen (topical ophthalmic use not included)
- d. Ketoprofen
- e. Morphine
- f. Nabumetone
- g. Oxycodone
- h. Cyclobenzaprine
- i. Baclofen
- j. Tramadol
- k. Hydrocodone
- l. Meloxicam
- m. Amitriptyline
- n. Pentoxifylline
- o. Orphenadrine
- p. Piroxicam

OR

3. Requested compound contains topical fluticasone. Topical fluticasone will NOT be approved unless:
   a. Topical fluticasone is intended to treat a dermatologic condition; AND
   b. Member has a contraindication to all commercially available topically fluticasone formulations

OR

4. Requested compound contains leuprolide when prescribed for off-label use (refer to leuprolide policy for criteria)

OR

5. Requested compound contains any of the following ingredients which are for cosmetic use:

   - k. Chrysin
   - l. Glutathione
   - m. Lactobacillus
   - n. Vitamin E
   - o. Ascorbic Acid
   - p. Melatonin

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
<table>
<thead>
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<th></th>
<th>PracaSil TM-Plus</th>
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<tr>
<td>Tocopheryl Acid Succinate</td>
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<td>Lipopen Ultra</td>
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Criteria subject to change based on documentation of FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization [1] American Hospital Formulary Service Drug Information, 2) DRUGDEX Information System, 3) United States Pharmacopia-Drug Information (or its successor publications), or 4) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium]
4 active ingredients:

- Virginia Premier will cover compounds with 4 active ingredients, plus vehicle base and preservatives.

5 active ingredients:

- Virginia Premier will cover compounds with 5 active ingredients, plus vehicle base and preservatives after a 60-day trial and failure of a compound with 4 active ingredients.

6 active ingredients:

- Virginia Premier will cover compounds with 6 active ingredients, plus vehicle base and preservatives after a 60-day trial and failure of a compound with 5 active ingredients.

7 active ingredients:

- Review by Virginia Premier.

References

1. Virginia Premier.

COPEGUS (RIBAVIRIN)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Coverage of ribavirin is recommended in those who meet the following criteria:

FDA-Approved Indication

1. Treatment of hepatitis C in combination with peginterferon alfa-2b, interferon alpha-2a or interferon alfa-2b. Should not be used as monotherapy for this indication. Patients should be clinically diagnosed hepatitis C with detectable HCV RNA levels. Patients have not been previously treated with interferon alpha. Must be used in combination with peginterferon alfa-2a or interferon alpha-2b. Liver biopsy, unless contraindicated, shows fibrosis and inflammatory necrosis.

- Must currently be prescribed by a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g. hepatologist) or a physician who has consulted with one of these specialists; AND

- Requests for concomitant use of two or more of the following; Incivek (telaprevir), Victrelis (boceprevir), Olysio (simeprevir), or Sovaldi (sofosbuvir) will not be approved.

Child Pugh Classification

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
2. Pediatric use of Rebetol capsules and solution. For use in children clinically diagnosed with hepatitis C with compensated liver disease previously untreated with alpha interferon; relapsed following alpha interferon therapy. Must be used in combination with interferon alfa-2b for injection. Must be 5 years of age or older for capsule use or 3 years of age or older for solution use.

**LAB REQUIREMENT:**

1. Bilirubin \(\leq 2\) mg/Dl
2. Albumin Stable and within normal limits
3. Prothrombin Time <3 seconds prolonged
4. WBC \(\geq 3000/mm\)
5. Platelets \(\geq 70,000/mm\)
6. Serum creatinine should be normal or near normal.
7. HCV RNA
8. genotype
9. Early Virological Response (EVR)
10. Liver Function Tests
11. Child Pugh Score Interpretation

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<tr>
<td>Class C</td>
<td>10-15 points</td>
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Parameters

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**EXCLUSIONS**

Do not approve coverage of peginterferon, ribavirin, Intron A, interferon alfacon, Incivek, and Victrelis for the treatment of Hepatitis C in the following instances:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
1. When the above criteria have not been met.
2. Members < 3 years of age for peginterferon
3. When known contraindications to interferon or ribavirin therapy are documented
4. Members < 18 years of age for Victrelis® and Incivek®
5. Members who have failed previous therapy with Victrelis® or Incivek®-based regimens
6. Hypersensitivity to interferon alpha or any other component of the product
7. Decompensated liver disease

Coverage of ribavirin is not recommended in the following circumstances:

1. Hypersensitivity to ribavirin or any components of the tablet.
2. Women who are pregnant.
3. Men whose female partners are pregnant.
4. Patients with hemoglobinopathies.
5. Patients with a history of significant or unstable cardiac disease.
6. Creatinine clearance < 50ml/min.
7. Coverage is not recommended

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

37. Schwarz KB, Gonzalez-Peralta RP, Murray KF et al. The combination of ribavirin and peginterferon is superior to peginterferon and placebo for children and adolescents with chronic hepatitis C. Gastroenterology. 2011; 140:450-458.e1.

CORLANOR (IVABRADINE)

Criteria for use (Bullet Points below are all inclusive unless otherwise noted)

- Must be ≥ 18 years of age
- Must be prescribed by a cardiologist
- Diagnosis of stable, symptomatic heart failure (NYHA II-IV)
- Left ventricular ejection fraction ≤ 35%
- Currently in Normal Sinus Rhythm
- Resting Heart rate ≥ 70 beats per minute
- Symptoms are present despite maximal beta-blocker therapy or have documented contraindication to beta-blocker use
- Trial and failure or intolerance or contraindication to ACE-Inhibitor or ARB therapy
- Blood pressure is greater than 90/50 mmHg
- Must not be dependent on a pacemaker
- Must have been hospitalized for heart failure within the previous 12 months
- Quantity limit of 60 tablets per 30 days

References:

COSENTYX (SECUKINUMAB)

FDA-approved uses:

- Treatment of moderate to severe plaque psoriasis (PP) in adult patients who are candidates for systemic therapy or phototherapy
- Treatment of adults with active psoriatic arthritis (PsA)
- Treatment of adults with active ankylosing spondylitis (AS)

Available dosage forms:

- Injection: 150mg/mL solution in a single-use Sensoready pen
- Injection: 150mg/mL solution in a single-use prefilled syringe
- For injection: 150mg, lyophilized powder in a single-use vial for reconstitution for healthcare professional use only

Usual dose:

1. PP 300mg SQ at Weeks 0, 1, 2, 3, and 4 followed by 300mg every 4 weeks. For some patients, a dose of 150mg may be acceptable.
2. PsA With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. Without a loading dosage is 150 mg every 4 weeks. Can consider a dosage of 300 mg
3. AS With a loading dosage is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. Without a loading dosage is 150 mg every 4 weeks.

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- Must be 18 years of age or older
- Plaque psoriasis
  - Must be clinically diagnosed with moderate to severe plaque psoriasis
  - Must be a candidate for phototherapy or systemic therapy
  - Must have tried and failed or been intolerant to at least one corticosteroid
  - Must have tried and failed or been intolerant to methotrexate
  - Must have tried and failed or been intolerant to Enbrel AND Humira
- Psoriatic arthritis
  - Prescribed by a rheumatologist
  - Clinically diagnosed with active psoriatic arthritis
  - Must have tried and failed or been intolerant to at least one corticosteroid
  - Must have tried and failed or been intolerant to methotrexate
  - Must have tried and failed or been intolerant to Enbrel AND Humira
- Ankylosing spondylitis
  - Clinically diagnosed with active ankylosing spondylitis
  - Must have tried and failed or been intolerant to at least one NSAID, unless contraindicated
  - If peripheral arthritis, must have tried and failed or been intolerant to at least one DMARD (sulfasalazine, methotrexate)
  - Must have tried and failed or been intolerant to Enbrel AND Humira

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Criteria for continuation of therapy:

- Patient responding to treatment
- Patient tolerating treatment
- Requested dose does not exceed 300mg every 4 weeks
- A dose reduction to 150mg every 4 weeks has been attempted or the patient is not a candidate for a dose reduction

Caution:

- Infections: Serious infections have occurred. Caution should be exercised when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection. If a serious infection develops, discontinue COSENTYX until the infection resolves.
- Tuberculosis (TB): Prior to initiating treatment with COSENTYX, evaluate for TB.
- Crohn’s Disease: Exacerbations observed in clinical trials. Caution should be exercised when prescribing COSENTYX to patients with active Crohn’s disease.
- Hypersensitivity Reactions: If an anaphylactic reaction or other serious allergic reaction occurs, discontinue COSENTYX immediately and initiate appropriate therapy.

Contraindication:

- Serious hypersensitivity reaction to secukinumab or to any of the excipients

Not approved if:

- Does not meet above criteria
- Has any contraindications to treatment

Special considerations:

- Patients may self-inject after proper training in subcutaneous injection technique using the Sensoready pen or prefilled syringe and when deemed appropriate.
- Phase 3 data has showed an increasing trend for some types of infection (candida, herpes viral, staphylococcal skin, and infections requiring treatment) with increasing serum concentration of secukinumab
- Patients may not receive live vaccinations
- Secukinumab clearance and volume of distribution increase as body weight increases.

Approval Duration:

- Initial 6 months
- Renewal 12 months

References:

1) Virginia Premier.
CRYSVITA (BUROSUMAB-TWZA)

- Patient has documented diagnosis of X-linked hypophosphatemia (XLH)
  AND
- Patient is at least 1 year of age
  AND
- Patient has not received oral phosphate and/or active vitamin D analogs within 1 week prior to start of therapy
  AND
- Prescribed by an endocrinologist or nephrologist
  AND
- Confirmed phosphate regulating gene homology to endopeptidases located on the X chromosome (PHEX) mutation in the patient or a directly related family member (mother, father, sibling) and provider must provide confirmatory genetic testing
  OR
- Serum Fibroblast growth factor 23 level greater than 30pg/mL by Kainos assay, test and results must be provided for documentation
  AND
- Baseline fasting serum phosphorus level with current hypophosphatemia, defined as a phosphate level below the lower limit of the normal laboratory range
  AND
- Patient does not have severe renal impairment, GFR of <30mL/min
  AND
- Patient has trial and failure/contraindication to phosphate and/or vitamin D analog based therapy

For Continuation of therapy
- Patient continues to meet above mentioned criteria
  AND
- Documented positive clinical response to therapy

Quantity Limits
- Crysvita 10mg/ml vial - 1 vial every 14 days
- Crysvita 20mg/ml vial – 1 vial every 14 days
- Crysvita 30mg/ml vial – 3 vials every 28 days


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

1. Diagnosis of Active Cancer pain, Sickle Cell Disease, or patient receiving palliative care or hospice care; **AND**
2. The prescriber attests that he/she will be managing the patient’s opioid therapy long term, has reviewed the CDC Guidelines for prescribing Opioids and acknowledges the warnings associated with high dose opioid therapy, and that therapy is medically necessary for this patient. **Required for APPROVAL.**

**OR**

1. Diagnosis of chronic non-cancer pain; **AND**
2. Provider has reviewed the PMP and is committed to monitoring the state’s Prescription Drug Monitoring Program (PDMP) to ensure controlled substance history is consistent with prescribing record. **Required for APPROVAL; AND**
3. Medication is being prescribed based on recommendation of pain specialist and/or member has been evaluated by pain specialist
   a. Date of evaluation by pain specialist and Name of pain specialist provided; **AND**
4. Member has signed pain contract or controlled substance contract in place with office; **AND**
5. Prescriber has provided counseling to the patient regarding the potential risks and benefits of opioid use, including the possible increased risk in patients with a remote history or a strong family history of addiction; **AND**
6. The prescriber attests that he/she will be managing the patient’s opioid therapy long term, has reviewed the CDC Guidelines for prescribing Opioids and acknowledges the warnings associated with high dose opioid therapy; and that they have read the FDA black box warning on prescribing of Opioids and Benzodiazepines and the dangers involved, and that therapy is medically necessary for this patient. **Required for APPROVAL.**

7. **AND**
8. All of the following has been addressed by the prescriber:
   a. Member has been advised of risks of chronic opioid therapy and has provided informed consent
   b. Member is an appropriate candidate for chronic opioid therapy
   c. Prescriber will continue to monitor for signs of severe respiratory depression, as well as misuse, abuse and addiction during therapy **AND**
9. For female patients between the ages of 18 and 45:
   a. The use of opioid analgesics during pregnancy has been associated with neonatal abstinence syndrome. The patient has been counseled regarding the risks of becoming pregnant while receiving this medication, including the risk of neonatal abstinence syndrome
   b. The patient is currently utilizing a form of contraception **AND**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
10. If patient is using CONCOMITANT BENZODIAZEPINE AND OPIOID THERAPY:
   a. Both medications must be prescribed for a medically accepted indication
   b. The prescriber must attest that he/she has checked the Virginia State PMP (Located at: https://virginia.pmpaware.net/login)
   c. Prescriber attests that they have read the FDA black box warning on prescribing of Opioids and Benzodiazepines and the dangers involved, and that therapy is medically necessary for this patient
      • A U.S. Food and Drug Administration (FDA) review has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. Opioids are used to treat pain and cough; benzodiazepines are used to treat anxiety, insomnia, and seizures. In an effort to decrease the use of opioids and benzodiazepines, or opioids and other CNS depressants, together, we are adding Boxed Warnings, our strongest warnings, to the drug labeling of prescription opioid pain and prescription opioid cough medicines, and benzodiazepines.
      • Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other CNS depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other CNS depressants, including alcohol.
   d. The prescriber has considered offering prescription for naloxone and overdose prevention counseling
   e. Attests that therapy with other, safer alternative(s) is not appropriate for patient's condition (e.g. NSAIDs, Lidocaine patch, Skeletal Muscle Relaxants)

RENEWAL
1. The prescriber attests that he/she will be managing the patient’s opioid therapy long term, has reviewed and acknowledges the warnings associated with high dose opioid therapy; AND
2. Prescriber has attempted a dosage reduction and/or will continue to attempt dosage reduction of opioid therapy in future; AND
3. All of the following has been addressed by the prescriber:
   a. Member has been advised of risks of chronic opioid therapy and has provided informed consent
   b. Member is an appropriate candidate for chronic opioid therapy
   c. Prescriber will continue to monitor for signs of severe respiratory depression, as well as misuse, abuse and addiction during therapy

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Prescriber has reviewed the state’s online controlled drug data base within the last 4 weeks (Located at: https://virginia.pmpaware.net/login)

**DURATION OF APPROVAL:**
- 6 months

**References**


**CUPRIMINE (PENICILLAMINE)**

**Criteria for use:** (bullet points are all inclusive unless otherwise noted)

- Require trial and failure, or intolerance to Depen Titra Tab as documented by medical records or recent paid claim history; AND
- Wilson’s Disease
  - Confirmation of diagnosis through genetic testing OR presence of three of the following diagnostic features:
    - Presence of Kayser-Fleisher rings
    - Serum ceruloplasmin (CPN) <20 mg/Dl
    - 24-hour urine Copper > 40 mcg
    - Liver biopsy with copper dry weight > 250 mcg/g
  - 5 years of age or older
- Cystinuria
  - 1 year of age or older
  - Failure to respond (or contraindication) to urinary alkalization therapy with potassium citrate in the last 180 days
- Severe, Active Rheumatoid arthritis
  - 18 years of age or older
  - Prescribed by a rheumatologist
  - Failure to respond (or contraindication) to at least two of the following non-biologic disease modifying anti-rheumatic drugs:
    - Hydroxychloroquine

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Leflunomide
- Methotrexate
- Sulfasalazine

- Failure to respond (or contraindication) to each of the following biologic therapies:
  - Enbrel (prior authorization required)
  - Humira (prior authorization required)

- Failure to respond (or contraindication) to at least two of the following biologic therapies (PA required for all):
  - Actemra
  - Cimzia
  - Orencia
  - Kineret
  - Remicade
  - Rituxan

- Must have tried and failed, or been intolerant to formulary alternative Depen Titra (Prior Authorization Required)

**Approval Duration:**

- Wilson’s Disease: Initial - 6 months, Renewal - 1 year
- Cystinuria: Initial - 3 months, Renewal - 6 months
- Severe, active RA: Initial - 3 months, Renewal - 6 months

**Contraindications:**
- Pregnancy (except in Wilson’s disease)
- Breastfeeding
- Hypersensitivity to penicillamine
- Rheumatoid arthritis patients with present or history of renal insufficiency

**Not approved if:**
Any of the above contraindications are present

**Black box warning:**
Physicians planning to use penicillamine should thoroughly familiarize themselves with its toxicity, special dosage considerations, and therapeutic benefits. Patients should be warned to report promptly any symptoms suggesting toxicity.

**Additional considerations:**
- Two types of patients with Wilson’s disease should be treated. Those with symptomatic disease and those with asymptomatic disease that is presumed to progress if patient is not treated.
- In patients with Wilson’s disease noticeable improvement may take up to three months. During initial treatment, neurologic symptoms may worsen. It is important that the drug is continued as interruption of therapy can increase the likelihood of developing a hypersensitivity reaction to the medication.
• Pregnant patients receiving penicillamine for Wilson’s disease should have dose decreased to ≤ 1 g and if cesarean is planned, dose should be reduced to 250 mg for the 6 weeks prior to delivery.
• Treatment with penicillamine for RA can take three months to see a clinical benefit due to slow titration of the medication. It is recommended that drug is not discontinued during that time due to increased sensitivity upon re-initiation of therapy.
• Dose increases for RA should be in 125 mg or 250 mg increments over one to three month intervals.
• Dose of penicillamine in cystinuria should limit 65ysteine excretion to 100-200 mg/day in patients with no history of stones and < 100 mg/day in those who have a history of stones and/or pain.
• *There is no minimum age requirement for the use of penicillamine for cystinuria or Wilsons Disease. In a cohort of 11 American children, the youngest documented child treated for cystinuria was 13 months at the beginning of therapy. Per the American Association for the Study of Liver Diseases (AASLD) Guidelines, Wilson’s disease is typically diagnosed after the age of 5, after presentation of liver disease.
• Maximum daily dose is 4 g/day, however, this is not recommended for all disease states treated with penicillamine.

References:

CYSTAGON (CYSTEAMINE BITARTRATE)

• Nephropathic cystinosis, AND
• Condition confirmed:
  o By leukocyte 65ysteine measurements greater than normal (nl range normal values are <0.2 nmol half-cystine/mg protein), OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
ое By DNA testing (two mutations in the CTNS gene; the only gene).

References


DALIRESP (ROFLUMILAST)

- Diagnosis of severe COPD associated with chronic bronchitis, AND
- History of exacerbations, AND
- Trial and failure on at least one first-line or second-line agent (Inhaled anticholinergics, long acting beta agonists or inhaled corticosteroids), AND
- Daliresp will be used as an adjunct to first or second-line therapy

DEPEN TITRA (PENICILLAMINE)

Criteria for use: (bullet points are all inclusive unless otherwise noted)

- Wilson’s Disease
  - Confirmation of diagnosis through genetic testing OR presence of three of the following diagnostic features:
    - Presence of Kayser-Fleisher rings
    - Serum ceruloplasmin (CPN) <20 mg/dL
    - 24-hour urine Copper > 40 mcg
    - Liver biopsy with copper dry weight > 250 mcg/g
  - 5 years of age or older
- Cystinuria

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval was approved.

- Severe, Active Rheumatoid arthritis
  - 18 years of age or older
  - Prescribed by a rheumatologist
  - Failure to respond (or contraindication) to at least two of the following non-biologic disease modifying anti-rheumatic drugs:
    - Hydroxychloroquine
    - Leflunomide
    - Methotrexate
    - Sulfasalazine
  - Failure to respond (or contraindication) to each of the following biologic therapies:
    - Enbrel (prior authorization required)
    - Humira (prior authorization required)
  - Failure to respond (or contraindication) to at least two of the following biologic therapies (PA required for all):
    - Actemra
    - Cimzia
    - Orencia
    - Kineret
    - Remicade
    - Rituxan

Approval Duration:
- Wilson’s Disease: Initial-6 months, Renewal- 1 year
- Cystinuria: Initial-3 months, Renewal- 6 months
- Severe, active RA: Initial-3 months, Renewal- 6 months

Contraindications:
- Pregnancy (except in Wilson’s disease)
- Breastfeeding
- Hypersensitivity to penicillamine
- Rheumatoid arthritis patients with present or history of renal insufficiency

Not approved if:
Any of the above contraindications are present

Black box warning:
Physicians planning to use penicillamine should thoroughly familiarize themselves with its toxicity, special dosage considerations, and therapeutic benefits. Patients should be warned to report promptly any symptoms suggesting toxicity.

Additional considerations:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval was approved.
• Two types of patients with Wilson’s disease should be treated. Those with symptomatic disease and those with asymptomatic disease that is presumed to progress if patient is not treated.

• In patients with Wilson’s disease noticeable improvement may take up to three months. During initial treatment, neurologic symptoms may worsen. It is important that the drug is continued as interruption of therapy can increase the likelihood of developing a hypersensitivity reaction to the medication.

• Pregnant patients receiving penicillamine for Wilson’s disease should have dose decreased to ≤ 1 g and if cesarean is planned, dose should be reduced to 250 mg for the 6 weeks prior to delivery.

• Treatment with penicillamine for RA can take three months to see a clinical benefit due to slow titration of the medication. It is recommended that drug is not discontinued during that time due to increased sensitivity upon re-initiation of therapy.

• Dose increases for RA should be in 125 mg or 250 mg increments over one to three month intervals.

• Dose of penicillamine in cystinuria should limit 68ulticen excretion to 100-200 mg/day in patients with no history of stones and < 100 mg/day in those who have a history of stones and/or pain.

• *There is no minimum age requirement for the use of penicillamine for cystinuria or Wilsons Disease. In a cohort of 11 American children, the youngest documented child treated for cystinuria was 13 months at the beginning of therapy. Per the American Association for the Study of Liver Diseases (AASLD) Guidelines, Wilson’s disease is typically diagnosed after the age of 5, after presentation of liver disease.

• Maximum daily dose is 4 g/day, however, this is not recommended for all disease states treated with penicillamine.

**DEXILANT (DEXLANSOPRAZOLE)**

The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.

• Must have at least one of the following clinically diagnosed conditions:
  o GERD symptoms and disease
  o Hypersecretory GI disease
  o Duodenal ulcers
  o On high dose steroids or NSAID and have failed therapy with H2antagonists,
  AND

• Must have tried either prescription or over the counter omeprazole for at least 4 weeks and failed, including maximum dose titration, OR Pantoprazole for at least 4 weeks and failed.

• Must have tried Lansoprazole or Prevacid 24HR (2 caps BID) for at least 4 weeks and failed.

• Approval duration is for 3 months for GERD. One year for all other diagnosis.

**Contraindication:***
• Hypersensitivity to a specific proton pump inhibitor.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Not approved if:
- The patient does not meet the above stated criteria
- The patient has any contraindications to the use of proton pump inhibitors

If previous recent history (last 60 days) approve.

References

1. Virginia Premier

**DICLEGIS (DOXYLAMINE/PYRIDOXINE)**
- Must be clinically diagnosed with pregnancy-induced nausea/vomiting
- Must try and fail individual products, Doxylamine Succinate and Pyridoxine HCl (B6) in combination; AND
- Must try and fail or intolerance to ondansetron; AND
- Must try and fail, or have an intolerance to, oral promethazine

References

1. Virginia Premier

**DIGESTIVE ENZYMES (PANCRELIPASE/CREON/ZENPEP)**
- Diagnosis of pancreatic insufficiency due to cystic fibrosis or chronic pancreatitis or pancreatectomy
- If request is for patient with Cystic Fibrosis, trial and failure of preferred alternatives not required (Zenpep, Creon, Pancrelipase are preferred)

**DRONABINOL**
- Diagnosis of severe, chemotherapy induced nausea and vomiting OR
- Diagnosis of Nausea or vomiting related to radiation therapy, moderate to highly emetogenic chemotherapy, or post-operative nausea and vomiting AND
- Has the member tried and failed therapeutic doses of, or has adverse effects or contraindications to, TWO different conventional antiemetics (e.g., promethazine, prochlorperazine, meclizine, metoclopramide, dexamethasone, etc.) OR
- Patient has tried and failed, intolerant to, or contraindicated to a combination of Emend, plus a 5HT3 receptor antagonist, plus a corticosteroid, OR
- Diagnosis of AIDS-related wasting, AND
- Patient has tried and failed megestrol acetate oral suspension OR has a contraindication, intolerance or drug-drug interaction, OR a medical reason megestrol cannot be used

**Authorizations** – 6 months

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
DUPIXENT (DUPILUMAB)

APPROVAL DURATION: Initial 6 months, Renewal 12 months.

APPROVAL CRITERIA
Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Must be at least 12 years of age
- Must have moderate to severe atopic dermatitis with a baseline EASI (Eczema Area and Severity Index) score of 25
- Must have moderate to severe atopic dermatitis which has not responded to the following therapies or cannot use the products due to side-effects:
  - Low potency topical steroid (i.e. Deosnide, Hydrocortisone 1%/2.5%, fluocinolone 0.01%)
  - High potency topical steroid (i.e. Halobetasol propionate, Augmented betamethasone dipropionate)
  - Oral steroid (i.e. prednisone)
  - Immunosuppressive agent (i.e. methotrexate, azathioprine, cyclosporine and mycophenolate)
  - Tacroliums Ointment
- Continuation of therapy will be allowed for patients who meet the following:
  - Reduction in EASI scores
  - Decrease in pruritus
  - Decrease in body area by 50%

- OR
  1. Patient is 12 years of age or older, AND
  2. Diagnosis of moderate to severe asthma with an eosinophilic phenotype OR with oral corticosteroid dependent asthma, AND
  3. Prescribed by, or in consultation with an allergist or pulmonologist, AND
  4. Member has experienced at least 2 exacerbations, within the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., high dose inhaled corticosteroid (ICS) plus either a long acting beta-2 agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindicated/intolerance):
     a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid)
     b. Urgent care visit or hospital admission
     c. Intubation; OR
  4. For patients without oral corticosteroid dependent asthma:
     a. Eosinophilic phenotype defined as EITHER of the following:
        i. Blood eosinophils greater than or equal to 150 cells/mcl within the previous 6 weeks OR
        ii. History of blood eosinophils greater than or equal to 300 cells/mcl, AND
        iii. Continued use of an inhaled corticosteroid AND another controller therapy (for example, long-acting beta-agonist, leukotriene receptor)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
5. Will not be used in combination with Xolair, Nucala, Cinqair or Fasenra, AND
6. FOR RENEWAL REQUESTS:
   a. Patient has experienced an improvement in symptoms (reduction in exacerbation, reduction in oral glucocorticoids, improvement in FEV1)
   b. Patient continues to tolerate treatment

-OR

INITIAL
1. Diagnosis of chronic rhinosinusitis with nasal polyps, AND
2. Medication will be used as add on therapy, AND
3. Member is at least 18 years of age or older, AND
4. Member has had an inadequate response, intolerance, or contraindication to ONE medication from each of the following classes:
   a. Nasal Corticosteroid spray (Mometasone, Fluticasone, Nasacort OTC, Rhinocrot OTC
   b. Oral corticosteroid (i.e. prednisone)

RENEWAL
1. Initial therapy criteria continues to be met AND
2. Prescriber attests to each of the following:
   a. Member has had improvement in sino-nasal symptoms
   b. Member has had a decrease in utilization of oral corticosteroids
   c. Member has been compliant on Dupixent therapy

DYSPORT (ABOBOTULINUM TOXINA)

Criteria for use (bullet points below are all inclusive unless otherwise noted):
• The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient’s medical records.
• Prescribed by a neurologist or physiatrist AND
• Must be greater than 18 years of age, AND
• Must have at least one of the following conditions:
  o Cervical dystonia, OR
  o Spasmodic torticollis, AND
• No contraindications:
  • Pregnancy, OR
  • Sensitivity or allergic reaction to other botulinum toxins, OR
  • Allergy to cow’s milk protein, OR
  • Contraindications to the use of dapsone, AND
  • Not being used used for treatment of moderate to severe glabellar lines.

Not approved if:
• Does not meet the above-stated criteria

Caution:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Potency of units between different preparations of botulinum toxin products is not interchangeable
• Spread of toxin effects may cause swallowing and breathing difficulties

Available dosage forms: 300unit and 500unit single-use vials
Cervical Dystonia: usual dose: 500 units per treatment – **QUANTITY LIMIT OF 2 VIALS** (1000units)
  • Cervical Dystonia
    a. Initial dose of DYSPORT® is 500 Units given intramuscularly as a divided dose among the affected muscles
    b. Re-treatment every 12 to 16 weeks or longer, as necessary, based on return of clinical symptoms with doses administered between 250 and 1000 Units to optimize clinical benefit
    c. **Re-treatment should not occur in intervals of less than 12 weeks**
  • Titration should occur in 250 Unit steps according to the patient's response

**References**

1. Virginia Premier

**EDURANT (RILPIVIRINE)**

**Duplicate therapy:**
• FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
• Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

**References**

1. Virginia Premier.

**ELAPRASE (IDURSULFASE)**

• Hunter syndrome (mucopolysaccharidosis II)

**References**


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

ELIGARD (LEUPROLIDE ACETATE)

- Endometriosis:
  - Tried/failed/intolerance to at least two of the following:
    - oral contraceptive
    - medroxyprogesterone
    - danazol, OR
- Prostate cancer:
  - Tried/failed/intolerance or documented unacceptable for orchectomy or estrogen, OR
- Uterine Leiomyoma (uterine fibroids), OR
- Central precocious puberty, OR
- Dysfunctional or excessive uterine bleeding:
  - Tried/failed/intolerance to oral contraceptive, OR
- Testicular cancer, OR
- Vascular cancer, OR
- Breast Cancer, OR
- Ovarian Cancer, OR
- Premenstrual syndrome

References


EMFLAZA (DEFLAZACORT)

APPROVAL DURATION: Initial 6 months, Renewal 12 months.

APPROVAL CRITERIA
Criteria for use (bullet points below are all inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must be clinically diagnosed with Duchenne Muscular Dystrophy (DMD); AND
  - Diagnosis has been confirmed by documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- Patient must not have any active infection, including Tuberculosis and Hepatitis B Virus; AND
- Patient is at least 5 years of age or older; AND
- Serum creatinine kinase activity at least 10 times the Upper Limit of Normal (ULN) prior to initiating therapy; AND
- Baseline muscle strength score from the 6-minute walk test (6MWT) has been obtained; AND
- The patient meets ONE of the following conditions (i or ii):
  i. The patient has tried prednisone for ≥ 6 months [documentation required] AND according to the prescribing physician, the patient has had at least one of the following significant intolerable adverse effects (AEs) [a, b, c, or d]:
    a) Cushingoid appearance [documentation required]; OR
    b) Central (truncal) obesity [documentation required]; OR
    c) Undesirable weight gain defined as a ≥ 10% of body weight gain increase over a 6-month period [documentation required]; OR
    d) Diabetes and/or hypertension that is difficult to manage according to the prescribing physician] [documentation required].
  ii. According to the prescribing physician, the patient has experienced a severe behavioral AE while on prednisone therapy that has or would require a prednisone dose reduction [documentation required].
- The medication is prescribed by, or in consultation with, a physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders.
- FOR CONTINUATION OF THERAPY, patient has had an improvement of at least 20 meters in the 6-minute walk test (6MWT) from baseline.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
References


EMGALITY (Galcanezumab)

EMSAM (SELEGILINE)
Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Clinically diagnosed depression.
- Failed/intolerant to at least one SSRI (i.e. sertraline, citalopram, paroxetine)
- Failed/intolerant to bupropion.
- Failed/intolerant to venlafaxine
- Failed/intolerant to at least one tricyclic antidepressant (i.e. amitriptyline)
Criteria for continuation of therapy:
- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.

Cautions:
- Dietary modifications with tyramine restrictions are recommended at dosages exceeding 6 mg per 24 hours.

Contraindications:
- Hypersensitivity to selegiline or to any component of the transdermal system.
- Should not be administered with:
  - Other antidepressants that affect serotonin levels (SSRIs, TCA’s, venlafaxine, or bupropion), some analgesics (meperidine, tramadol, methadone, or propoxyphene), dextromethorphan, St. John’s wort, mirtazapine, buspirone, or cyclobenzaprine
  - Agents that can increase risk of hypertensive crisis such as sympathomimetic agents (phenylpropanolamine or some weight loss products)
  - Carbamazepine or oxcarbazepine

EMTRIVA (EMTRICITABINE)

Duplicate therapy:
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
1. Virginia Premier.

**ENTRESTO (SACUBITRIL/VALSARTAN)**

Criteria for use (Bullet Points below are all inclusive unless otherwise noted)

- Must be ≥ 18 years of age
- Diagnosis of stable, chronic heart failure (NYHA II-IV)
- Left ventricular ejection fraction ≤40 %
- Quantity limit of 60 tablets per 30 days

**AUTHORIZATION:** 1 year

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

**EPANED (ENALAPRIL)**

**Authorization Criteria**

1. One of the following diagnoses:
   a. Hypertension
   b. Heart failure
   c. Asymptomatic left ventricular dysfunction, defined as left ventricular ejection fraction less than or equal to 35%
   
   **AND**

2. One of the following:
   a. Patient is less than 13 years of age; OR
   b. History of failure, contraindication, or intolerance to two formulary oral antihypertensive (eg, ACE Inhibitor, ACE Inhibitor Combination, ARB, ARB Combination, Thiazide Diuretic); OR
   c. Patient is unable to ingest a solid dosage form (e.g. an oral tablet or capsule) due to one of the following:
      i. Oral/motor difficulties
      ii. Dysphagia

**Authorization will be issued for 12 months**

**EPIDIOLEX (CANNABIDIOL)**

**Criteria for Approval**

- Diagnosis of Dravet Syndrome (DS) or Lennox-Gastaut Syndrome (LGS) AND
- Patient is 2 years of age or older AND
- Medication is prescribed by or in conjunction with a neurologist or epileptologist appropriate for patient age

**Auth Duration: 12 months**

**EPIVIR (LAMIVUDINE)**

**Duplicate therapy:**
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

**References**

1. Virginia Premier.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
EPOGEN (EPOETIN ALFA)

Criteria for approval is ONE of the following:

1. Erythropoietin Stimulating Agent (ESA) is being prescribed to reduce the possibility of allogeneic blood transfusion in a surgery patient AND patient’s hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL OR

2. ESA is being prescribed for anemia due to chemotherapy for a non-myeloid malignancy AND BOTH of the following:
   a. Patient’s hemoglobin level is less than 10 g/dL for patients initiating ESA therapy or stabilized on therapy (measured within the previous four weeks) AND
   b. Patient is being concurrently treated with chemotherapy, with or without radiation (treatment period extends to eight weeks post chemotherapy) OR

3. ESA is prescribed for a patient with anemia associated with chronic renal failure in a patient NOT on dialysis AND patient’s hemoglobin level is less than 10 g/dL for patients initiating ESA therapy or stabilized on therapy (measured within the previous 4 weeks) AND BOTH of the following:
   a. Rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion AND
   b. Goal is to reduce risk of alloimmunization and/or other RBC transfusion related risks OR

4. ESA is prescribed for a patient with anemia due to myelodysplastic syndrome or a patient with anemia resulting from zidovudine treatment of HIV infection AND patient’s hemoglobin level is less than 12 g/dL for patients initiating ESA therapy or less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous four weeks) OR

5. ESA is prescribed for another indication AND BOTH of the following:
   a. There is clinical evidence supporting therapy with an ESA for the intended use or the prescriber has submitted documentation in support of the requested therapeutic use for the requested agent AND
   b. Patient’s hemoglobin level is less than 12 g/dL for patients initiating ESA therapy or less than or equal to 12 g/dL for patients stabilized on therapy (measured within the previous four weeks)

Required lab tests for hemoglobin must be performed within 90 days of the authorization request and required iron tests (ferritin or transferrin saturation) must be performed within 90 days of the authorization request.

Authorization Requirements for Erythropoiesis Stimulating Agents by Indication

Chronic Kidney Disease not on Dialysis (erythropoietin or darbepoietin):

Initial or continuation:
Documentation of diagnosis; submission of lab findings confirming Hgb level < 10 g/dL; serum ferritin ≥100 ng/mL or transferrin saturation of ≥ 20%; and that ESA therapy is required to raise Hgb to a level necessary to reduce the need for RBC transfusion.

Re-authorization is required at 3 month intervals
Chronic Kidney Disease on Dialysis (erythropoietin or darbepoietin):

Initial:
Documentation of diagnosis; submission of lab findings confirming Hgb level < 10 g/dL; serum ferritin ≥100 ng/mL or transferrin saturation of ≥ 20%.

Continuation:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Submission of lab findings confirming Hgb level ≤ 11 g/dL, serum ferritin ≥ 100 ng/mL or transferrin saturation of ≥ 20%.

**Re-authorization is required at 3 month intervals**

Chemotherapy-Induced Anemia in Cancer Patients (erythropoietin or darbepoietin):  
*Initial:*  
Documentation of non-myeloid malignancy and chemotherapy regimen, symptomatic anemia; submission of lab findings confirming Hgb level < 10 g/dL; serum ferritin ≥ 100 ng/mL or transferrin saturation of ≥ 20%.  
*Continuation:*  
Submission of lab findings confirming Hgb level ≤ 10 g/dL, serum ferritin ≥ 100 ng/mL or transferrin saturation of ≥ 20%.

**Re-authorization is required at 1 month intervals**

HIV Patients with anemia secondary to zidovudine use (erythropoietin):  
*Initial:*  
Documentation of HIV diagnosis and concurrent use of zidovudine as part of an appropriate highly-active anti-retroviral therapy regimen confirmed by review of prescription claims; submission of Hgb level < 10 g/dL and serum ferritin ≥ 100 ng/mL or transferrin saturation of ≥ 20%.  
*Continuation:*  
Submission of lab findings confirming Hgb level ≤ 12 g/dL, serum ferritin ≥ 100 ng/mL or transferrin saturation of ≥ 20%, and documentation that the member Hgb levels have increased by at least 1 g/dL from pretreatment baseline.

**Re-authorization is required at 3 month intervals**

Myelodysplastic Disease (erythropoietin):  
*Initial:*  
Documentation of diagnosis, submission of laboratory findings confirming Hgb level < 10 g/dL, serum ferritin ≥ 100 ng/mL or transferrin saturation ≥ 20%.  
*Continuation:*  
Submission of lab findings confirming Hgb level ≤ 12 g/dL, serum ferritin ≥ 100 ng/mL or transferrin saturation of ≥ 20%, and documentation that the member Hgb levels have increased by at least 1 g/dL from pretreatment baseline.

**Re-authorization is required at 3 month intervals**

Hepatitis C Patients with anemia secondary to combination peginterferon/ribavirin therapy (erythropoietin):  
*Initial:*  
Documentation of diagnosis and concurrent use peginterferon / ribavirin therapy confirmed by review of prescription claims, submission of laboratory findings confirming Hgb level < 10 g/dL and serum ferritin ≥ 100 ng/mL, or transferrin saturation ≥ 20%.  
*Continuation:*  
Submission of lab findings confirming Hgb level ≤ 12 g/dL, serum ferritin ≥ 100 ng/mL or transferrin saturation of ≥ 20%, documentation that previous ribavirin dose did not require reduction due to symptomatic anemia; and documentation that the member Hgb levels have increased by at least 1 g/dL from pretreatment baseline.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Re-authorization is required at 3 month intervals
**Anemia of Chronic Disease – Rheumatoid Arthritis, Crohn’s Disease, Ulcerative Colitis (erythropoietin):**
*Initial:*
Documentation of the underlying chronic disease, submission of laboratory findings confirming Hgb level < 10 g/dL, serum ferritin ≥100 ng/mL or transferrin saturation ≥ 20%.
*Continuation:*
Submission of lab findings confirming Hgb level ≤ 12 g/dL, serum ferritin ≥100 ng/mL or transferrin saturation of ≥ 20%, and documentation that the member Hgb levels have increased by at least 1 g/dL from pretreatment baseline.

Re-authorization is required at 3 month intervals
**Pre-Surgery (erythropoietin):**
*Initial:*
Documentation of intended high-risk surgery (must be elective, non-cardiac, and non-vascular), submission of lab findings confirming Hgb level between 10 -13 g/dL, serum ferritin ≥ 100 ng/mL or transferrin saturation ≥ 20%. Requests meeting criteria will be approved as follows: 15 days of therapy at 300 units/kg/day OR 4 days of therapy at 600 units/kg/week.

EXCLUSIONS

1. **Anemia associated with cancer in patients not receiving cancer chemotherapy.**
   Epoetin is not indicated in cancer patients who are not receiving cancer chemotherapy. The ASCO/ASH guidelines for the use of epoetin and darbepoetin in adult patients with cancer recommend that ESAs not be used in treatment of anemia associated with malignancy in those who are not receiving concurrent myelosuppressive chemotherapy.

2. **Anemia associated with acute myelogenous leukemias (AML), chronic myelogenous leukemias (CML) or other myeloid cancers.**
   Epoetin is indicated for use in non-myeloid cancers when chemotherapy is given. AML and CML are examples of myeloid cancers.

3. **Anemia associated with radiotherapy in cancer.**
   Epoetin is not indicated for use in cancer patients who are given only radiation therapy.

4. **To enhance athletic performance.**
   Epoetin is not recommended for approval because this indication is excluded from coverage in a typical pharmacy benefit.

5. **Anemia in patients due to acute blood loss.**
   Use of Epoetin is not appropriate in these types of situations.

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
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**EPZICOM (ABACAVIR/LAMIVUDINE)**

**Duplicate therapy:**
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, **AND**
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

**References**

1. Virginia Premier.

**ERBITUX (CETUXIMAB)**

- Prescribed by Oncologist, Hematologist, or Pulmonologist, **AND**
- Metastatic colorectal cancer (CRC) which expresses the KRAS wild type gene, **OR**
- Treatment of epidermal growth factor receptor (EGFR)—expressing metastatic colorectal cancer after tried/failed/intolerance to both irinotecan- and oxaliplatin-based regimens, **OR**
- Metastatic, or recurrent squamous cell carcinoma of the head and neck (SCCHN), **OR**
- Advanced (stage IIIb or IV) non-small cell lung cancer (NSCLC) with all of the following:
  - Tumor expresses epidermal growth factor receptor (EGFR), **AND**
  - No known brain metastasis, **OR**
- Gastric cancer, **OR**
- Malignant neoplasm of cardio-esophageal junction of stomach, **OR**
- Chorrmoma used in combination with Erlotinib

**References**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


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**ERLEADA (APALUTAMIDE)**

**Initial:**
- Diagnosis of NON-metastatic castration-resistant prostate cancer (nmCRPC)
- Prescribed by oncologist
- Patient is 18 years of age or older
- Patient will receive a gonadotropin-releasing hormone (GnRH)-analog or the member has had a bilateral orchiectomy

**Renewal:**
- Member continues to meet initial criteria

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• There is tumor response with stabilization of disease or decrease in size of tumor or tumor spread
• Absence of unacceptable toxicity from the drug? Examples of unacceptable toxicity include seizures, excessive falls and/or fractures, and any other Grade 3 or above side effects that are intolerable to the member.

Authorization Dates:
Initial – 6 months
Renewal – 12 months

EUFLEXXA (HYALURONIC ACID DERIVATIVE, INTRA-ARTICULAR)
• Osteoarthritis of the knee, AND
• Tried/failed/intolerance to mild analgesic therapy (e.g. acetaminophen) OR tried/failed/intolerance to generic NSAIDs or COX-2 Inhibitors.
• Tried/failed/intolerance to the following:
  o Intra-articular corticosteroid injection (relief <6-8 weeks)
  o Physical therapy, AND
• Must not have large effusions of the knee, AND
• No infections or skin diseases in the knee area.

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

EVZIO (NALOXONE HCL INJ)

CRITERIA FOR USE:

Evzio will be authorized for one year with a quantity limit of two auto-injectors (one box) per claim per 30 day period if the following criteria are met:

- The prescriber provides documentation that the patient or caregiver is unable to quickly and correctly use Narcan Nasal Spray due to issues related to poor eyesight, dexterity, literacy or comprehension.

References:


EXJADE (DEFERASIROX)

Medication Prior Authorization Criteria Initial Therapy
Exjade® tablet for oral suspension is available in 125 mg, 250 mg, and 500 mg tablets.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Documentation of the following:
1. The prescriber is a hematologist or oncologist; AND
2. A diagnosis of chronic transfusional iron overload due to blood transfusions; AND
   a. Serum ferritin levels that are consistently > 1000 mcg/L (demonstrated by at least two lab values in the previous 3 months); AND
   b. Member’s age is 2 years or older; OR
1. A diagnosis of chronic iron overload resulting from nontransfusion-dependent thalassemia (NTDT); AND
   a. Liver iron levels >10mg/g and serum ferritin levels >300 mcg/L (demonstrated by lab values in the previous 3 months); AND
   b. Member’s age is 10 years or older

Re-Authorization-Exjade® (deferasirox).

Documentation of the following:
1. For chronic transfusional iron overload due to blood transfusions: Clinical response to treatment and continues to require therapy for serum ferritin level consistently >500mcg/L (demonstrated by at least two lab values in the previous 3 months); OR
2. For non-transfusion-dependent thalassemia (NTDT): Clinical response to treatment. (demonstrated by decreased liver iron levels in the previous 6 months compared to baseline but no less than 3mg/g, and serum ferritin level no less than 300mcg/L within last month)

References
8. 4. Ferriprox (package insert). Rockville, MD: ApoPharma USA, Inc; October 2011
9. 5. Deferiprone (Ferriprox); for iron overload. The Medical Letter 2012; 54:1384
EXTAVIA (INTERFERON BETA-1B)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Coverage of interferon beta 1-b is recommended in those who meet both of the following criteria:

1. Patients with a diagnosis of MS or have experienced an attack and who are at risk of MS. These recommendations are based upon an expert opinion paper published in 2007 by the national clinical advisory board for the National MS Society. Interferon beta-1b is FDA approved for the treatment of relapsing forms of MS to reduce the frequency of clinical exacerbations. The guidelines from the National MS Society also stated that this agent can reduced future disease activity and improve quality of life for many patients with relapsing forms of MS, including those with secondary progressive disease who continue to experience relapses.

AND

2. Prescribed by, or after consultation with, a neurologist or an MS-specialist.

***BETASERON and COPAXONE and REBIF are the preferred drugs. Member must have tried/failed Betaseron or Copaxone first unless contraindicated.***

EXCLUSIONS

Coverage of interferon beta-1b is not recommended in the following circumstances:

1. Concurrent use of interferon beta-1b with interferon beta-1a (Avonex®, Rebi®) or glatiramer acetate (Copaxone®) is not recommended.
2. Patient is receiving natalizumab (Tysabri®). Natalizumab is indicated as monotherapy for MS patients with relapsing forms of the disease.
3. Patient is concurrently receiving fingolimod. Use of interferon beta-1b SC with fingolimod has not been studied or established.

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval


FARYDAK (PANOBINOSTAT)

**Criteria for use (bullet points below are all inclusive unless otherwise noted):**

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Must be clinically diagnosed with multiple myeloma
- Must have tried and failed two previous therapies, including the following:
  - Revlimid, Thalomid, or Pomalyst; AND
  - Velcade
- Farydak must be taken in combination with Velcade AND dexamethasone
- Must have an ECOG performance status between 0 and 2:

<table>
<thead>
<tr>
<th>ECOG PERFORMANCE STATUS</th>
<th>ECOG</th>
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<tbody>
<tr>
<td>Grade 0</td>
<td></td>
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<tr>
<td>Fully active, able to carry on all pre-disease performance without restriction</td>
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</table>
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

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<tr>
<td>1</td>
<td>Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work</td>
</tr>
<tr>
<td>2</td>
<td>Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours</td>
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<tr>
<td>3</td>
<td>Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours</td>
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<td>4</td>
<td>Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair</td>
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<td>5</td>
<td>Dead</td>
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</table>

**Additional Information:**
- If authorized, Virginia Premier will cover maximum of 16 cycles of Farydak in a lifetime
- Each fill is limited to 6 capsules
- Request for any condition not listed as covered require evidence of current medical literature that substantiates drug’s efficacy or that recognized oncology organizations generally accept the treatment for that condition.

**References**
1.) DRUGDEX®, accessed 03/13/2015.

**FASENRA (BENRALIZUMAB)**

**INITIAL**
- Must have a documented diagnosis of severe asthma with an eosinophilic phenotype; **AND**
- Must NOT be used for the relief of acute bronchospasm or status asthmaticus; **AND**
- Must have baseline absolute blood eosinophil count greater than or equal to 150 cells/microL at initiation of therapy or greater than or equal to 300 cells/microL within the last 12 months; **AND**
- Patient must still be symptomatic despite being compliant to a trial of a combination of at least a medium dose inhaled corticosteroid with either a long acting beta agonist (LABA), leukotriene modifier, or theophylline; **AND**
- Patient is 12 years of age or older; **AND**
- Prescribed by, or in consultation with, an allergist, pulmonologist, or immunologist

**RENEWAL**
- Continue to meet initial criteria; **AND**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Patient has responded to Fasenra therapy as determined by the prescriber (e.g. decreased asthma exacerbations, decreased asthma symptoms, decreased requirement for oral corticosteroid, or decreased hospitalizations/emergency department visits)

COVERAGE DURATION
• Initial – 6 months
• Renewal – 12 months

EXCLUSION CRITERIA
• Not for treatment of other eosinophilic conditions
• Not for relief of acute bronchospasm or status asthmaticus
• Known hypersensitivity to benralizumab or its excipients

FENTANYL PATCH
• Required for 37.5, 62.5, and 87.5 mcg strengths of fentanyl patch
• Must have a diagnosis of chronic severe pain in opioid-tolerant patients who require daily, around-the-clock, long-term opioid treatment
• Must have tried and failed formulary Fentanyl patches in combination equal to the requested Non-Formulary strength (i.e. 12mcg patch and 25mcg patch in place of 37.5mcg, or 12mcg patch and 50mcg patch instead of 62.5mcg, or 12 mcg patch and 75mcg patch in place of 87.5 mcg patch)

References
1. Virginia Premier

FENTORA (FENTANYL CITRATE) TABLET

Criteria for use (bullet points below are all inclusive unless otherwise noted):
• The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient's medical records.
• Only approved for management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for underlying persistent cancer pain
• Patients considered opioid-tolerant are those who are taking at least: 60 mg morphine/day or an equianalgesic dose of another opioid for a week or longer.
• Must be 18 years of age or older (16 or over for Actiq).
• Must be prescribed by oncologist or pain specialist.
• Must be able to comply with instructions to keep medication out of the reach of children and to discard open units properly.
• Maximum of a quantity of 4 units total for any combination of fentanyl oral products.
• Must try and fail an adequate dose of a formulary immediate release narcotic for breakthrough pain.
• Must be on an adequate dose of a long-acting (maintenance, around-the-clock) opioid.

REFERENCES
3. Virginia Premier

FERRIPROX (DEFERIPRONE)

Documentation of the following:

1. A diagnosis of transfusional iron overload due to thalassemia syndrome; AND
2. An inadequate response, intolerance or a contraindication to deferoxamine or Exjade; AND
3. Serum ferritin levels that are consistently > 2500 mcg/L (demonstrated by at least two lab values in the previous 3 months); AND
4. An absolute neutrophil count (ANC) >1.5 x 10⁹/L; AND
5. The prescriber is a hematologist or oncologist.

Re-Authorization- Ferriprox® (deferiprone)

Documentation of the following:

1. Clinical response to treatment and continues to require therapy for serum ferritin level consistently >500mcg/L (demonstrated by at least two lab values in the previous 3 months); AND

2. An absolute neutrophil count (ANC) >1.5 x 10⁹/L

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Clinical Background Information and References
4. Ferrispro (package insert). Rockville, MD: ApoPharma USA, Inc; October 2011
5. Deferiprone (Ferrispro); for iron overload. The Medical Letter 2012; 54:1384

FIRDAPSE (AMIFAMPIDINE)

CRITERIA FOR USE

• The indicated diagnosis must be Lambert-Eaton myathenic gravis (LEMS) in adults
  AND
• Patient must be 18 years of age or greater
  AND
• Prescribed by or in conjunction with a neurologist or rheumatologist
  AND
• Prescriber attests patient does not have a history of seizures
  AND
• Prescriber attests that small cell lung cancer (SCLC) diagnosis has been ruled out OR if patient has a diagnosis of SCLC, patient is being treated for SCLC unless intolerant or contraindications exist
  AND
• Patient has moderate to severe muscle weakness (i.e. proximal weakness affecting legs, eyes, face, or throat) that interferes with daily function
  AND
• Prescriber has a baseline evaluation of muscle strength in patient

Criteria for Renewal

• Patient continues to meet initial criteria
  AND
• Prescriber attests to clinical improvement while on medication

Not approved if:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
- Does not meet above criteria
- Any contraindication to treatment

**Approval Duration:** Initial Approval – 3 months, Renewal Approval – 6 months

**FLOLAN/VELETRI (EPOPROSTENOL SODIUM)**

- Patient has clinically diagnosed primary or secondary pulmonary arterial hypertension
  - (defined as a mean pulmonary arterial pressure >25mm Hg at rest or >30mm Hg during exercise, with a normal pulmonary capillary wedge pressure)
- Patient exhibits Class III or IV symptoms; AND
- Patient has had an intolerance to, or treatment failure of a calcium channel blocker after favorable response to acute vasoreactivity testing; OR
- Failure to have a pulmonary vasodilator response to an acute challenge of a short acting vasodilator; AND
- Intolerance to, contraindication* or treatment failure to bosentan
  - Contraindications to bosentan include: pregnancy, LFT abnormalities, co-administration with either cyclosporine or glyburide
- New York Heart Association functional classification:
  - Class 1: No symptoms with ordinary physical activity.
  - Class 2: Symptoms with ordinary activity. Slight limitation of activity.
  - Class 3: Symptoms with less than ordinary activity. Marked limitation activity.
  - Class 4: Symptoms with any activity or event at rest.

Administered through a central venous catheter. Chronic infusion of Flolan should be initiated at 2 ng/kg/min and increased in increments of 2 ng/kg/min every 15 minutes or longer until dose-limiting pharmacologic effects are elicited or until a tolerance limit to the drug is established and further increases in the infusion rate are not clinically warranted.

**References:**

1. Flolan full prescribing information GlaxoSmithKline.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

FORTEO (TERIPARATIDE)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Criteria for approval are ALL of the following:

1. ONE of the following:
   a. Patient has a diagnosis of osteoporosis defined as a T-score that is \(-2.5\) or lower (2.5 or more standard deviations below the mean bone mineral density (BMD) value for a young adult) AND ONE of the following:
      i. Patient has a very low BMD defined as a T-score that is \(-3.5\) or lower OR
      ii. Patient has a history of prevalent vertebral fracture(s) or low trauma or fragility fracture(s) [e.g., prior fracture from minor trauma such as falling from standing height or less] OR
      iii. Patient’s medication history includes a first-line agent (bisphosphonate or SERM for women, bisphosphonate for men) OR
      iv. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to SERM and bisphosphonate (bisphosphonate only if male) OR
   b. Patient has a history of prevalent vertebral fracture(s) or low trauma or fragility fracture(s) (without a diagnosis of osteoporosis) AND ONE of the following:
      i. Patient’s medication history includes a first-line agent (bisphosphonate or SERM for women, bisphosphonate for men) OR
      ii. Patient has documented intolerance, FDA labeled contraindication, or hypersensitivity to SERM and bisphosphonate (bisphosphonate only if male) AND

2. Patient is not receiving concomitant bisphosphonate, SERM, or Prolia (denosumab) therapy AND

3. Total duration of treatment with Forteo has not exceeded 2 years

Alendronate is the preferred drug. Member must have tried/failed Biphosphonates first unless contraindicated.

EXCLUSIONS

Coverage of Forteo is not recommended in the following circumstances:

- Prevention of osteoporosis (women and men).

Forteo has not been studied in this patient population and the benefits of building bone in a condition in which substantial bone loss has not occurred have not been investigated.

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval


**FUZEON (ENFUVIRIDTE)**

- HIV-1 infection, AND
- At least 5 log (10) copies of HIV-1 RNA per ml of plasma, AND
- Tried/failed/intolerance to ≥ 3 classes of anti-HIV therapy (nucleoside reverse transcriptase inhibitor, non-nucleoside reverse transcriptase inhibitor, and protease inhibitor) after 3 or more months of therapy.

**References**


**FYCOMPA™ (PERAMPANEL)**

- Patient must be ≥12 years old for tonic-clonic seizures, or 4 years of age or older for partial-onset seizures
- Being used in one of the following:
  - Treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy OR
  - Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy
- Patient must have a history of trial and failure of:
  - At least 2 concomitant Antiepileptic Drugs OR
  - At least 3 different Antiepileptic Drugs OR
  - History Vagal Nerve Stimulator (VNS) implantation or lobectomy.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Serious or life-threatening psychiatric and behavioral adverse reactions including aggression, hostility, irritability, anger, and homicidal ideation and threats have been reported in patients taking FYCOMPA (5.1)
  o Monitor patients for these reactions as well as for changes in mood, behavior, or personality that are not typical for the patient, particularly during the titration period and at higher doses
• Maximum recommended daily dose is 12 mg once daily.

References

1. Virginia Premier.

GAMUNEX/GAMUNEX C (IMMUNE GLOBULIN, HUMAN INTRAVENOUS)

• Primary immune deficiency:
  o Common Variable Immunodeficiency (hypogammaglobulinemia), OR
  o IgG deficiency (IgG<400mg/dl and/or a significant inability to respond with IgG antibody production after antigenic challenge), OR
  o Bruton’s or X-linked agammaglobulinemia, OR
  o Severe Combined Immunodeficiency (SCID), OR
  o Wiskott-Aldrich Syndrome, OR
  o X-linked Hyper IgM Syndrome, OR
• Kawasaki disease, OR
• Chronic lymphocytic leukemia-related IgG deficiency, OR
• Bone Marrow Transplant (prevention of graft-versus-host disease and/or infection), OR
• HIV infection-related IgG deficiency, OR
• Guillain-Barre Syndrome, OR
• Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), AND
  o Tried/failed/intolerance of corticosteroids or plasma exchange, OR
• Dermatomyositis (including juvenile) or Polymyositis, AND
  o Tried/failed/intolerance to corticosteroids and adjuvant therapy (methotrexate, hydroxychloroquine, cyclosporine, etc.), OR
• Systemic Lupus Erythematosus (SLE), AND
  o Tried/failed/intolerance of NSAIDs, corticosteroids and/or antimalarials) AND immunosuppressants, OR
• Relapsing-Remitting Multiple Sclerosis, AND
  o Tried/failed/intolerance to Avonex, Betaseron, Copaxone, and/or Rebif, OR
• Autoimmune hemolytic anemia, OR
• Autoimmune neutropenia, OR
• Cytomegalovirus infection, OR
• Dermatomyositis, OR
• Kidney disease, OR
• Myasthenia gravis, OR
• Toxic shock syndrome, OR
• Hemolytic disease of fetus OR newborn due to RhD isoimmunization; Prophylaxis
• Motor neuropathy with multiple conduction block
• Multiple myeloma

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Polymyositis
• Stiff-man syndrome
• Thrombocytopenia, Antenatal and neonatal
• Kidney transplant – Pretransplant desensitization, OR
• Neonatal jaundice, OR
• Pemphigus vulgaris, OR
• Renal Transplant rejection, OR
• Respiratory syncytial infection, OR
• Sepsis, OR
• Uveitis, OR
• Von Willebrand disorder, or
• Idiopathic (immune) thrombocytopenic purpura, AND
  o Pretreatment platelet count < 30,000/mm3 (30 x 10^9/L or 30,000/ml) or a platelet count < 50,000/mm3 (50 x 10^9/L or 50,000/ml) with significant mucous membrane bleeding or risk factors for bleeding, AND
  o Tried/failed/intolerance to corticosteroids or splenectomy.
  o Reauthorization/continuing treatment:
    ▪ Platelet count of at least 50,000/mm3), OR
    ▪ Increase in platelet count over baseline to a level sufficient to avoid clinically important bleeding

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

GATTEX (TEDUGLUTIDE)

A prior authorization request will be required for all prescriptions for Gattex®. These requests will be approved when the following criteria are met:

**Initial Therapy - (Duration of Approval – Maximum of 6 months)**

Documentation of the following:

1. A diagnosis of short bowel syndrome; **AND**
2. Age is 18 years of age or older; **AND**
3. Prescribed by or in consultation with a gastroenterologist or an endocrinologist; **AND**
4. Short bowel syndrome management has been dependent on parenteral nutrition support for at least 12 months prior to initiation of therapy with Gattex
5. Documentation of colonoscopy to rule out polyps within the last 6 months.

**Re-authorization – (Duration of Approval – Maximum of 6 months)**

Documentation of the following:

1. Parenteral nutrition support is no longer required as a result of Gattex treatment and there has not been treatment-related adverse events (medical records must be included)

GLEEVEC (IMATINIB)

- Prescribed by a Hematologist or Oncologist, **AND**
- Adult patient with Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in chronic phase, in blast crisis, or in accelerated phase, **OR** with molecular or cytogenetic relapse, **OR** patients not in cytogenetic remission, after hematopoietic stem cell transplant (HSCT), **OR** who are resistant to interferon-alpha therapy, **OR**
- KIT (CD117) positive, resectable, unresectable, recurrent and/or metastatic malignant gastrointestinal stromal tumors (GIST), **OR**
- Adult patient with Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL), **OR**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Pediatric patient with Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML), And the pediatric patient is in a chronic phase or whose disease has recurred after stem cell transplant or who are resistant to interferon-alpha therapy, OR
- Pediatric patient with diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in a newly diagnosed patient being used in combination with chemotherapy, OR
- Adult patient with hypereosinophilic syndrome (HES), OR
- Adult patient with chronic eosinophilic leukemia (CEL), OR
- Adult patient with aggressive systemic mastocytosis (ASM), and the patient does not have a D816V C-Kit mutation or the c-Kit mutation status is unknown, OR
- Adult patient with myelodysplastic/myeloproliferative disease (MDS/MPD), and the MDS/MPD is associated with PDGFR (platelet-derived growth factor receptor) gene rearrangements, OR
- Adult patient with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP), OR
- Desmoid tumors, OR
- Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT), OR
- Adult patient with Chordoma, OR
- Adult patient with advanced or metastatic Melanoma with C-Kit mutated tumors

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

**GOCOVRI (AMANTADINE)**

- Patient is experiencing dyskinesia associated with a Diagnosis of Parkinson’s Disease
- Patient is 18 years of age or older
- Patient is currently on concomitant levodopa-based therapy
- Patient has had an adequate trial of, or is intolerant to, amantadine immediate-release
- Member does not have end-stage renal disease (creatinine clearance <15 mL/min/1.73m²)
- Patient will NOT receive live vaccines during treatment (inactivated vaccines may be utilized)

**Authorization Dates:**

Renewal – 12 months

**INFORMATIONAL:**

Quantity Limit:

- 68.5 mg = 34 capsules/34 days
- 137 mg = 68 capsules/34 days
The following criteria must be met for approval of Grastek coverage:

- the member is 5 years of age or older for **Grastek**
- the medication is prescribed by an allergist, immunologist, or ENT (ear, nose, throat) specialist, or the prescriber is from BLAND COUNTY MEDICAL CLINIC
- **Grastek** therapy is initiated 12 weeks prior to the expected onset of the grass pollen season or therapy is being dosed daily continuously for consecutive grass pollen seasons
- the diagnosis of grass pollen-induced allergic rhinitis is confirmed by either a positive skin test response to a grass pollen from the Pooidae subfamily of grasses (this includes, but is not limited to sweet vernal, Kentucky blue grass, Timothy grass, orchard, or perennial rye grass) OR positive in vitro test (blood test for allergen-specific IgE antibodies) for a grass in the Pooidae subfamily of grasses.
- the member is NOT currently receiving subcutaneous allergen immunotherapy.

When approved, members may obtain 30 sublingual **Grastek** tablets per 30 days

**References:**
GROWTH HORMONE
PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

<table>
<thead>
<tr>
<th>Indication &gt;</th>
<th>Growth Hormone Deficiency</th>
<th>Growth failure due to Chronic Renal Insufficiency</th>
<th>Growth failure in children born small for gestational age</th>
<th>Prader-Willi Syndrome in children</th>
<th>Turner's Syndrome</th>
<th>Cachexia AIDS-related</th>
<th>Short Bowel Syndrome</th>
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*Genotropin and Nutropin AQ Nuspin are the preferred drugs. Member must have tried/failed Genotropin and Nutropin AQ Nuspin first unless contraindicated.*

- Diagnosis of one of the following AND meets the corresponding criteria:
  1. Pediatric Growth Hormone GH Deficiency, OR
  2. Idiopathic Short Stature, OR
  3. Familial Short Stature, OR
  4. Small for Gestational Age (SGA), OR
  5. Turner Syndrome, OR
  6. Noonan Syndrome, OR
  7. Prader Willi Syndrome (PWS), OR
  8. Chronic Renal Insufficiency, OR
  9. SHOX Deficiency, OR
  10. Pediatric Chronic Kidney disease, OR
  11. Adult GH Deficiency, OR
  12. Short Bowel Syndrome, AND

- Prescribed by, or in consultation with, an Endocrinologist or Nephrologist

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
1. Pediatric Growth Hormone GH Deficiency

**INITIAL THERAPY**

a. Member’s pretreatment height and age have been provided including documentation from medical record, AND

b. Member’s pretreatment height meets one of the following:
   i. Greater than or equal to 2.25 standard deviations (SD) below the mean for age and gender, or
   ii. Greater than or equal to 2 SD below the mean for age and gender, AND

c. Member’s pretreatment growth velocity meets one of the following:
   i. Greater than 1 SD below the mean for age and gender
   ii. 1 SD below the mean for age and gender AND

d. Documentation from medical record showing at least 2 heights measured by a pediatric endocrinologist at least 6 months apart (data for 1 year) OR At least 4 heights measured by a primary care physician at least 6 months apart (data for 2 years), AND

e. Member had a GH response of less than 10 ng/mL (or otherwise abnormal as determined by the lab) of at least two (2) GH stimulation tests **(medical record documentation required)**, OR

e. Member has a defined CNS pathology, history of cranial irradiation or genetic condition associated GH deficiency, OR

e. Member had abnormally low GH level in association with neonatal hypoglycemia, OR

e. Member has both IGF-1 and IGFBP-3 levels below normal for age and gender **(medical record documentation required)**, OR

e. Member has 2 or more documented pituitary hormone deficiencies other than GH

**CONTINUING THERAPY**

a. Member’s growth velocity is at least 2 cm per year while on GH therapy **(medical record documentation required)**, AND

b. Patient’s growth plates remain open

2. Idiopathic Short Stature (ISS)/Familial Short Stature/SGA/Turner Syndrome/Noonan Syndrome/Prader Willi Syndrome/SHOX Deficiency

a. Member’s pretreatment height and age have been provided including documentation from medical record, AND

b. Member’s pretreatment height meets one of the following:
   i. Greater than or equal to 2.25 standard deviations (SD) below the mean for age and gender, or
   ii. Greater than or equal to 2 SD below the mean for age and gender, AND

c. Member’s pretreatment growth velocity meets one of the following:
   i. Greater than 1 SD below the mean for age and gender
   ii. 1 SD below the mean for age and gender AND

d. Documentation from medical record showing at least 2 heights measured by a pediatric endocrinologist at least 6 months apart (data for 1 year) OR At least 4 heights measured by a primary care physician at least 6 months apart (data for 2 years), AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

**CONTINUING THERAPY**

a. Member’s growth velocity is at least 2 cm per year while on GH therapy (medical record documentation required), AND

b. Patient’s growth plates remain open

**10. Pediatric Chronic Kidney Disease/Chronic Renal insufficiency**

a. Member’s pretreatment height and age have been provided including documentation from medical record, AND

b. Member’s pretreatment height meets one of the following:
   i. Greater than or equal to 2.25 standard deviations (SD) below the mean for age and gender, or
   ii. Greater than or equal to 2 SD below the mean for age and gender, AND

c. Member’s pretreatment growth velocity meets one of the following:
   i. Greater than 1 SD below the mean for age and gender
   ii. 1 SD below the mean for age and gender AND

d. Documentation from medical record showing at least 2 heights measured by a pediatric endocrinologist at least 6 months apart (data for 1 year) OR At least 4 heights measured by a primary care physician at least 6 months apart (data for 2 years), AND

e. Patient has any ONE of the following:
   i. Creatinine clearance of 75 mL/min/1.73m2 or less
   ii. Serum creatinine greater than 3.0 g/dL
   iii. Dialysis dependent

**CONTINUING THERAPY**

a. Member’s growth velocity is at least 2 cm per year while on GH therapy (not required for restarts) (medical record documentation required), AND

b. Patient’s growth plates remain open

c. Member’s current height is provided documented in medical record

**11. Adult GH Deficiency**

a. Member has irreversible hypothalamic/pituitary structural lesions or ablation, OR

b. Member has a defect in GH synthesis, OR

c. Member had GH deficiency diagnosed during childhood, AND
   i. Member was retested for GH Deficiency after an at least 1-month break in GH therapy, AND
   ii. One of the following agents was used in GH stim test to measure peak GH level
      ▪ Insulin
      ▪ Clonidine
      ▪ Levodopa
      ▪ Glucagon

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Arginine
  - iv. Peak GH level was shown to be below normal (medical record documentation required)

12. Short Bowel Syndrome
   a. Member will receive specialized nutritional support
   b. GH will be used in conjunction with optimal management of short bowel syndrome

EXCLUSIONS

Coverage of Genotropin, Humatrope, Norditropin, Nutropin, Nutropin AQ, Omnitrope, Saizen, Tev-Tropin, and Zorbtive (all listed products except Serostim) is not recommended in the following circumstances, unless the criteria in 1 or 2 above have been met. For some of the following indications, authorization for coverage is not recommended because this indication is excluded from coverage in a typical pharmacy benefit.

1. Acute critical illness due to complications following surgery, multiple accidental trauma, or with acute respiratory failure.
2. Aging (i.e., antiaging); to improve functional status in elderly patients; and somatopause.
3. Athletic ability (enhancement).
4. Bone marrow transplantation without total body irradiation (cranial radiation).
5. Bony dysplasias (achondroplasia, hypochondroplasia).
7. Cardiac transplantation.
8. Central precocious puberty.
9. Chronic fatigue syndrome.
11. Constitutional delay of growth and puberty.
12. Corticosteroid-induced short stature, including a variety of chronic glucocorticoid-dependent conditions, such as asthma, Crohn's disease, juvenile rheumatoid arthritis, as well as after renal, heart, liver, or bone marrow transplantation.
14. Cystic fibrosis.
15. Dilated cardiomyopathy and heart failure.
17. End-stage renal disease in adults undergoing hemodialysis.
18. Familial dysautonomia (Riley-Day syndrome, hereditary sensory autonomic neuropathy).
19. Fibromyalgia.
20. HIV-infected patients with alterations in body fat distribution (e.g., increased abdominal girth, buffalo hump). Somatropin is not FDA-approved for the treatment of HIV-associated adipose redistribution syndrome (HARS). HARS is a subset of HIV 110ulticenter110y and is defined as maldistribution of body fat characterized by central fat accumulation (lipohypertrophy) with or without lipoatrophy. In HARS, fat may also accumulate in the upper body subcutaneous area such as the dorsocervical area (buffalo hump).
23. Liver transplantation.
24. Multiple system atrophy (MSA).

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

25. Myelomeningocele.
27. Osteogenesis imperfecta.
29. Thalassemia.
30. X-linked hypophosphatemic rickets (familial hypophosphatemia, hypophosphatemic rickets).

**CONTRAINDICATIONS**

**a) Somatropin, E-Coli Derived**

1) closed epiphyses, in pediatric patients
2) diabetic retinopathy, active proliferative or severe non-proliferative
3) hypersensitivity to somatropin, *Escherichia coli*, or any of its excipients or diluents
4) hypersensitivity to benzyl alcohol (Omnitrope, Saizen, Tev-Tropin, Zorbtivel)
5) hypersensitivity to metacresol (Genotropin Lyophilized powder)
6) malignancy, active, including intracranial tumor; discontinue with evidence of recurrent activity
7) Prader-Willi syndrome, in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment; sudden death has been reported
8) treatment of acute critical illness (off-label use), due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma; may increase mortality risk
9) treatment of acute respiratory failure (off-label use); may increase mortality risk
10) underlying intracranial tumor, evidence of progression or recurrence

**b) Somatropin, Mammalian Derived**

1) acute critical illness due to complications following open heart surgery, abdominal surgery, or multiple accidental trauma; increased mortality has been reported
2) acute respiratory failure; increased mortality has been reported
3) closed epiphyses, in pediatric patients (Nutropin, Nutropin AQI, Saizen)
4) diabetic retinopathy, active proliferative or severe non-proliferative (Nutropin, Nutropin AQI, Saizen, Serostim)
5) hypersensitivity to somatropin, mammalian-derived or any excipients
6) hypersensitivity to benzyl alcohol (Saizen, Serostim, Zorbtivel)
7) malignancy, active
8) Prader-Willi syndrome, in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment; sudden death has been reported (Nutropin, Nutropin AQI, Saizen)

**References**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

HEPATITIS C AGENTS PREFERRED (MAVYRET/SOFOSBUVIR/VELPATASVIR)

- Member must have a diagnosis of Chronic Hepatitis C with or without, Compenstaed cirrhosis, Hepatocellular Carcinoma, Decompenstated cirrhosis (child-pugh class b or c,) or status post liver transplant AND
- HCV genotype 1 (with or without polymorphism), 2, 3, 4, 5, or 6 (test results must be submitted) AND
- Prescriber must attest that they have assessed the member for adherence with medical and pharmacological treatment

Auth Duration: 8 – 24 weeks depending upon genotype and diagnosis

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
HEPATITIS C AGENTS NON-PREFERRED (HARVONI, VOSEVI, DAKILINZA, SOVALDI, EPCLUSA, LEDIPASVIR/SOFOSBUVIR, VIEKIRA)

- Medication must be prescribed by or in consultation with a gastroenterologist, hepatologist, transplant specialist, or infectious disease specialist
- Member must have a diagnosis of Chronic Hepatitis C with or without, Compensated cirrhosis, Hepatocellular Carcinoma, Decompensated cirrhosis (child-pugh class b or c,) or status post-liver transplant AND
- Genotype and polymorphism (if available), must be documented
- Must be utilized for an FDA approved treatment regimen
- Prescriber must:
  - Assess the member for adherence with medical and pharmacological treatments
  - Evaluate member for current substance use disorder including alcohol use disorder
- Members identified with a substance use disorder should be referred for treatment
- Testing for illicit drug and/or alcohol use is not required
- Member cannot be denied Hepatitis C treatment for sole reason of substance use
- If member has decompensated cirrhosis (child pugh score greater than 6) or history of severe renal impairment (eGFR<30mL/min/1.73m²) or ESRD requiring hemodialysis then details must be provided
- Member must have trial/failure or intolerance to preferred agents of Mavyret/Epclusa
- If request is for Harvoni, member must have a trial and failure of the authorized generic Ledipasvir-Sofosbuvir

Auth Duration: 8 – 24 weeks depending upon genotype and diagnosis

HEREDITARY ANGIOEDEMA AGENTS

- Must be prescribed by and under direct care of a board-certified allergist, immunologist or hematologist; AND
- For prophylaxis the patient must:
  - Have HAE attacks that occur at least once monthly; AND
  - Be disabled at least 5 days per month; AND
  - Have history of attacks with airway compromise / hospitalization AND
  - Have history of prior prophylaxis with danazol:
    - danazol contraindicated (pediatric, hepatic or renal impairment, pregnancy, breast-feeding, abnormal genital bleeding); OR
    - Developed danazol toxicity; OR
    - Diminished danazol efficacy.

- FDA Indications and Quantity Limits
  - Berinert®: Acute abdominal, facial or laryngeal HAE attacks. Four vials per attack (plus four for emergency).
  - Cinryze™: Prevention of HAE attacks. 20 vials per 34 days.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

- Kalbitor®: Acute HAE attacks in patients 12 years of age and older. Three vials per attack (plus three vials for emergency).
- Firazyr®: Acute attacks of (HAE) in adults 18 years of age and older. One syringe (plus one for emergency).
- Ruconest®: Acute attacks of hereditary angioedema (HAE) in people over 13 years of age. Two vials (plus two for emergency).

**HETLIOZ (TASIMELTEON)**

- Approvable for the diagnosis of non-24-hour sleep wake disorder (non-24 or N24) in completely blind members.
- Age 18 years of age or older.
- Member must have tried OTC melatonin and failed to achieve an adequate response.
- NONE the following:
  - Severe hepatic impairment (Child-Pugh Class C)
- Length of Authorization: 1 year

**References**

1. Virginia Premier.

**HIZENTRA (IMMUNE GLOBULIN, HUMAN SUBCUTANEOUS)**

- Primary immune deficiency:
  - Common Variable Immunodeficiency (hypogammaglobulinemia), OR
  - IgG deficiency (IgG<400mg/dl and/or a significant inability to respond with IgG antibody production after antigenic challenge), OR
  - Bruton’s or X-linked agammaglobulinemia, OR
  - Severe Combined Immunodeficiency (SCID), OR
  - Wiskott-Aldrich Syndrome, OR
  - X-linked Hyper IgM Syndrome, OR
  - Kawasaki disease, OR
  - Chronic lymphocytic leukemia-related IgG deficiency, OR
  - Bone Marrow Transplant (prevention of graft-versus-host disease and/or infection), OR
  - HIV infection-related IgG deficiency, OR
  - Guillain-Barre Syndrome, OR
  - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), AND
    - Tried/failed/intolerance of corticosteroids or plasma exchange, OR
  - Dermatomyositis (including juvenile) or Polymyositis, AND
    - Tried/failed/intolerance to corticosteroids and adjuvant therapy (methotrexate, hydroxychloroquine, cyclosporine, etc.), OR
  - Systemic Lupus Erythematosus (SLE), AND
    - Tried/failed/intolerance of NSAIDs, corticosteroids and/or antimalarials) AND immunosuppressants, OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
- Relapsing-Remitting Multiple Sclerosis, AND
  - Tried/failed/intolerance to Avonex, Betaseron, Copaxone, and/or Rebif, OR
- Autoimmune hemolytic anemia, OR
- Autoimmune neutropenia, OR
- Cytomegalovirus infection, OR
- Dermatomyositis, OR
- Kidney disease, OR
- Myasthenia gravis, OR
- Toxic shock syndrome, OR
- Hemolytic disease of fetus OR newborn due to RhD isoimmunization; Prophylaxis
- Motor neuropathy with multiple conduction block
- Multiple myeloma
- Polymyositis
- Stiff-man syndrome
- Thrombocytopenia, Antenatal and neonatal
- Kidney transplant – Pretransplant desensitization, OR
- Neonatal jaundice, OR
- Pemphigus vulgaris, OR
- Respiratory syncytial infection, OR
- Sepsis, OR
- Uveitis, OR
- Von Willebrand disorder, or
- Idiopathic (immune) thrombocytopenic purpura, AND
  - Pretreatment platelet count < 30,000/mm3 (30 x 10^9/L or 30,000/ml) or a platelet count < 50,000/mm3 (50 x 10^9/L or 50,000/ml) with significant mucous membrane bleeding or risk factors for bleeding, AND
  - Tried/failed/intolerance to corticosteroids or splenectomy.

**Reauthorization/continuing treatment:**
- Platelet count of at least 50,000/mm3), OR
- Increase in platelet count over baseline to a level sufficient to avoid clinically important bleeding

**References**


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
**HORIZANT (GABAPENTIN EXTENDED RELEASE)**

***Partially approve the EOC and submit to the PA Hub External queue. Send an e-mail to Adam @ aharbert@rxoptions.net and the “CC” the CDPharmacist e-mail distribution box, noting the EOC # and requested indication for use.***

**Generic name:** gabapentin extended release  **Brand name:** Horizant

**Medication class:** anticonvulsant

**FDA-approved uses:** treatment of moderate to severe primary restless legs syndrome (RLS) in adults.

**Available dosage forms:** 600mg tablets  **Usual dose:** 600mg daily at 5pm

**Duration of therapy:** indefinite

**Criteria for use (bullet points below are all inclusive unless otherwise noted):**

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Must have clinically diagnosed restless leg syndrome.
- Must have tried and failed pramipexole.  **AND**
- Must have tried and failed ropinirole.  **AND**
- Must have tried and failed generic gabapentin.

**Contraindication:**

- None reported at this time.

**Not approved if:**

- Does not meet the above stated criteria.

**Special considerations:**

- Gabapentin is considered second line therapy.
- Pramipexole and ropinirole is first line therapy.

**References**

1. Virginia Premier.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
HYALGAN (HYALURONIC ACID DERIVATIVE, INTRA-ARTICULAR)

_Euflexxa is the preferred drugs. Member must have tried/failed Euflexxa first unless contraindicated._

- Osteoarthritis of the knee, AND
- Tried/failed/intolerance to mild analgesic therapy (e.g. acetaminophen) OR tried/failed/intolerance to generic NSAIDs or COX-2 Inhibitors.
- Tried/failed/intolerance to the following:
  - Intra-articular corticosteroid injection (relief <6-8 weeks)
  - Physical therapy, AND
- Must not have large effusions of the knee, AND
- No infections or skin diseases in the knee area, AND
- Trial and failure, intolerance, or contraindication to Euflexxa

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


**ILARIS (CANAKINUMAB)**

- Prescribed by a Rheumatologist or Immunologist, AND
- Diagnosed with one of the following:
  - Cryopyrin-Associated Periodic Syndromes (CAPS) disorder in adult or child 4 years of age and older, including:
    - Familial Cold Autoinflammatory Syndrome, OR
    - Muckle-Wells Syndrome; OR
  - Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS); OR
  - Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD); OR
  - Familial Mediterranean Fever (FMF); OR
  - Active, Systemic Juvenile Idiopathic Arthritis (sJIA) in patient 2 years of age or older AND
  - Negative tuberculin skin test results or negative chest x-ray within the previous six months to rule out latent tuberculosis infection.

- **Note:** Must NOT be the following CAPS disorders:
  - Neonatal-Onset Multisystem Inflammatory Disease (NOMID), OR
  - Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA)

**References**


**IMBRUVICA (IBRUTINIB)**

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- ECOG performance status ≤ 1; **AND**
- Prescribed by an oncologist or hematologist; **AND**
- Clinically diagnosed with mantle cell lymphoma or chronic lymphocytic leukemia or Waldenström’s macroglobulinemia (WM); **AND**
- Received at least one prior therapy; **OR**
- Patient has chronic lymphocytic leukemia with 17p deletion.

**Criteria for continuation of therapy:**

- Patient responding to treatment without disease progression
- Patient tolerating treatment

**Caution:**

- Hemorrhage
- Infection
- Myelosuppression
- Renal toxicity
- Second primary malignancies
- Embryo-fetal toxicity
- Tumor lysis syndrome

**Monitoring:**

- Complete blood counts monthly
- Creatinine levels periodically

**Not approved if:**

- Does not meet above criteria
- Has any contraindications to treatment

**Authorization Approval Duration:**

- Initial 3 months
- Renewal 3 months

**References:**


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

Appendix 1

ECOG Performance status:

The ECOG performance status is a scale used to assess how a patient’s disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis.

Grade 0: Fully active, able to carry on all pre-disease performance without restriction

Grade 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work

Grade 2: Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours

Grade 3: Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours

Grade 4: Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair

Grade 5: Dead

INCRELEX (MECASERMIN)

- Prescribed by a Pediatric Endocrinologist
- Diagnosis of severe primary insulin-like growth factor deficiency (IGFD) or patients with growth hormone gene deletion who have developed neutralizing antibodies to GH as defined by:
  - IGF-1 level that is considered “low” (< -2 standard deviations below the mean) based on the lab’s reference range, AND
  - Lab results within 3 months of initial request, AND
  - Height standard deviation score ≤ -3.0, AND
  - Normal or elevated growth hormone level, (except for growth hormone (GH) deletion), based on growth hormone stimulation test with peak greater than 10 ng/mL.
- Indications of secondary IGF-1 ruled out:
  - Growth Hormone Deficiency
  - Hypothyroidism
  - Malnutrition
  - Open epiphyses
  - Age ≥ 2 and ≤ 20 years of age

Reauthorization continuing therapy:

- Increase in height velocity > 2.5cm total growth in 1 yr, AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• No evidence of epiphyseal closure, AND
• Patient has not met their expected final adult height or targeted height based on min-parental height calculation or their current absolute height is <= the 25th percentile (defined as 68 inches in males and 63 inches in females).

References

INGREZZA (VALBENAZINE)

Criteria for use (bullet points below are all inclusive unless otherwise noted):
• Member is 18 years of age or older, AND
• Member has a diagnosis of moderate to severe Tardive Dyskinesia AND
• Member has an Abnormal Involuntary Movement Scale (AIMS) score greater than or equal to 6, AND
• Medication is prescribed by, or in consultation with, a Neurologist or Psychiatrist, AND
• Member has attempted an alternative method to manage the condition such as dose reduction, tapering, discontinuation of the offending agent, switching to an alternative agent AND
• Member has an intolerance or treatment failure of Austedo AND
• Member is not receiving concurrent therapy with MAOI or VMAT2 inhibitors AND
• Member does not have any suicidal thoughts/behaviors or untreated or inadequately treated depression, congenital long QT syndrome, or arrhythmias associated with long prolonged QT

FOR RENEWAL:
• Documentation of positive clinical response to Ingrezza and improvement in AIMS score (decrease from baseline by at least 2 points) AND
• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of allergic-anaphylactic reactions, QT prolongation, and depression/suicidal thoughts AND
• Must not be taking other MAOI or VMAT2 inhibitors

DURATION:
Initial – 3 months, Renewal 12 months

INVEGA (PALIPERIDONE)

Criteria for use: (bullet points below are all inclusive unless otherwise noted)
• Clinically diagnosed schizophrenia, or schizoaffective disorder, or Bipolar I disorder, acute manic and mixed episodes.
  o Failed / intolerant to Risperdal (risperidone)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Failed / intolerant to one of the following: Zyprexa (olanzapine) Or Geodon (ziprasidone)

Cautions:
- Extrapyramidal symptoms.
- QTc prolongation
- Tachycardia
- Rarely associated with obstructive gastrointestinal symptoms.
- Should not be used with other drugs that prolong QTc interval (view QT drug lists at www.arizonacert.org)
- High fat meals can increase absorption by 50% or more.
- Max dose should be 6mg/day in mild renal impairment (CrCl 50-80mL/min)
- Max dose should be 3mg/day in severe renal impairment (CrCl 10-50 mL/min)

Contraindications:
- Hypersensitivity to any components in Invega or to risperidone. Not approved if:
  - Elderly patient have dementia with psychosis, since increased mortality has been reported.
  - Patient does not meet the above stated criteria
  - Patient has any contraindications to the use of Invega.

Special considerations:
- Paliperidone is the active metabolite of the atypical antipsychotic risperidone.
- Utilizes the OROS osmotic delivery technology.
- No head to head comparisons with risperidone.
- One study compared Invega to one other antipsychotic, Olanzapine, and it showed that Invega appeared similar in efficacy.
- Side effects similar to risperidone.
- No specific advantages of the new formulation have been demonstrated other than being dosed once a day.
- Longer studies and adequate comparisons with other antipsychotics are needed.

- Serum concentrations peak in 24 hours and it takes 4-5 days to achieve steady state.

References
1. Virginia Premier
JADENU (DEFERASIROX)

Transfusional Iron Overload initiation of Therapy:

1. Clinical trial and failure of Exjade is required prior to consideration of Jadenu (convenience, disliking the taste of Exjade, etc. are not considered failure).
2. Patient must be ≥2 years of age on the date of request for Jadenu.
3. Documentation of iron overload related to anemia found in patient’s medical conditions, progress notes, and/or discharge notes.
4. Documentation in medical records (e.g., progress notes, discharge notes...) of a recent history of frequent blood transfusions that has resulted in chronic iron overload.
5. Serum ferritin must be consistently >1000 mcg/L. (Lab results submitted should be dated within the past month.)
6. Starting dose is 14 mg/kg/day. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg).

Transfusional Iron Overload continuation of therapy:

1. Serum ferritin must have been measured within 30 days of continuation of therapy request (copy lab results must be submitted).
2. Ferritin levels must be >500mcg/L.
3. Dose must not exceed 28mg/kg/day.
4. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg).

Non-Transfusional Iron Overload initiation of therapy:

1. Clinical trial and failure of Exjade is required prior to consideration of Jadenu (convenience, disliking the taste of Exjade, etc. are not considered failure).
2. Patient must be ≥10 years of age on the date of request for Jadenu.
3. Documentation of iron overload related to anemia found in patient’s medical conditions, progress notes, and/or discharge notes.
4. Serum ferritin and liver iron concentration (LIC) must have been measured within 30 days of initiation (copy lab results must be submitted).
5. Serum ferritin levels must be >300mcg/L.
6. Liver iron concentration (LIC) must be >5 mg Fe/g dried weight (dw)
7. Starting dose is 7mg/kg/day. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg).

Non-Transfusional Iron Overload continuation of therapy:

1. Serum ferritin and liver iron concentration (LIC) must have been measured within 30 days of continuation of therapy request (copy lab results must be submitted).
2. Serum ferritin levels must be >300mcg/L.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
3. Liver iron concentration (LIC) must be >3 mg Fe/g dw.
4. Dose must not exceed: 14mg/kg/day.
5. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg).

AUTHORIZATION – 3 months

References

1. Virginia Premier

KALETRA (LOPINAVIR/RITONAVIR)

Duplicate therapy:
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

KALYDECO

- Diagnosis of Cystic fibrosis; AND
- Confirmed presence of the a G1244E, G1349D, G178R, G551S, G970R, S1251N, S1255P, S549N, or S549R mutation in the CFTR gene (medical records must be included); AND
- Medication is prescribed by an appropriate specialist such as pulmonologist or endocrinologist; AND
- Patient is not have homozygous for the F508del mutation in the CFTR gene.
- Member is 6 years of age or older

References

Virginia Premier

KINERET (ANAKINRA)

STEP THERAPY ALERT:
*Humira and Enbrel are the preferred drugs. Member must have tried/failed Humira AND Enbrel first unless contraindicated.*

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Coverage of anakinra is recommended in those who meet one of the following criteria:

FDA-Approved Indications

**Adults with rheumatoid arthritis.**
Approve if the patient has tried both adalimumab and etanercept, for at least 2 months or was intolerant to these TNF antagonists.

Initiating DMARD therapy with a biologic agent such as anakinra alone should be rare. Most patients will have received initial therapy with an oral DMARD(s) (e.g., hydroxychloroquine, sulfasalazine, MTX). If MTX is contraindicated another oral DMARD should be tried. Some patients with important markers of poor prognosis (e.g., functional limitations, rheumatoid factor positivity and/or positive anti-CCP antibodies, extraarticular manifestations of RA [e.g., vasculitis, Sjögren’s syndrome, RA lung disease]) or with joint erosions may be started early on biologic agents.

**Neonatal Onset Multisystem Inflammatory Disease (NOMID) or chronic infantile neurological cutaneous and articular (CINCA) syndrome.**
Approve for 12 months. In an open-label phase 2 study (n = 18), anakinra immediately improved clinical symptoms and laboratory markers of inflammation in patients with NOMID with or without cold-induced autoinflammatory syndrome 1 (CIAS1) gene mutations. All patients had active disease despite therapy with NSAIDs and DMARDs or corticosteroids. Sustained efficacy in the treatment of systemic inflammation and, in some cases, neurologic involvement and growth parameters, when patients (n = 10) were treated with anakinra for up to 42 months. Rilonacept and canakinumab are FDA approved for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) including MWS and FCAS. However, information is not available with their use in NOMID which is the most severe form of CAPS.

Other Uses with Supportive Evidence

**Juvenile idiopathic arthritis (JIA) or Juvenile rheumatoid arthritis (JRA), polyarticular course (regardless of the type of onset).**
Approve if the patient has tried both etanercept and adalimumab for at least 2 months or was intolerant to these agents.

Etanercept, adalimumab, and abatacept are FDA-approved for moderately to severely active polyarticular JIA in patients aged ≥ 2 years, ≥ 4 years, and ≥ 6 years, respectively. Infliximab is not FDA-approved in the treatment of JIA, but it has been used extensively for this indication. The evidence for the effectiveness of non-biologic DMARDs other than MTX for JIA is weak. In a 12-week open-label study (n = 82), anakinra was effective in some patients with active polyarticular-course JRA.

**Systemic onset juvenile idiopathic arthritis (JIA).**
Approve if patient has tried a systemic corticosteroid (e.g., prednisone, methylprednisolone).

In a small open-label trial (n = 9), patients with active systemic onset JIA who were unresponsive to conventional treatment (corticosteroids and MTX) responded (clinical and

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

In a case series, 20 children with active systemic onset JIA who had been treated with corticosteroids for a mean duration of 5.7 years received anakinra 1 to 2 mg/kg/day. The percentage of patients attaining a 30, 50, and 70% improvement using ACR pedi core set criteria were: 55%, 30%, 0% at 3 months, respectively; 50%, 25%, and 10% at 6 months, respectively; and 45%, 20%, and 10% at the latest follow-up, respectively (12 to 27 months from the start of anakinra). The steroid dose was reduced by 15 to 78% at 6 months compared to baseline in 9 patients. In a retrospective case review, monotherapy with anakinra was associated with a complete response (control of both arthritis and systemic clinical features) in 8 out of 10 patients when anakinra was used as first-line therapy for new-onset systemic JIA. Controlled clinical trials are needed to better describe clinical response, remission duration, and to determine whether anakinra can be substituted for corticosteroids as first-line therapy. TNF blockers seem less effective in children with systemic arthritis than in polyarthritis.

Chronic infantile neurological, cutaneous and articular syndrome, Treatment-refractory
Although not an FDA approved indication, there is supportive evidence to approve. Administration of anakinra was effective in resolving the clinical symptoms and improving laboratory parameters in patients with chronic infantile neurological cutaneous articular (CINCA) syndrome, also called neonatal-onset multisystem inflammatory disease (NOMID), in one time series trial and several case studies. Symptoms of fever, rash, headache, arthralgia, vomiting, hepatomegaly, and lymphadenopathy; neurologic complications (eg, papilledema, sensorineural hearing loss, cochlear enhancement); and laboratory parameters (eg, serum levels of amyloid A, C-reactive protein, erythrocyte sedimentation rate) showed rapid and marked improvement following initiation of anakinra. A mutation in the cold-induced auto-inflammatory syndrome 1 gene, which may regulate inflammation caused by interleukin-1-beta and nuclear factor-kappa B, is seen in approximately 60% of patients with a clinical diagnosis, but did not appear to predict anakinra response to treatment. Adverse events reported include injection site reactions, upper respiratory infection, urinary tract infection, and nonbacterial diarrhea leading to hospitalization.

Ankylosing spondylitis.
Approve if the patient has tried both adalimumab and etanercept, for at least 2 months or was intolerant to these TNF antagonists.

Etanercept, infliximab, golimumab, and adalimumab are FDA-approved for ankylosing spondylitis. According to the Assessment in Ankylosing Spondylitis (ASAS) working group and the European League Against Rheumatism (EULAR) recommendations for ankylosing spondylitis, all patients should have an adequate trial of at least 2 NSAIDs for pain and stiffness. Recommendations for other therapies before receiving etanercept, infliximab, golimumab, or adalimumab vary according to the manifestations of the disease, level of current symptoms, clinical findings, etc. According to these recommendations, patients with only axial manifestations do not have to try traditional DMARDs before using anti-TNF therapy; patients with symptomatic peripheral arthritis should have an insufficient response to at least one local corticosteroid injection, if appropriate; patients with persistent peripheral arthritis must have a trial of sulfasalazine; and patients with enthesitis should try appropriate local therapy (corticosteroid injection in selected cases). Anti-TNF agents (adalimumab, etanercept, golimumab, infliximab) should be used in patients with persistently high disease activity despite conventional therapy.
Anakinra has been beneficial in a few patients with ankylosing spondylitis, but results are not consistent. In a small \( n = 20 \) open-label study, patients with active ankylosing spondylitis who were refractory to NSAIDs received anakinra 100 mg daily. The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score decreased over a 6-month period but was not significant (5.8 at baseline vs. 5.0 at week 12 \( P > 0.05 \), and 4.8 at week 24 \( P > 0.05 \)). No significant change was found in Bath Ankylosing Spondylitis Functional Index (BASFI), patients’ and physicians’ global assessment or general pain during the study. After 12 weeks, both the ASAS 20 and 40 responses improved in 10.5% of patients (intent-to-treat analysis). After 24 weeks, ASAS 20 was attained in 26% of patients, ASAS 40 in 21%, and ASAS 70 in 10.5% of patients.

**Adult with Still’s Disease.**
Approve for 12 months if the patient has tried a corticosteroid AND has had an inadequate response to one non-biologic DMARD such as methotrexate given for at least 2 months or was intolerant to a non-biologic DMARD. Anakinra has been effective in reducing fever, symptoms, and markers of inflammation in patients who were refractory to treatment with prednisone and MTX.

**Muckle-Wells Syndrome (MWS).**
Approve for 12 months if the patient has tried two other drugs (e.g., rilonoept [Arcalyst™], canakinumab [Ilaris®], colchicine, corticosteroids, chlorambucil, antihistamines, dapsone, azathioprine, mycophenolate mofetil) for MWS. Anakinra has been effective in decreasing plasma concentrations of serum amyloid A protein and decreasing the amyloid-related proteinuria in case reports of patients with MWS and nephrotic syndrome due to AA amyloidosis. Note: MWS, NOMID, and familial cold autoinflammatory syndrome (FCAS) are syndromes attributed to mutations in the gene encoding NALP3 (also known as CIAS-1). Anakinra has been effective in treating the dermatologic and rheumatic manifestations in patients with NALP3-associated periodic fever syndromes and also in resolution of AA amyloidosis-associated nephrotic syndrome. Patients have maintained control of the inflammatory manifestations of MWS while on anakinra for up to almost 5 years without disease progression. Rilonocept and canakinumab are FDA approved for the treatment of MWS and FCAS.

**Familial cold autoinflammatory syndrome (FCAS).**
Approve for 12 months if the patient has tried two other drugs (e.g., colchicine, corticosteroids, antihistamines, azathioprine, mycophenolate mofetil, rilonoept, canakinumab) for FCAS. In 8 family members with FCAS, anakinra 100 mg daily for 4 weeks was effective in resolving the signs and symptoms of FCAS and in decreasing CRP and serum amyloid A protein. The effect was sustained at 4 and 16 months follow-up in the 5 patients who continued with anakinra. Patients have maintained control of the inflammatory manifestations of MWS while on anakinra for up to almost 5 years without disease progression. Rilonocept and canakinumab are FDA approved for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) including MWS and FCAS.

**Schnitzler’s syndrome.**
Approve for 12 months if patient has tried one other prescription medication for Schnitzler’s syndrome. In several individual case reports, anakinra has been effective in producing complete remission of Schnitzler’s syndrome. NSAIDs, antihistamines, colchicine, immunosuppressive drugs, and corticosteroids are not consistently effective in treating this syndrome.

**Acute gout.**
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Approve 3 doses if the patient has acute gout and has tried standard therapies for acute gout (an NSAID, colchicine, and a corticosteroid) or cannot tolerate or has contraindications to standard therapies. In an open-label pilot study, 10 patients with acute gout who had a long history of either recurrent gouty attacks or tophaceous gout were treated with anakinra 100 mg daily for 3 days. All patients had either failed conventional therapy with NSAIDs, colchicine, or corticosteroids for at least 48 hours or had developed significant side effects on these drugs in the past. All patients responded rapidly to anakinra with subjective symptoms of gout being greatly relieved by 48 hours after the first injection.

**Familial Mediterranean fever.**
Approve for 12 months in patients who have tried colchicine. Colchicine is the standard therapy for prophylaxis of attacks and amyloid deposition in this condition and has been the most studied therapy. Anakinra has been effective in case reports where adults and adolescents with familial Mediterranean fever were refractory to or could not tolerate colchicine.

**Tumor necrosis factor receptor-associated periodic syndrome (TRAPS).**
Approve for 12 months in patients who have tried corticosteroids. Limited information is available on the use of anakinra for TRAPS. In 4 children and 1 adult with TRAPS, anakinra 1.5 mg/kg/day was effective in reversing symptoms and normalizing acute phase reactant levels including serum amyloid A. Continuous therapy with anakinra prevented disease relapse. In patients with TRAPS, episodes of fever are responsive to corticosteroids but some patients may require continuous steroids. Etanercept has been effective in some patients with TRAPS but response is variable and may not be sustained. Immunosuppressives are ineffective in reducing the frequency and intensity of the episodes of inflammation and/or preventing the development of amyloidosis in patients with TRAPS.

**Patient has been started on anakinra. (Grandfathered)**
Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications).

**EXCLUSIONS**

Coverage of anakinra is *not* recommended in the following circumstances:

1. **Osteoarthritis, symptomatic.**
   In a phase II study in patients with painful osteoarthritis (OA) of the knee, anakinra 150 mg administered by intra-articular injection was well tolerated. The study was not designed to assess the analgesic efficacy of anakinra since there was no control group. Intra-articular injections are often associated with a significant placebo effect. Patients with OA of the knee were enrolled in a multicenter, double-blind, placebo-controlled study and randomized to anakinra 50 mg, anakinra 150 mg, or placebo for intraarticular injection. Although the injections were well tolerated, there were no significant differences in improvement in knee pain, stiffness, function or cartilage turnover between anakinra doses and placebo. Similar to other studies in this population, there was a significant placebo effect noted.

2. **Lupus arthritis.**
   The effectiveness and safety of anakinra was evaluated in an open 3-month pilot trial in patients (n = 4) with systemic lupus 130ultracentral130y (SLE) and severe, therapy-refractory non-erosive polyarthritis (3 patients had deforming Jaccoud’s arthropathy) and no other uncontrolled major organ involvement. Patients were refractory to NSAIDs, antimalarials, and/or immunosuppressives. Anakinra 100 mg daily for 3 months was well tolerated and resulted in significant improvement in arthritis symptoms, as well as significant decreases in erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and anti-dsDNA antibodies. Anakinra increased the mean number of swollen joints from 2.2 to 1.1 joints and the mean number of tender joints from 10.8 to 7.4 joints. Anakinra also significantly decreased the mean number of new DMARDs started from 1.2 to 0.2 DMARDs.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
corticosteroids, MTX, cyclophosphamide, and azathioprine. SLE was controlled with stable doses of corticosteroids and/or antirheumatic or immunosuppressive agents; pain was managed with NSAIDs and/or other medications. Patients had improved clinically after 4 weeks on anakinra, but after 12 weeks the clinical activity parameters tended to increase again. The results from this study are too preliminary.

(3) **Diabetes mellitus, type 2.**

In a double-blind trial, 70 patients with type 2 diabetes were randomized to 100 mg of anakinra daily or placebo for 13 weeks. The average absolute difference in glycated hemoglobin (HbA1C) levels between baseline and 13 weeks was a decrease from 8.69 to 8.37 with anakinra and an increase from 8.23 to 8.37 with placebo (P = 0.03). On anakinra, 21 of 34 patients had reductions in glycated hemoglobin vs. 10 of 33 on placebo. Patients on anakinra also had improved glycaemia and beta-cell secretory function and reduced markers of systemic inflammation. A second part of the above study (defined a priori) was a 39-week follow-up commencing at the time of withdrawal of anakinra to test the durability of the intervention (anakinra) on beta-cell function, inflammatory markers, insulin requirement and insulin sensitivity. A total of 64 patients completed the 39-week follow-up. The proinsulin/insulin ratio was lower in patients formerly treated with anakinra than in those treated with placebo (difference 0.07; P = 0.011). Inflammatory markers C-reactive protein (CRP) and interleukin-6 (IL-6) were significantly reduced at 39-weeks in patients formerly treated with anakinra compared to placebo. No significant differences were noted in C-peptide, HbA1C, insulin or metformin doses. This study suggests that anakinra may have a possible therapeutic potential in the treatment of type 2 diabetes.

3. **Anakinra should not be given in combination with TNF blocking agents (etanercept, adalimumab, infliximab, certolizumab pegol, and golimumab) or with abatacept, rituximab, or tocilizumab.** Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.

**References**


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
KUVAN (SAPROPTERIN DIHYDROCHLORIDE)

- Hyperphenylalaninemia due to 132ulticenter132y132terin- (BH4-) responsive phenylketonuria, AND
- Tried/failed/intolerance to a phenylalanine restricted diet alone, AND
- Phe levels > 6 mg/dL for ≤ 12 years of age, OR
- Phe levels >15 mg/dL on average for >12 years of age.

Reauthorization continuing therapy:
- Decrease in Phe levels by at least 30% within 60 days of initiation of therapy (indicating response to treatment), OR
- Phe levels maintained below baseline levels, AND
- Dosage not > 20mg/kg/day.

References

LEUKINE (SARGRAMOSTIM)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Cancer patients receiving myelosuppressive chemotherapy.
1. Approve Leukine if prescribed by, or in consultation with, an oncologist or hematologist.
2. Leukine is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
3. ANC must be < 1000 cells/mm³.

NOTE: Approve if undergoing cyclic chemotherapy and ANC not < 1000 cells/mm³.

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
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**LEUPROLIDE (GENERIC)**

- **Endometriosis:**
  - **Request for initial therapy with Lupron for endometriosis** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
    - Provider is gynecologist or obstetrician; **AND**
    - Confirmed diagnosis of endometriosis (via ultrasound, laparoscopy, etc); **AND**
    - Moderate to severe pain secondary to endometriosis; **AND**
    - Inadequate response to at least a three (3) month trial of hormonal therapy (i.e., medroxyprogesterone acetate or oral contraceptives); **OR**
    - Documented contraindication to hormonal therapy;
  - If criteria are met, may approve Lupron 3.75mg monthly (#6 injections) OR Lupron 11.25mg every three (3) months (#2 injections) for a total of six (6) months of therapy.
  - **Request for continuation of therapy with Lupron for endometriosis** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
    - **Prostate cancer:**
      - Tried/failed/intolerance or documented unacceptable for orchiectomy or estrogen, OR
    - **Uterine Leiomyoma (uterine fibroids), OR**
    - **Central precocious puberty, OR**
    - **Dysfunctional or excessive uterine bleeding:**
      - Tried/failed/intolerance to oral contraceptive, OR
    - **Testicular cancer, OR**
    - **Vascular cancer, OR**
    - **Breast Cancer, OR**
    - **Ovarian Cancer, OR**
    - **Premenstrual syndrome**

**References**


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
LINZESS (LINACLOTIDE)

- Diagnosis of Idiopathic Chronic Constipation or Constipation-Predominant Irritable Bowel Syndrome (IBS), AND
- Patient is at least 6 years of age, AND
- Trial and failure of at least ONE (1) agent from TWO (2) of the following classes:
  - Osmotic Laxatives (examples: lactulose, polyethylene glycol (PEG), sorbitol);
  - OR
  - Bulk Forming Laxatives (examples: Metamucil® (psyllium), Citrucel®, fiber);
    OR
  - Stimulant Laxatives (examples: bisacodyl, senna)

Authorization: 6 months

Lodosyn (Carbidopa)

- Diagnosis of Parkinson’s disease or Parkinsonism; AND
- Being used as an adjunct to therapy with Carbidopa/Levodopa; AND
- Documented allergy to Carbidopa (generic of Lodosyn)

References

Lotronex (Alosetron)

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Clinically diagnosed severe diarrhea-predominant irritable bowel syndrome (IBS)
- Adult female
- Only physicians who have enrolled in the Prometheus Prescribing Program for Lotronex should prescribe Lotronex.
- Must have diarrhea and one or more of the following:
  - Frequent and severe abdominal pain/discomfort
  - Frequent bowel urgency or fecal incontinence
  - Disability or restriction of daily activities due to IBS
- IBS symptoms are chronic (generally lasting 6 months or longer)
- Other GI medical conditions that could explain the symptoms have been ruled out
- Failed conventional therapy including:
  - Dietary changes (including fiber), or stress reduction, or behavioral changes
  - Antidiarrheals (ie, loperamide, diphenoxylate and atropine)
  - Antidepressants (ie, desipramine, imipramine)
  - Antispasmodics (ie, dicyclomine, hyoscyamine)

Cautions: Infrequent but serious gastrointestinal adverse reactions have been reported with the use of Lotronex. These events, including ischemic colitis and serious complications of constipation, have resulted in hospitalization and, rarely, blood transfusion, surgery, and death.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
**Contraindications:** Patient has any of the following:

- Constipation
- History of chronic or severe constipation or with a history of sequelae from constipation
- History of intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions
- History of ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state
- Current or history of Crohn’s disease or ulcerative colitis
- Active diverticulitis or a history of diverticulitis
- Unable to understand or comply with the Patient-Physician Agreement
- Known hypersensitivity to any component of the product

**Not approved if:**

- Patient has any contraindications to the use of alosetron.
- Patient does not meet the above-stated criteria. (See dosing and duration notes)

**Duration of therapy:** ONE MONTH. May renew 6 months at a time with clinical notes demonstrating adequate control of IBS symptoms. (see underlined note above).

**References**

1. Virginia Premier

**LUCEMYRA (LOFEXIDINE)**

- Being used in the mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation
- Patient is 18 years of age or older
- Patient has clinical trial and failure or contraindication to therapy with Clonidine
- Max dosing allowed of 3 tablets 4 times daily for 14 days

**LUCENTIS (RANIBIZUMAB)**

- Approved for the following indications:
  - For the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD)
  - For the treatment of patients with Macular Edema Following Retinal Vein Occlusion
  - For the treatment of patients with Diabetic Macular Edema
  - Diabetic Retinopathy in patients with DME
- confirmed by an ophthalmologist
- Reauthorization for 6 months will be made upon receipt of documentation the patient has not lost > 15 letters from baseline visual acuity or final Best Corrected Visual Acuity (BCVA) of <20/400

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
QL: 0.05 mL (of a 10mg/ml or 6mg/ml solution) administered by one (1) intravitreal injection every 28 days.

References:


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

LUNESTA (ESZOPICLONE)

• PA criteria for FDA age indications:
  • Breathing-related sleep disorder; Diagnosis – Polysomnography
  • Generalized anxiety disorder – Insomnia
  • Insomnia
  • Insomnia – Major depressive disorder
  • Insomnia – Menopause
• Patient must have tried and failed:
  • Zolpidem and benzodiazepine or trazodone

References

1. Virginia Premier

LUPRON/DEPOT (LEUPROLIDE ACETATE)

• Endometriosis:
• Request for initial therapy with Lupron for endometriosis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:
  o Provider is gynecologist or obstetrician; AND
  o Confirmed diagnosis of endometriosis (via ultrasound, laparoscopy, etc); AND
  o Moderate to severe pain secondary to endometriosis; AND
  o Inadequate response to at least a three (3) month trial of hormonal therapy (i.e., medroxyprogesterone acetate or oral contraceptives);
    OR
  o Documented contraindication to hormonal therapy;
• If criteria are met, may approve Lupron 3.75mg monthly (#6 injections) OR Lupron 11.25mg every three (3) months (#2 injections) for a total of six (6) months of therapy.
• Request for continuation of therapy with Lupron for endometriosis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:
  o Member still symptomatic with pain after initial six (6) months of therapy; AND
  o Member is taking concurrent norethindrone therapy (unless contraindicated such as in cerebral apoplexy, thrombophlebitis, or thromboembolic disorders retreatment with Lupron is not recommended);

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
If criteria are met, may approve Lupron 3.75mg monthly (#6 injections) OR
Lupron 11.25mg every three (3) months (#2 injections) for a total of six (6)
months of additional therapy (only 1 additional course of 6 months of therapy
allowed).

- Diagnosis of advanced prostate cancer, OR
- Uterine Leiomyoma (uterine fibroids), OR
- Central precocious puberty, OR
- Dysfunctional or excessive uterine bleeding:
  - Tried/failed/intolerance to oral contraceptive, OR
- Testicular cancer, OR
- Vascular cancer, OR
- Breast Cancer, OR
- Ovarian Cancer, OR
- Premenstrual syndrome

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


12. Virginia Premier

MAYZENT (SIPONIMOD)

CRITERIA FOR USE

(Criteria listed is all inclusive unless otherwise noted)

- Patient must have a diagnosis of Multiple Sclerosis AND
- Member must have a relapsing form of MS (relapsing-remitting MS, secondary-progressive MS with relapses) AND
- Prescriber is a physician specializing in Neurology or in consultation with a Neurologist
- Tested for CYP2C9 variants to determine CYP2C9 genotype AND
- Recommended maintenance dosing in patients with CYP2C9*1/*3 or CYP2C9*2/*3 is 1mg AND
- No contraindications of CYP2C9*3/*3 genotype, MI in the last 6 months, unstable angina, stroke or TIA, decompensated heart failure requiring hospitalization, Class III/IV heart failure, Mobitz Type II 2nd/3rd degree AV block, sick sinus syndrome, unless patient has a functioning pacemaker.
- Patient must have a trial and failure of at least two (2) of the following medications; Avonex, Betaseron, Copaxone, Tecfidera

Continuation Criteria

- Patient must continue to meet initial criteria AND
- Prescriber attests to improvement of disease state while on Mayzent therapy

Auth Duration: Initial, 6 months. Continuation, 12 months

MEKINIST (TRAMETINIB; MEK-INHIBITOR)

- Patient must be >= 18 years old; AND
- Prescribed by an Oncologist or Hematologist; AND
- A diagnosis of unresectable or metastatic melanoma; AND
- BRAF mutation V600E or V600K; AND
- Confirmation of mutation by FDA-approved test, AND
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0 – 1; AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
- Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- Completely disabled: cannot carry on any self-care; totally confined to bed or chair
- Baseline LVEF assessed prior to initiation of therapy and within acceptable limits; AND
- Performed ophthalmic evaluation; AND
- No concomitant BRAF-inhibitor or ipilimumab therapy.

References
1 Virginia Premier

**MEPSEVII (VESTRONIDASE ALFA)**

**INITIAL THERAPY:**

- Diagnosis of Mucopolysaccharidosis VII confirmed by leukocyte or fibroblast glucuronidase enzyme assay or genetic testing; **AND**
- Patient has elevated uGAG excretion at a minimum of 3-fold over the mean normal for age

**RENEWAL THERAPY**

- Continue to meet the initial therapy criteria; **AND**
- Medical record documentation of improvement from baseline while on therapy

**COVERAGE DURATION**

- Initial- 12 months
- Renewal – 12 months

**METHADONE**

**CRITERIA FOR USE:**

- Member is an infant discharged from the hospital on a methadone taper (under 1 year of age) **OR**
- Member has a diagnosis of one of the following:
  - Metastatic Neoplasia
  - Sickle Cell
  - Chronic Severe Pain, **AND**
- Member is not currently taking any of the following:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
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- Single entity immediate release or extended release opioids,
- Benzodiazepines,
- Barbiturates
- Carisoprodol
- Meprobamate, **AND**

- Patient does not have a history of (or ever received treatment for) drug dependency or drug abuse, **AND**
- Member has a contraindication to Morphine Sulfate ER tablets and Fentanyl patches (FDA MedWatch form required), **AND**
- Prescriber has checked the state Prescription Monitoring Program (PMP) on the date of this request to determine whether the member is receiving opioid dosages or dangerous combinations (such as opioids and benzodiazepines) that put him or her at high risk for fatal overdoses, **AND**
- Date of last opioid fill must be documented, **AND**
- Date of last benzodiazepine fill must be documented, **AND**
- Member’s total Morphine Milligram Equivalent (MME) must be documented from the state PMP, **AND**
- For MME from 51 to 90/day, prescriber should consider offering a prescription for naloxone and overdose prevention education, OR
- For MME greater than 90 prescriber should consider offering a prescription for naloxone and overdose prevention education plus consider consultation with a pain specialist, **AND**
- Prescriber has counseled patient on risks associated with the combined use of benzodiazepines and opioids, **AND**
- Prescriber attests that a treatment plan with goals that addresses benefits and harm has been established with the patient and the following bullets are included. PLUS there is a signed agreement with the patient:
  - Established expected outcome and improvement in both pain relief and function or just pain relief, as well as limitations (i.e., function may improve yet pain persist OR pain may never be totally eliminated)
  - Established goals for monitoring progress toward patient-centered functional goals; e.g., walking the dog or walking around the block, returning to part-time work, attending family sports or recreational activities, etc.
  - Goals for pain and function, how opioid therapy will be evaluated for effectiveness and the potential need to discontinue if not effective.
  - Emphasize serious adverse effects of opioids (including fatal respiratory depression and opioid use disorder, OR alter the ability to safely operate a vehicle)
  - Emphasize common side effects of opioids (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, withdrawal), **AND**
- A presumptive urine drug screen (UDS) MUST be done at least annually. The UDS must check for the prescribed drug plus a minimum of 10 (ten) substances including heroin, prescription opioids, cocaine, marijuana, benzodiazepines, amphetamines, and metabolites, **AND**
- A copy of the most recent UDS must be attached
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

**MONOVISC (HYALURONIC ACID DERIVATIVE, INTRA-ARTICULAR)**

_Euflexxa is the preferred drugs. Member must have tried/failed Euflexxa first unless contraindicated._

- Osteoarthritis of the knee, AND
- Tried/failed/intolerance to mild analgesic therapy (e.g. acetaminophen) OR tried/failed/intolerance to generic NSAIDs or COX-2 Inhibitors.
- Tried/failed/intolerance to the following:
  - Intra-articular corticosteroid injection (relief <6-8 weeks)
  - Physical therapy, AND
- Must not have large effusions of the knee, AND
- No infections or skin diseases in the knee area, AND
- Trial and failure, intolerance, or contraindication to Euflexxa

**References**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

**MOTEGRITY (PRUCALOPRIDE)**

**CRITERIA FOR USE**

Documentation of the following:

1. Diagnosis of Chronic Idiopathic Constipation
   
   AND

2. Age is 18 years or older;
   
   AND

3. An inadequate response to at least one agent from within EACH of the following laxative types:
   - Fiber laxatives (psyllium, methylcellulose, calcium polycarbophil)
   - Stimulant laxatives (bisacodyl, senna)
   - Osmotic laxatives (Polyethylene glycol, milk of magnesia, sorbitol, lactulose)
   
   AND

4. An inadequate response/intolerance to, Linzess AND Amitiza

**Not Approved if:**

- Does not meet above criteria
- Any contraindication to treatment

**Approval Duration:** 6 months

**MYALEPT (METRELEPTIN)**

**Initial:**

- Patient has a diagnosis of congenital generalized lipodystrophy (i.e. Berardinelli-Seip syndrome), acquired generalized lipodystrophy (i.e. Lawrence Syndrome) or partial lipodystrophy, AND
- Prescriber attests that the patient does not have Anti-retroviral therapy-induced lipodystrophy or drug-induced localized lipodystrophy
- Requested medication is being used as an adjunct to diet, AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Medication is being prescribed by, or in consultation with, an Endocrinologist or Geneticist
• Patient has leptin deficiency confirmed by laboratory testing, AND
• Patient has at least one (1) of the following complications of lipodystrophy:
  o Diabetes mellitus
  o Hypertriglyceridemia
  o Increased fasting insulin levels

Renewal:
• Initial criteria continues to be met, AND
• Prescriber attests that patient has experienced an improvement from baseline in metabolic control (e.g., improved glycemic control, decrease in triglycerides, decrease in hepatic enzyme levels)

Authorization: Initial – 16 weeks, Renewal – 12 months

References:

MYOBLOC (RIMABOTULINUMTOXIN B)
• Cervical dystonia or spasmodic torticollis with documentation of involuntary contractions of the neck muscles resulting in twisting and repetitive movements, and/or abnormal postures, OR
• Excessive salivation (Sialorrhea):
  o tried/failed/intolerance to oral therapy:
    o Glycopyrrolate, OR
• Overactive Bladder:
• Tried/failed/intolerance to oral therapy:
  o Oxybutynin/oxybutynin er, and trospium, AND
  o Propantheline with bladder training,

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NEULASTA (PEGFILGRASTIM)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Cancer patients receiving myelosuppressive chemotherapy.
1. Approve Neulasta if prescribed by, or in consultation with, an oncologist or hematologist.
2. Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
3. **ANC must be < 1000 cells/mm³.**

   NOTE: Approve if undergoing cyclic chemotherapy and ANC not < 1000 cells/mm³.

Other Uses with Supportive Evidence

Harvesting of peripheral blood stem cells, Prior to autologous stem-cell transplantation

   FDA Approval: Adult, no; Pediatric, no
   Efficacy: Adult, Evidence favors efficacy
   Recommendation: Adult, Class Iia
   Strength of Evidence: Adult, Category B

Radiation Injury

Approve pegfilgrastim under the following circumstances:

a. It is prescribed by, or in consultation with, a physician with experience in treating acute radiation syndrome, **AND**

b. The estimated whole body or significant partial-body exposure is at least 3 Grays in adults aged < 60 years; OR at least 2 Grays in children (aged < 12 years) and in adults aged ≥ 60 years OR in those who have major trauma injuries or burns.

The National Stockpile Radiation Working Group published recommendations for the medical management of acute radiation syndrome in 2004. In any adult with a whole body or significant partial body-exposure greater than 3 Grays, treatment with a CSF should be initiated as soon as biodosimetry results suggest that such an exposure has occurred or when clinical signs and symptoms indicate a level 3 or 4 degree of hematotoxicity. People at the extremes of age (children aged < 12 years and adults
aged > 60 years) may be more susceptible to irradiation and therefore, a lower threshold exposure dose (2 Grays) for initiation of CSF therapy is appropriate, as in patients who have major trauma injuries or burns. Some data suggest that use of CSF products after radiation accidents appeared to have a faster neutrophil recovery.

EXCLUSIONS

1. **Patients undergoing peripheral blood progenitor cell (PBPC) mobilization or use after PBPC transplantation.** Studies have investigated use of pegfilgrastim in this patient population. However, the dosing, safety and efficacy are not clearly established and it is not a standard of care for transplant patients.

2. **Myelodysplastic syndrome (MDS).** Only limited data report use of pegfilgrastim for patients with MDS and guidelines from the NCCN for MDS do not discuss use of pegfilgrastim.

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
NEUPOGEN (FILGRASTIM)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Cancer patients receiving myelosuppressive chemotherapy.
1. Approve Neupogen if prescribed by, or in consultation with, an oncologist or hematologist.
2. Neupogen is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
3. **ANC must be < 1000 cells/mm³.**

   **NOTE:** Approve if undergoing cyclic chemotherapy and ANC not < 1000 cells/mm³.

Other FDA Approved Indications include:

- Febrile neutropenia, in non-myeloid malignancies, in patients undergoing myeloablative chemotherapy followed by marrow transplantation; Prophylaxis
- Febrile neutropenia, in non-myeloid malignancies following myelosuppressive chemotherapy; Prophylaxis
- Febrile neutropenia, in patients with acute myeloid leukemia receiving chemotherapy; Prophylaxis
- Harvesting of peripheral blood stem cells

Neutropenic disorder, chronic (Severe), Symptomatic

REFERENCES


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


24. Moore JO, Dodge RK, Amrein PC et al. Granulocyte-colony stimulating factor (filgrastim) accelerates granulocyte recovery after intensive postremission chemotherapy for acute

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval


NEXAVAR (SORAFENIB)

- Prescribed by Oncologist, Hepatologist or Nephrologist, AND
- Hepatocellular carcinoma and the carcinoma is surgically unresectable, OR
- Relapsed/refractory metastatic osteosarcoma, AND
  - The patient has tried and failed or intolerant to cisplatin and doxorubicin, or MAP (high dose methotrexate, cisplatin, and doxorubicin), or high dose methotrexate, doxorubicin, cisplatin, and ifosfamide, or ifosfamide, cisplatin and epirubicin chemotherapy regimen, OR
- Metastatic (advanced) thyroid cancer, AND
  - The patient has tried and failed or intolerant to vandetanib and carbozantinib, OR
- Gastrointestinal Stromal Tumor (GIST) and GIST is unresectable and/or metastatic malignant, AND
  - The patient has tried and failed or intolerant to imatinib and sunitinib OR
- Metastatic (advanced) renal cell carcinoma and the carcinoma is surgically unresectable, AND
  - If the patient is female and of childbearing years, she is NOT pregnant, has NO plans for pregnancy and has been educated on the potential dangers of Nexavar therapy in pregnancy, AND
  - The patient will NOT be treated with interferon alfa (Roferon-A, Pegasys, Intron-A, Peg-Intron) or interleukin-2 (Proleukin) therapy in combination with Nexavar treatment.

Reauthorization/continuing treatment:
- Evidence of clinical improvement from the pretreatment report and/or the patient has stable disease (tumor size within 25% of baseline).

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval


NEXIUM (ESOMEPRAZOLE)

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Must have at least one of the following clinically diagnosed conditions:
  - GERD symptoms and disease
  - Hypersecretory GI disease
  - Duodenal ulcers
  - On high dose steroids or NSAID and have failed therapy with H2antagonists, AND
- Must have tried omeprazole or Pantoprazole for at least 4 weeks and failed.
- Must have tried Lansoprazole for at least 4 weeks and failed.
- Must have tried Nexium OTC for at least 4 weeks and failed.
  - Prescriber must include an adverse event documented on an FDA MEDWATCH form, regardless of continuation of therapy
- Approval duration is for 3 months for GERD. One year for all other diagnoses.

Contraindication:
- Hypersensitivity to a specific proton pump inhibitor.

Not approved if:
- The patient does not meet the above stated criteria
- The patient has any contraindications to the use of proton pump inhibitors

Criteria for use for children for oral packet for oral suspension (bullet points below are all inclusive unless otherwise noted):

The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.

- Must have at least one of the following clinically diagnosed conditions:
  - GERD symptoms and disease
  - Hypersecretory GI disease
  - Duodenal ulcers
  - On high dose steroids or NSAID and have failed therapy with H2antagonists.
- Unable to take a solid oral dosage form

References

Virginia Premier
NON FORMULARY EXCEPTIONS

- Must be used for an FDA approved, or medically accepted off label indication as listed in our official compendia for review
- Must try and fail, be intolerant to, or have a contraindication to two (2) formulary alternatives indicated for treating the same diagnosis. If less than two (2) formulary alternatives are available for treatment, there must be a trial and failure of one (1) formulary alternative
- Certain non-formulary medications are subject to individualized criteria

References

1. Virginia Premier

NORTHERA (DROXIDOPA)

Initial Criteria (Duration of Approval – 3 months)

Documentation of the following:

1. Must be 18 years of age or older; AND
2. Northera® is being prescribed by or in consultation with a cardiologist or neurologist; AND
3. Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH); AND
4. nOH is being caused by one of the following diagnoses:
   a. Primary autonomic failure (i.e., Parkinson’s disease, multiple system atrophy, or pure autonomic failure)
   b. Dopamine beta-hydroxylase deficiency
   c. Non-diabetic autoimmune neuropathy; AND
5. Documentation that at least one of the following non-pharmacologic interventions has been tried but has not been successful:
   a. Discontinuation of drugs that can cause orthostatic hypotension
   b. Raising the head of the bed 10 to 20 degrees
   c. Wearing compression stockings
   d. Performing physical maneuvers to improve venous return
   e. Increasing salt and water intake (if appropriate)
   f. Avoiding factors that may cause symptoms (e.g., overexertion in the hot weather, standing or sitting up too quickly); AND
6. An inadequate response, intolerance, or contraindication to a trial of midodrine AND fludrocortisone

Re-authorization (Duration of approval – 6 months)

Documentation of the following:

1. The neurogenic orthostatic hypotension has stabilized without adverse effects from Northera®

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Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
NUCALA (MEPOLIZUMAB)

1. Being used as add-on maintenance in patients who have severe asthma, with eosinophilic phenotype; AND
2. Patient must be ≥ 12 years of age; AND
3. Medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; AND
4. Patient has a peripheral blood eosinophil count of ≥ 150 cells per microliter within previous 6 weeks (prior to treatment with Nucala) OR Peripheral blood eosinophil level greater than or equal to 300 cells/microliter within the past 12 months; AND
5. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following:
   - Inhaled corticosteroid (e.g. Asmanex, Aerospan, Pulmicort Flexhaler, Qvar)
   - Inhaled long acting beta agonist, OR Leukotriene receptor antagonist (montelukast)
6. Patient’s asthma continues to be uncontrolled as defined by ONE of the following:
   - Patient has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year
   - Patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year
   - Patient has a forced expiratory volume in 1 second (FEV1) <80% predicted
   - Patient has an FEV1/forced vital capacity (FVC) <0.80
   - Patient’s asthma worsens upon tapering or oral corticosteroid therapy

For RENEWAL THERAPY,

1. The patient has responded to Nucala therapy as determined by the prescribing physician (e.g. decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy).

NOT COVERED FOR:

- Atopic Dermatitis
- Chronic Obstructive Pulmonary Disease
- Concurrent use of Nucala with Xolair
- Eosinophilic esophagitis, eosinophilic gastroenteritis, eosinophilic colitis
- Hypereosinophilic Syndrome
- Nasal polyps

Approval Duration: Initial – 6 months, Renewal – 12 months

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

**NUDEXTA (DEXTROMETHORPHAN/QUINIDINE)**
- Diagnosed with pseudobulbar affect

References:
1. Virginia Premier

**NUVIGIL (ARMODAFINIL)**

Criteria for Use: Narcolepsy: (bullet points below are all inclusive unless otherwise noted)
- Clinically diagnosed narcolepsy confirmed via sleep study, AND
- 17 years of age or older

OR

Criteria for Use: SWSD (bullet points below are all inclusive unless otherwise noted)
- Clinically diagnosed shift work sleep disorder.
- Documentation of the patient work shift (defined as working “all night shift”), AND
- 17 years of age or older

OR

Criteria for use: OSA (bullet points below are all inclusive unless otherwise noted)
- Clinically diagnosed obstructive sleep apnea
- Diagnosis confirmed via sleep study or documentation that C-PAP has been maximized, AND
- 17 years of age or older

Approval Duration: 6 months – SWSD, 12 months – OSA, Narcolepsy

References
1. Virginia Premier

**OLEPTRO (TRAZODONE EXTENDED RELEASE)**

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Must have clinically diagnosed major depressive disorder
- Must be 18 years of age or older.
- Failed or intolerant to at least 2 SSRI's.
- Failed or intolerant to at least one SNRI.
- **Must be intolerant to immediate release generic trazodone.**

Contraindication:
- None listed at this time

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Not approved if:
- Does not meet the above stated criteria.
- Being used for convenience purposes only.

References
1. Virginia Premier

**OPIOIDS**

**Required**

4) All long acting opioids
5) Any short-acting opioid prescribed for > 7 days or two (2) 7 day supplies is a 60 day period. The Virginia BOM regulations limit the treatment of acute pain with opioids to 7 days and post-op pain to no more than 14 days
6) Any cumulative opioid prescription exceeding 120 morphine milligram equivalents (MME) per day. Quantity limits apply to each drug

**Long-Acting**

- Prescriber attest that the member has intractable pain associated with active cancer, palliative care (treatment of symptoms associated with life limiting illnesses), or hospice care OR
- Member is in remission from cancer and prescriber is safely weaning member off opioids with a tapering plan OR
- Member is in a long-term care facility OR
- Diagnosis of Acute pain (less than 90 days), Post-operative pain, or Chronic pain AND

- The prescriber MUST check the Prescription Monitoring Program (PMP) on the date of this request to determine whether the patient is receiving opioid dosages or dangerous combinations (such as opioids and benzodiazepines) that put him or her at high risk for fatal overdose

- Prescriber must provide members active daily MME AND
- If member daily MME greater than 120, prescriber must attest that he/she will be managing the members’ opioid therapy long term has reviewed the Virginia BOM Regulations for Opioid Prescribing, has prescribed naloxone, and acknowledges the warnings associated with high dose opioid therapy including fatal overdose, and that therapy is medically necessary for this member AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Provider must provide **last fill** date from PMP for opioid and benzodiazepine prescription AND
- If benzodiazepine filled within the last 30 days, prescriber must attest that he/she has counseled the member on the FDA black box warning on the dangers of prescribing Opioids and Benzodiazepines including fatal overdose, has documented that the therapy is medically necessary, and has recorded a tapering plan to achieve the lowest possible effective doses of both opioids and benzodiazepines per the Board of Medicine Opioid Prescribing Regulations.
- If member is a female between the ages of 18-45 prescriber must attest to discussing the risk of neonatal abstinence syndrome and provided counseling on contraceptive options.
- For Chronic Pain the prescriber must order a UDS or serum medication level PRIOR to initiating treatment with short and/or long acting opioids.

**Renewal**

- Prescriber must order and review UDS or serum medication level every three (3) months for the first year of treatment and every six (6) months thereafter to ensure medication adherence.

**Short Acting**

- The prescriber MUST check the Prescription Monitoring Program (PMP) on the date of this request to determine whether the patient is receiving opioid dosages or dangerous combinations (such as opioids and benzodiazepines) that put him or her at high risk for fatal overdose.

- Prescriber must provide members active daily MME AND
- If member daily MME greater than 120, prescriber must attest that he/she will be managing the members’ opioid therapy long term has reviewed the Virginia BOM Regulations for Opioid Prescribing, has prescribed naloxone, and acknowledges the warnings associated with high dose opioid therapy including fatal overdose, and that therapy is medically necessary for this member AND
- Provider must provide **last fill** date from PMP for opioid and benzodiazepine prescription AND
- If benzodiazepine filled within the last 30 days, prescriber must attest that he/she has counseled the member on the FDA black box warning on the dangers of prescribing Opioids and Benzodiazepines including fatal overdose, has documented that the therapy is medically necessary, and has recorded a tapering plan to achieve the lowest possible effective doses of both opioids and benzodiazepines per the Board of Medicine Opioid Prescribing Regulations.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Consideration only

- If the patient exhibits any of the following signs of opioid use disorder, please consider referring the patient to a substance use disorder treatment program
  - History of addiction to the requested drug
  - Frequent request for odd quantities
  - Requests for short term or PRN use of long-acting narcotics
  - Frequent requests for early refills
  - Frequent reports of lost or stolen tablets
  - Receiving opioids from more than one prescriber

- Sample Physician/Patient Agreement:
  https://www.drugabuse.gov/sites/default/files/files/SamplePatientAgreementFor ms.pdf

- Tapering Guidelines for Opioids and Benzodiazepines:

**OPSUMIT (MACITENTAN)**

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Clinically diagnosed with pulmonary arterial hypertension WHO Group 1, patients with NYHA class II-IV
  - The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- Prescribed by a pulmonologist or cardiologist
- Patient is not smoking cigarettes
- Must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test.
- Must have tried and failed sildenafil
- Must have tried and failed either bosentan or ambrisentan
- Requested dose does not exceed 10mg per day (QL of 30/30)
- Patient is not pregnant (if female of childbearing age)

Criteria for continuation of therapy:

- Patient responding to treatment without disease progression

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

- Patient tolerating treatment
- Prescriber is monitoring for anemia, Hepatoxicity
- Patient is not pregnant (if female of childbearing age)

References:

ORACEA (DOXYCYCLINE) DELAYED-RELEASE

PA criteria for FDA age indications. Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
- Clinically documented inflammatory lesions (papules and pustules) of rosacea
- Must be 18 years of age or older.
- Failed topical treatments. (rosacea)
- Must have tried immediate release doxycycline and intolerant to excipients in the immediate release doxycycline

Approve for only 16 weeks max.

References
1. Virginia Premier

ORALAIR

The following criteria must be met for approval of Oralair coverage:
- the member is 5 years of age or older for Oralair,
- the medication is prescribed by an allergist, immunologist, or ENT (ear, nose, throat) specialist – AND –
- Oralair therapy is initiated 4 months prior to the expected onset of the grass pollen season.
- the diagnosis of grass pollen-induced allergic rhinitis is confirmed by either a positive skin test response to a grass pollen from the Pooideae subfamily of grasses (this includes, but is not limited to sweet vernal, Kentucky blue grass, Timothy grass, orchard, or perennial rye grass) OR positive in vitro test (blood test for allergen-specific IgE antibodies) for a grass in the Pooideae subfamily of grasses.
- the member is NOT currently receiving subcutaneous allergen immunotherapy.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval is needed. When approved, members may obtain 30 sublingual Oralair tablets per 30 days. Oralair must be obtained through Caremark specialty pharmacy. Members ages 10-17 will be given coverage for the initial titrating doses as well.

**References:**

**ORAL CONTRACEPTIVES (BEYAZ, GENERESS FE, LO LOESTRIN FE, MINASTRIN 24 FE, ORTHO TRI-CYCLEN LO)**

- Must have medically accepted indication; AND
- An inadequate response, intolerance, or contraindication to TWO OF THE FOLLOWING:
  - GILDESS FE 1/20, JUNEL 1/20, JUNEL FE 1.5/30, JUNEL FE 1/20, LOW-OGESTREL, MICROGESTIN FE, SPRINTEC, or TRI-SPRINTEC.

**ORAL HYPOGLYCEMICS (JANUMET, JANUVIA, TRADJENTA, JENTADUETO)**

- For newly diagnosed type 2 diabetics only (no GII 27* in past 180 days)
- Diagnosed with Type 2 diabetes
- Hemoglobin A1c <9% requires a trial and failure of Metformin
  - Hemoglobin A1c >9% does not require trial and failure of metformin, patients should be started on metformin (unless contraindicated) plus a second agent (e.g., DPP-IV, SGLT2, GLP-1 receptor agonists, TZDs, sulfonylureas).

**ORENCIA (ABATACEPT)**

Criteria for use: (bullet points below are all inclusive unless otherwise noted)
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Prescribed by a rheumatologist
- Must have a negative tuberculosis test or received treatment if tested positive.
- Must have clinically diagnosed adult RA or juvenile RA.

Criteria for adult RA:
- Intolerant or inadequate response after 3 months of treatment to methotrexate

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Intolerant or inadequate response after 3 months of treatment to etanercept (Enbrel) and adalimumab (Humira)
• Intolerant or inadequate response after 3 months of treatment to Remicade

Criteria for juvenile RA:
• Intolerant or inadequate response after 3 months of treatment to methotrexate
• Intolerant or inadequate response after 3 months of treatment to etanercept (Enbrel) and adalimumab (Humira)

Criteria for continuation of therapy:
• Documentation that there is disease stability or improvement.

Cautions:
• Patients should not receive live vaccines while they are being treated or for 3 months afterwards.
  Patients with COPD had more respiratory adverse effects compared to placebo.
• Higher incidence of infections

Contraindications:
• History of hypersensitivity to any of the product ingredients.

Not approved if:
• Being used concurrently with TNF antagonists or anakinra.
• Does not meet the above stated criteria
• Has any contraindications to the use of Orencia
• Positive tuberculosis test and not being treated.

Special considerations:
• For adult RA, may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.
• For juvenile RA, may be used as monotherapy or concomitantly with methotrexate.
• Linked to a spike in serious infections—particularly when used in combination with other biologics TNF antagonists.
• It appears effective in patients failing to respond to MTX, Enbrel, or Remicade when used in combination with MTX or other nonbiological DMARD therapy.
• Additional clinical efficacy and adverse effect information is necessary to identify the best place for abatacept in the treatment of RA.

References

1. Virginia Premier
ORENITRAM (TREPROSTINIL)

Criteria for use (bullet points below are ALL inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- Prescribed by pulmonologist or cardiologist
- Patient is not using any tobacco products
- Clinically diagnosed with pulmonary arterial hypertension WHO Group I
- Patient has WHO Functional Class II or III symptoms
- Must have tried and failed a calcium channel blocker if the patient has had a positive vasoreactivity test
- Must have tried and failed sildenafil
- Must have tried and failed either bosentan (Tracleer) or ambrisentan (Letairis)
- Must have baseline 6 minute walking distance
- QL of 60/30

Criteria for continuation of therapy

- Patient is tolerating treatment
- By 12 weeks, the patient has shown an increase in exercise ability, demonstrated by a 10% improvement in 6 minute walking distance

Not approved if:

- Does not meet above criteria
- Any contraindication to treatment
- Orenitram is being used in combination with other vasodilators

Approval Duration:

- Initial: 3 months
- Renewal: 1 year

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

**ORILISSA (ELAGOLIX)**

**CRITERIA FOR USE**

- Patient must have a diagnosis of moderate to severe pain associated with endometriosis AND
- Medication is prescribed by or in consultation with an Obstetrics/Gynecologist or Reproductive Endocrinologist AND
- Patient must have had a trial and failure/contraindication to two of the following; Combination oral contraceptive (estrogen/progesterone), Danazol, Progestins, Two (2) analgesics AND
- Treatment duration of Orilissa cannot have exceeded 24 months

Auth Duration: 12 months

**ORKAMBI (LUMACAFTOR/IVACAFTOR)**

**Initial Therapy:**

1. Must be ≥ 2 years of age AND
2. Must have diagnosis of cystic fibrosis (CF) with *documented* homozygous F508del mutation confirmed by FDA-approved CF mutation test. (Submission of laboratory results confirming that patient is homozygous for the F508del mutation in the CFTR gene.) AND
3. Must be prescribed by, or in conjunction with, a pulmonologist or is from a CF center accredited by the Cystic Fibrosis Foundation AND
4. Baseline FEV1 ≥ 40% AND
5. Baseline liver function tests (ALT/AST and bilirubin) provided

**Authorization will be issued for 6 months.**

**Continuation of therapy (12 months):**

1. Provider attests that the patient has achieved a clinically meaningful response while on Orkambi therapy to one of the following:
   a. Lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
   b. Body mass index (BMI)
   c. Pulmonary exacerbations
   d. Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
2. Adherence to therapy is confirmed (supported by documentation from patient’s chart notes or electronic claim history)
   **AND**

3. Liver function tests (ALT/AST and bilirubin) provided with each renewal during first year of treatment and annually thereafter
   **AND**

4. ALT or AST does not exceed 5 times the upper limit of normal
   **AND**

5. ALT or AST does not exceed 3 times upper limit of normal with bilirubin greater than 2 times upper limit of normal
**Authorization will be issued for 12 months for renewal of therapy.**

**References**


**ORTHOVISC (HYALURONIC ACID DERIVATIVES, INTRA-ARTICULAR)**

*Euflexxa is the preferred drugs. Member must have tried/failed Euflexxa first unless contraindicated.*

- Osteoarthritis of the knee, **AND**
- Tried/failed/intolerance to mild analgesic therapy (e.g. acetaminophen) OR tried/failed/intolerance to generic NSAIDs or COX-2 Inhibitors.
- Tried/failed/intolerance to the following:
  - Intra-articular corticosteroid injection (relief <6-8 weeks)
  - Physical therapy, **AND**
- Must not have large effusions of the knee, **AND**
- No infections or skin diseases in the knee area, **AND**
- Trial and failure, intolerance, or contraindication to Euflexxa

**References**


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


OTREXUP (METHOTREXATE)

- Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- Clinically diagnosed with one of the following:
  - Severe, active rheumatoid arthritis or polyarticular juvenile idiopathic arthritis, who are intolerant of or had an inadequate response to first-line therapy
  - Severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Trial and failure of oral methotrexate
- Trial and failure of methotrexate given intravenously or intramuscularly
- Requested dose must be 10mg, 15mg, 20mg, or 25mg subcutaneously once weekly*
- Caution:
  - Organ system toxicity: Potential for serious toxicity. Only for use by physicians experienced in antimetabolite therapy
  - Embryo-fetal toxicity: Exclude pregnancy before treatment. Avoid pregnancy if either partner is receiving Otrexup. Advise males to avoid pregnancy for a minimum of three months after therapy and females to avoid pregnancy for at least one ovulatory cycle after therapy
  - Risks from improper dosing: Mistaken daily use has led to fatal toxicity
  - Patients with impaired renal function, ascites, or pleural effusions: Elimination is reduced
- Dizziness and fatigue: May impair ability to drive or operate machinery
- Monitoring:
  - Effects on reproduction: May cause impairment of fertility, oligospermia and menstrual dysfunction
  - Laboratory tests: Monitor complete blood counts, renal function and liver function tests
- Contraindication:
  - Pregnancy; Avoid pregnancy if either partner is receiving Otrexup. Advise males to avoid pregnancy for a minimum of three months after therapy and females to avoid pregnancy for at least one ovulatory cycle after therapy
  - Nursing mothers
  - Alcoholism or liver disease
  - Immunodeficiency syndromes
  - Preexisting blood dyscrasias
  - Hypersensitivity to methotrexate

- Not approved if:
  - Does not meet above criteria
  - Has any contraindications to treatment
  - Being used for the treatment of neoplastic diseases
- Special considerations:
  - *Another formulation of methotrexate should be used for patients requiring doses less than 10mg per week, doses above 25mg per week, high-dose regimens, or dose adjustments of less than 5mg increments
  - Systemic exposure of methotrexate was found to be similar between Otrexup and intramuscular or subcutaneous administration of methotrexate injection at the same doses
  - Systemic exposure of methotrexate from Otrexup at doses of 10, 15, 20, and 25mg was higher than that of oral methotrexate by 17, 13, 31, and 36%, respectively.
OXANDRIN (OXANDROLONE)

PA criteria for FDA age indications;
Adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who, without definite pathophysiologic reasons, fail to gain or to maintain normal weight; to offset protein catabolism with prolonged corticosteroid administration; relief of bone pain associated with osteoporosis. Criteria for Use: (bullet points below are all inclusive unless otherwise noted)

- Must have one of the following diagnosis:
  - Used as an adjunctive therapy to promote weight gain following:
    - Extensive Surgery
    - Chronic Infection
    - Severe Trauma

Or

- Therapy to offset protein catabolism associated with long-term use of corticosteroids

Or

- Treatment of bone pain associated with osteoporosis

Contraindications:

- Known or suspected carcinoma of the prostate or the male breast.
- Carcinoma of the breast in females with hypercalcemia (anabolic steroids stimulate osteolytic bone resorption).
- Pregnancy (Pregnancy Category X)
- Hypersensitivity to the drug
- Nephrosis
- Hypercalcemia

References

1. Virginia Premier

PAMIDRONATE (GENERIC AREDIA)

- Hypercalcemia and patient's hypercalcemia must be associated with malignancy or tamoxifen-induced tumor flare and lab reports verify high calcium levels, OR
- Osteolytic metastases and the patient is also diagnosed with multiple myeloma, OR
- Paget's disease and disease is moderate to severe and lab reports verify high alkaline phosphatase and normal calcium levels, OR
- Complex regional pain syndrome, type I, OR
- Prophylaxis for drug-induced osteoporosis-Gonad regulating hormone adverse reaction, OR
- Prophylaxis of total hip replacement osteopenia, OR
- Quadriplegic cerebral palsy osteopenia, OR
- Osteoporosis due to corticosteroids, AND
- Tried/failed/intolerance to alendronate, OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Postmenopausal osteoporosis, AND
  o Tried/failed/intolerance to alendronate

References


PDE-5 INHIBITORS (SILDENAFIL/ADCIRCA)
• Diagnosis of pulmonary artery hypertension, AND
• Prescribed by pulmonary specialist or cardiologist, AND
• 18 years of age or older for Adcirca

PREVACID ODT (LANSOPRAZOLE ODT)
The following are all inclusive unless otherwise noted
• If member is 10 years of age or less – APPROVE, OR
• >10 years of age, AND
• Symptomatic GERD, OR
• Esophageal-Schatzki’s ring, OR
• Erosive Esophagitis (EE), OR
• Esophageal Stricture, OR
• Extra-esophageal: vocal cord damage/nodules, asthma, laryngitis and pharyngitis, OR
• Barrett’s Esophagus, OR
• Laryngopharyngeal reflux, OR
• Zollinger-Ellison Syndrome, OR
• Gastric Ulcer (GU), OR
• Duodenal Ulcer, OR
• H. Pylori, OR
• High risk-individuals on NSAIDs with one of the following
  • History of complicated Peptic Ulcer Disease (PUD), OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Age > 60 years, OR
• Concurrent anticoagulant, platelet inhibitors (warfarin, aspirin, clopidogrel) or oral corticosteroid (e.g. prednisone) therapy, AND
  • Must have clinical documentation of a swallowing disorder
  • Tried/failed/intolerance to a minimum of 4 week trial of Lansoprazole capsules opened and mixed in applesauce/applejuice.

Exclusion

Prevacid ODT/Lansoprazole ODT will not be covered in patients with any of the following exclusion criteria:

1. The patient has recent paid claims (Within past 3 months) for tablets/capsules
2. Any contraindication to therapy

References

1. Virginia Premier

PREVYMIS (LETERMOVIR)

• Must be used for prophylaxis of cytomegalovirus infection and disease
• Must have a documented seropositivity for Cytomegalovirus; AND
• Patient must have received an allogeneic hematopoietic stem cell transplant (HSCT) within the last 28 days (provider must provide transplant date); AND
• Prescribed by, or in consultation with, a hematologist/oncologist or infectious disease specialist;

COVERAGE DURATION

• Up to day 100 post-transplant

EXCLUSION CRITERIA

• Co-administration with pimozide or ergot alkaloids
• Co-administration with pitavastatin and simvastatin when co-administered with cyclosporine

PROCYSBI (CYSTEAMINE BITARTRATE)

Criteria for use (bullet points below are all inclusive unless otherwise noted):

• The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• The patient is six years of age or older and Must have a documented diagnosis of nephrotic cystinosis by a nephrologist or genetic specialist.
• Target WBC cysteine levels must be monitored
• End organ damage must be monitored
• Must be able to be taken on an empty stomach (30 minutes before eating or 2.5 hours after eating)
• Must be unable or intolerant to take cysteamine immediate release tablets 4 times a day or has a contraindication to the immediate release formulation of cysteamine bitartrate such as Cystagon.

Criteria for continuation of therapy:
• Patient is tolerating and responding to medication and there continues to be a medical need for the medication
• WBC cysteine levels must be kept <1nmol half cysteine/mg protein

Contraindication:
• If the WBC cysteine level is >1nmol half cysteine/mg protein and the plasma cysteamine is >0.1mg/L must confirm that patient is adherent and conforming to food administration restrictions
• If patient is adherent must look at relationship of eating and dosing
• WBC cysteine levels every month for 3 months then every 3 months for 1 year, the twice a year after that

Not approved if:
• Have any contraindications to the use of
• Does not meet the above stated criteria.

References
1. Virginia Premier

PRODIGY VOICE KIT METER AND TEST STRIPS
• Clinically diagnosed with Diabetes Mellitus
• Must have clinical need for a speaking meter and corresponding test strips (i.e. patient is blind)
• Quantity limit of 100 strips in 30 days

References
1. Virginia Premier

PROLIA (DENOSUMAB)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient's medical records.

FDA-approved uses:
- Postmenopausal women who require treatment of osteoporosis and are at high risk for fracture. (According to the WHO diagnostic classification, osteoporosis is defined by BMD at the hip or spine that is less than or equal to 2.5 standard deviations below the young normal mean reference population. (1 SD = 10-15% of the BMD value in g/cm2.)

  1. Failed at least 2 bisphosphonates or intolerant to at least 1 bisphosphonate. AND
  2. Contraindication to ORAL bisphosphonate use. OR

  OR

- Men receiving androgen deprivation therapy for nonmetastatic prostate cancer:
  1. ECOG ≤ 2
  2. One of the following:
      - T score at the lumbar spine, total hip, or femoral neck of less than -1.0
      - 70 years or older
      - History of osteoporotic fracture

OR

- Women receiving adjuvant aromatase inhibitor therapy for nonmetastatic breast cancer, AND
- T score at the lumbar spine, total hip, or femoral neck of less than -1.0

Cautions:
- Denosumab has the potential to cause the same serious side effects like the bisphosphonates, such as osteonecrosis of the jaw.

Contraindications:
- Uncorrected pre-existing hypocalcemia.

Not approved if:
- Does not meet the above stated criteria.
- Have any contraindications to the use of Prolia.

Approval Duration of therapy: Indefinite

Special Considerations:
- Medical Benefit. Must be administered by a healthcare professional.
- Patient should be advised to take 1000mg daily of Calcium and at least 400IU of vitamin D daily.
- Denosumab appears to prevent fractures in postmenopausal women at a similar rate to bisphosphonates but there have not been any head to head comparisons.
- Used for treatment…not prevention.
- Osteoporosis is characterized by low bone mass, deterioration of bone tissue and disruption of bone architecture, compromised bone strength and an increase in the risk of fracture.
- Risk factors included in the WHO fracture risk assessment model
  - Current age
  - Gender

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
- A prior osteoporotic fracture
- Femoral neck BMD
- Low body mass index
- Oral glucocorticoids > 5 mg/d of prednisone for > 3 mo (ever)
- Rheumatoid arthritis
- Secondary osteoporosis
- Parental history of hip fracture
- Current smoking
- Alcohol intake (3 or more drinks/d)

Other risk factors include:
- Lifestyle factors
- Genetic factors
- Hypogonadal states
- Endocrine disorders
- Gastrointestinal disorders
- Hematologic disorders
- Rheumatic and autoimmune diseases
- Medications

Available dosage forms: Single use prefilled syringe and a single use vial containing 1 ml of 60 mg/ml solution.

Usual dose: 60 mg subcutaneously administered by a healthcare professional once every 6 months.

References
- Virginia Premier

**PROMACTA (ELTROMBOPAG)**

- >1 year of age, AND
- Chronic Immune (idiopathic) thrombocytopenic purpura (ITP), AND
- Pretreatment platelet count < 30,000/mm³ (30 x 10⁹/L or 30,000/ml) or a platelet count < 50,000/mm³ (50 x 10⁹/L or 50,000/ml) with significant mucous membrane bleeding or risk factors for bleeding, AND
- Tried/failed/intolerance to corticosteroids, immunoglobulins (IVIG, IgIV, or anti-Rh(D)), or splenectomy, OR
- Thrombocytopenia secondary to cirrhosis of the liver due to hepatitis C.
- Maximum daily dosage of 100 mg/day

Reauthorization/continuing treatment:
- Platelet count of at least 50,000/mm³ (after 4 weeks at a maximum dose of 75 mg/day), OR
- Increase in platelet count over baseline to a level sufficient to avoid clinically important bleeding.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

References


PROVIGIL (MODAFINIL)

Criteria for Use: Narcolepsy: (bullet points below are all inclusive unless otherwise noted)
- Clinically diagnosed narcolepsy confirmed via sleep study, AND
- 16 years of age or older

OR

Criteria for Use: SWSD (bullet points below are all inclusive unless otherwise noted)
- Clinically diagnosed shift work sleep disorder.
- Documentation of the patient work shift (defined as working “all night shift”), AND
- 16 years of age or older

OR

Criteria for use: OSA (bullet points below are all inclusive unless otherwise noted)
- Clinically diagnosed obstructive sleep apnea
- Diagnosis confirmed via sleep study or documentation that C-PAP has been maximized, AND
- 16 years of age or older

OR

Criteria for use: Chronic Fatigue Secondary to Multiple Sclerosis
- Clinically diagnosed Chronic Fatigue Secondary to Multiple Sclerosis
- Patient is 16 years of age or older

Approval Duration: 6 months – SWSD, 12 months – ALL OTHER CONDITIONS LISTED

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
QUDEXY ER (TOPIRAMATE ER)

- The patient has a diagnosis of:
  - Adjunct treatment for Lennox-Gastaut syndrome, OR
  - Migraine prophylaxis, OR
  - Partial seizure, OR
  - Tonic-clonic seizure, OR
  - Tried/failed/intolerance to topiramate IR and topiramate ER; AND
  - Must have a documented inadequate response, intolerance, or contraindication to topiramate IR and topiramate ER by chart notes.
  - If the member has been stabilized on the medication, the provider must submit a form or chart notes, or the patient has claims history for the medication within the previous 90 days.

RABEPRAZOLE

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- Must have at least one of the following clinically diagnosed conditions:
  - GERD symptoms and disease
  - Hypersecretory GI disease
  - Duodenal ulcers or on high dose steroids or NSAID and have failed therapy with \( \text{H2} \) antagonists, AND
- Must have tried either prescription or over the counter omeprazole for at least 4 weeks and failed, including maximum dose titration, AND
- Must have tried either over the counter Prevacid24 OTC or Omeprazole-Bicarbonate (2nd step in step therapy) OTC for at least 4 weeks and failed.

- Approval duration is for 3 months for GERD. One year for all other diagnosis.

Contraindication:
- Hypersensitivity to a specific proton pump inhibitor.

Not approved if:
- The patient does not meet the above stated criteria
- The patient has any contraindications to the use of proton pump inhibitors

References

1. Virginia Premier

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
RAGWITEK

The following criteria must be met for approval of Ragwitek coverage:

- the member is 18 years of age or older
- the medication is prescribed by an allergist, immunologist, or ENT (ear, nose, throat) specialist, or the prescriber is from BLAND COUNTY MEDICAL CLINIC
- Ragwitek therapy is initiated 12 weeks prior to the expected onset of the short ragweed pollen season
- the diagnosis of short ragweed pollen-induced allergic rhinitis is confirmed by either a positive skin test response to short ragweed pollen OR positive in vitro test for short ragweed pollen (blood test for allergen-specific IgE antibodies)
- the member is NOT currently receiving subcutaneous allergen immunotherapy.

When approved, members may obtain 30 Ragwitek sublingual tablets per 30 days.

References

1. Virginia Premier

REBETOL (RIBAVIRIN)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Coverage of ribavirin is recommended in those who meet the following criteria:

FDA-Approved Indication

1. Treatment of hepatitis C in combination with peginterferon alfa-2b, interferon alpha-2a or interferon alfa-2b. Should not be used as monotherapy for this indication (only approved when used in combination with other FDA approved products). Patients should be clinically

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

1. Diagnosed hepatitis C with detectable HCV RNA levels. Patients have not been previously treated with interferon alpha. Must be used in combination with peginterferon alfa-2a or interferon alpha-2b. Liver biopsy, unless contraindicated, shows fibrosis and inflammatory necrosis.

2. Pediatric use of Rebetol capsules and solution. For use in children clinically diagnosed with hepatitis C with compensated liver disease previously untreated with alpha interferon; relapsed following alpha interferon therapy. Must be used in combination with interferon alfa-2b for injection. Must be 5 years of age or older for capsule use or 3 years of age or older for solution use.

**LAB REQUIREMENT:**

1. Bilirubin \( \leq 2 \text{ mg/dL} \)
2. Albumin Stable and within normal limits
3. Prothrombin Time < 3 seconds prolonged
4. WBC \( \geq 3000/\text{mm}^3 \)
5. Platelets \( \geq 70,000/\text{mm}^3 \)
6. Serum creatinine should be normal or near normal.
7. HCV RNA
8. genotype
9. Early Virological Response (EVR)
10. Liver Function Tests

**EXCLUSIONS**

Do *not* approve coverage of peginterferon, ribavirin, Intron A, interferon alfacon, Incivek, and Victrelis for the treatment of Hepatitis C in the following instances:

1. When the above criteria have not been met.
2. Members < 3 years of age for peginterferon
3. When known contraindications to interferon or ribavirin therapy are documented
4. Members < 18 years of age for Victrelis® and Incivek®
5. Members who have failed previous therapy with Victrelis® or Incivek®-based regimens
6. Hypersensitivity to interferon alpha or any other component of the product
7. Decompensated liver disease

Coverage of ribavirin is not recommended in the following circumstances:

1. Hypersensitivity to ribavirin or any components of the tablet.
2. Women who are pregnant.
3. Men whose female partners are pregnant.
4. Patients with hemoglobinopathies.
5. Patients with a history of significant or unstable cardiac disease.
6. Creatinine clearance < 50ml/min.
7. Coverage is not recommended

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**RECLAST (Zoledronic Acid)**

- History of osteoporotic fracture or low trauma fracture, OR
- Osteoporosis, with BMD T-score: < -2.5 SD from the mean, OR
- BMD T-score between: -1 and -2.5 SD with the presence of one or more of the following:
  - Age > 50 years old
  - Postmenopausal status in women
  - Hypogonadal status in men
  - Currently taking certain medications that can decrease BMD:
    - Glucocorticoids (equivalent of >5mg/day of prednisone for > 3 months), cyclosporine, chemotherapy, anticonvulsants, aluminum salts, gonadotropin-releasing hormone agonists, heparin, lithium, high doses of thyroxine
  - Concurrent disease state that increases the risk of osteoporosis:
    - Hypogonadal diseases, endocrine disorders, nutritional and gastrointestinal disorders, rheumatic disorders, hematologic/oncologic disorders, organ transplantation, selected inherited disorders, chronic obstructive pulmonary disease, pregnancy and lactation, scoliosis, multiple sclerosis, sarcoidosis, amyloidosis, acromegaly, diabetes mellitus type 1, chronic liver disease, or states of immobilization.
- Other risk factors:
  - Vitamin D or calcium deficiency, alcohol intake (3 or more drinks per day), parental history of hip fracture, small frame or stature, early menopause, and low body mass index (BMI in kg/m²; BMI for healthy weight is between 18.5 to 24.9 kg/m², current smoking.
- Tried/failed/intolerance to alendronate, OR
- Paget's disease of bone with elevations in serum alkaline phosphatase (ALP) of ≥2 x ULN of the age-specific normal reference range with:
  - Symptomatic disease (bone pain, hearing loss, bone deformities, fractures, arthritis), AND
  - At risk of complications from Paget's disease (e.g., osteoarthritis, heart failure, kidney stones, broken bones), AND
  - Concomitant treatment with calcium and vitamin D, AND
  - Tried/failed/intolerance to alendronate and pamidronate, and generic zolendronic acid, OR
  - Hypercalcemia of malignancy
    - Bone metastasis - Solid tumor configuration
    - Multiple myeloma
    - Osteopenia, Secondary to androgen-deprivation therapy in prostate cancer patients; Prophylaxis

**References**


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

RECTIV (NITROGLYCERIN)

APPROVAL DURATION: 21 days

APPROVAL CRITERIA
Criteria for use (bullet points below are all inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Must be clinically diagnosed with chronic anal fissures and have moderate to severe pain associated with it.
- Must have tried and failed the compounded version of topical nitroglycerin.

Contraindication:

- Use of PDE5 inhibitors as these are shown to potentiate the hypotensive effects of organic nitrates.
- Severe anemia.
- Increased intracranial pressure
- Known hypersensitivity to nitroglycerin, other nitrates, or any components of the ointment.

Not approved if:

- Does not meet the above stated criteria.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Have any contraindications to the use of Rectiv.

Special considerations:
• 0.4% w/w (4mg/1g). 1 inch of ointment = 375mg of ointment= 1.5mg of nitroglycerin.

1 tube should last up to 40 days.

**REGRANEX (BECAPLERMIN)**
• Diabetic neuropathic ulcer must be on lower extremity with adequate blood, AND
• Full-thickness ulcer (i.e., Stage III or IV), extending through dermis into subcutaneous tissues, AND
• Wound is free from infection, AND
• Prescriber confirms to provide wound follow-up care, including debridement if needed.

**References**

**RELISTOR (METHYLNALTREXONE)**
• Diagnosed with an advanced illness (e.g., incurable cancer, end-stage life threatening disease) requiring palliative treatment with opioids (diagnosis and specific opiate therapy must be documented); OR
• Diagnosed with Chronic Non-Cancer Pain; AND
• Patient has been taking an opioid analgesic for at least 4 weeks immediately prior to request (evidence by pharmacy claims); AND
• An indication of opioid induced constipation; AND
• An inadequate response or intolerance to a trial of at least one osmotic laxative (e.g., polyethylene glycol, lactulose, sorbitol, glycerine).
• Quantity limits 2 vials/day and 8 kits/28 days and 90 tablets/30 days

**References**
1. Virginia Premier

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
REMUDULIN (TREPROSTINIL)

- Patient has clinically diagnosed primary or secondary pulmonary arterial hypertension
  - (defined as a mean pulmonary arterial pressure >25mm Hg at rest or >30mm Hg during exercise, with a normal pulmonary capillary wedge pressure)
- Patient exhibits Class II-IV symptoms; AND
- Patient has had an intolerance to, or treatment failure of a calcium channel blocker after favorable response to acute vasoreactivity testing; OR
- Failure to have a pulmonary vasodilator response to an acute challenge of a short acting vasodilator; AND
- Intolerance to, contraindication*, or treatment failure to bosentan
  - Contraindications to bosentan include: pregnancy, LFT abnormalities, coadministration with either cyclosporine or glyburide
- New York Heart Association functional classification:
  - Class 1: No symptoms with ordinary physical activity.
  - Class 2: Symptoms with ordinary activity. Slight limitation of activity.
  - Class 3: Symptoms with less than ordinary activity. Marked limitation activity.
  - Class 4: Symptoms with any activity or event at rest.

The infusion rate is initiated at 1.25 ng/kg/min. If this dose cannot be tolerated because of systemic effects, the infusion rate should be reduced to 0.625 ng/kg/min. The infusion rate should be increased in increments of no more than 1.25 ng/kg/min per week for the first four weeks, and then no more than 2.5 ng/kg/min per week for the remaining duration of infusion, depending on clinical response. There is little experience with doses >40 ng/kg/min.

References:

1. Remodulin full prescribing information United Therapeutics.

REPATHA (EVOLOCUMAB)

- Must have one of the following diagnoses:
  - Diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by genotypine OR Simon Broome criteria as listed below:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Simon Broome:
  • Total cholesterol >290mg/dL or LDL cholesterol >190mg/dL, PLUS one of the following:
  • Tendon xanthomas in patient, or in 1st degree relative (parent, sibling, child), or in 2nd degree relative (grandparent, uncle, aunt)
  -OR-
  • DNA-based evidence of an LDL receptor mutation, familial defective apo B-100, or a PCSK9 mutation
  o Diagnosis of clinical atherosclerotic cardiovascular disease (CVD) as defined as one of the following:
    • Acute coronary syndrome
    • Coronary or other arterial revascularization
    • History of myocardial infarction
    • Obstructive peripheral arterial disease presumed to be atherosclerotic region
    • Stable/unstable angina
    • Stroke
    • Transient ischemic stroke (TIA)
  o Homozygous familial hypercholesterolemia (HoFH) confirmed by genotyping OR a clinical diagnosis based on the following:
    • Documented history of untreated LDL-C > 500 mg/dL AND xanthoma before 10 years of age;
    -OR-
    • Documented evidence of HeFH in both parents
  • Must meet ALL of the following criteria
    • Appropriate lifestyle modifications have been implemented, including an appropriate lipid-lowering diet that will continue during treatment, supported by documentation of counseling in chart notes
      • Total dietary fat <35% of total calories
      • Weight loss in overweight patients
      • Aerobic exercise
      • Diet rich in fruits and vegetables
    • Baseline and current LDL-C is provided
    • Patient requires additional LDL-C reduction after a 12-week trial of both of the following:
      • High-intensity statin (atorvastatin 40-80mg OR rosuvastatin [Crestor] 20-40mg); AND
      • In combination with ezetimibe (Zetia)
    • Patient has been adherent to lipid-lowering therapy defined as proportion of days covered (PDC) ≥ 80%
    • LDL-C ≥ 100mg/dL
    • Will be used in combination with a maximally tolerated high-intensity statin; OR
    • Member is statin intolerant, as demonstrated by experiencing:
      • Documented statin-associated rhabdomyolysis to one statin; OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
- Documented skeletal-muscle related symptoms with either:
  - Rosuvastatin;
  - OR-
  - Atorvastatin
  - Patient must be 18 years of age or older if treating CVD or HeFH OR 13 years of age or older if treating HoFH
  - Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or lipid specialist
- FOR CONTINUING THERAPY
  - Documented response to Praluent, defined as ONE of the following:
    - Percentage reduction of LDL is ≥ 40% compared to baseline level prior to starting Praluent;
    - OR-
    - Absolute LDL is < 70 mg/dL
  - The patient is tolerating the medication
  - Medication will continue to be used in combination with a maximally tolerated statin
  - Patient has remained adherent to therapy, defined as proportion of days covered (PDC) ≥ 80%

COVERAGE DURATION:

Initial approval: 3 months

Renewal approval: 6 months

Quantity restrictions

HoFH: 3 injections every 4 weeks

CVD/HeFH: 2 injections every 4 weeks

References


RESTASIS (CYCLOSPORINE)

- Sjogren syndrome (moderate to severe keratoconjunctivitis sicca / chronic dry eye disease (CDED)) confirmed by an ophthalmologist or optometrist, AND
- Functional lacrimal gland, AND
- Tried/failed/intolerance to any non-prescription wetting agents (e.g., artificial tears) in the form of drops, ointments, or gels, AND
- No presence of current ocular infection (e.g. herpes keratitis).

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


**RETROVIR (ZIDOVUDINE)**

**Duplicate therapy:**
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

**References**

1. Virginia Premier

**REVCOVI (ELAPEGASEMASE)**

**CRITERIA FOR USE**

- Used For the treatment of severe combined immunodeficiency disease (SCID) due to adenosine deaminase (ADA) deficiency determined by one of the following: deficient ADA catalytic activity (less than 1% normal) or detection of pathogenic mutations in the ADA gene by genetic testing

AND

- Prescribed by a physician who is an expert in the treatment of immune deficiencies

AND

- Patient has failed or is not a candidate for bone marrow transplantation (BMT)

AND

- Patient will NOT be receiving pegademase bovine (Adagen) concurrently with Revcovi

**Continuation of therapy**

- Patient continues to meet above criteria
- Prescriber attest to successful response to Revcovi therapy

**Approval Duration:** Initial – 3 months; Renwal – 6 months

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
REVLIMID (LENALIDOMIDE)

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.

- Myelodysplastic Syndromes (MDS):
  - Prescribed by an oncologist or a hematologist
  - Clinically diagnosed low to intermediate risk MDS associated with deletion 5q cytogenic abnormality with or without additional chromosomal abnormalities
  - Transfusion dependent anemia (2 or more units of RBC every 8 weeks).
  - OR
  - Symptomatic anemia with hgb less than 10g/dl
  - Absolute neutrophil count (ANC) of at least 500/ml
  - Platelet count of at least 50,000/ml
  - Serum creatinine < 2.5 mg/dl.

- Multiple Myeloma (MM):
  - Prescribed by an oncologist or a hematologist.
  - Clinically diagnosed with Multiple Myeloma
  - Member has ONE of the following:
    - Medication will be used in combination with Dexamethasone, OR
    - Revlimid will be used as maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT)
  - Absolute neutrophil count (ANC) of at least 500/ml.
  - Platelet count of at least 50,000/ml.
  - Serum creatinine < 2.5 mg/dl.

- Mantle Cell Lymphoma
  - Prescribed by an oncologist or a hematologist.
  - Clinically diagnosed MCL
  - Failed or intolerant to 2 prior therapies, one of which included bortezomib
  - Absolute neutrophil count (ANC) of at least 500/ml.
  - Platelet count of at least 50,000/ml.
  - Serum creatinine < 2.5 mg/dl.

- Continuing therapy
  - Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient’s condition at this time.
  - Patient is tolerating treatment and there continues to be a medical need for the medication
  - Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)
  - For Myelodysplastic Syndromes (MDS) must also meet both criteria below:
    - Transfusion independence or decrease in need.
    - Cytogenic response. (50% or greater reduction in abnormal metaphases)

Approval Duration:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

**Initial - 3 months**

**Renewal - 3 months**

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**References**

1.) DRUGDEX®, accessed 03/2/2016.

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**Rexulti (Brexpiprazole)**

VPHP will cover Rexulti when the following criteria have been met:

1) Diagnosed with Schizophrenia and at least 18 years of age or older, AND
2) Must have tried and failed all of the following: risperidone, quetiapine, olanzapine, ziprasidone, and aripiprazole (prior authorization required), AND
3) Must be 18 years of age or older,

**OR**

1) Must have clinically diagnosed Major Depressive Disorder, AND
2) Must have tried and failed Quetiapine, Olanzapine, and Aripiprazole (Prior Authorization Required), AND
3) Must have failed or been intolerant to at least 3 other antidepressant therapies (ex. sertraline, paroxetine, fluoxetine, mirtazapine, citalopram, escitalopram, etc), AND
4) Must be used as adjunctive or add-on treatment to ADT and not as monotherapy, AND
5) Must be 18 years of age or older.

**References**

1) Virginia Premier.

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**Rhopressa (Netarsudil)**

- Diagnosis of open angle glaucoma with optic nerve damage with or without visual field loss; **AND**
- Trial and failure, intolerance, or contraindication to therapy with latanoprost; **AND**
- Patient is 18 years of age or older

**Coverage Duration**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

RIBAPAK (RIBAVIRIN)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Coverage of ribavirin is recommended in those who meet the following criteria:

FDA-Approved Indication

1. Treatment of hepatitis C in combination with peginterferon alfa-2b, interferon alpha-2a or interferon alfa-2b. Should not be used as monotherapy for this indication (only approved when used in combination with other FDA approved products). Patients should be clinically diagnosed hepatitis C with detectable HCV RNA levels. Patients have not been previously treated with interferon alpha. Must be used in combination with peginterferon alfa-2a or interferon alfa-2b. Liver biopsy, unless contraindicated, shows fibrosis and inflammatory necrosis.

2. Pediatric use of Rebetol capsules and solution. For use in children clinically diagnosed with hepatitis C with compensated liver disease previously untreated with alpha interferon; relapsed following alpha interferon therapy. Must be used in combination with interferon alfa-2b for injection. Must be 5 years of age or older for capsule use or 3 years of age or older for solution use.

LAB REQUIREMENT:

1. Bilirubin $\leq 2$ mg/dL
2. Albumin Stable and within normal limits
3. Prothrombin Time $\leq 3$ seconds prolonged
4. WBC $\geq 3000$/mm$^3$
5. Platelets $\geq 70,000$/mm$^3$
6. Serum creatinine should be normal or near normal.
7. HCV RNA
8. genotype
9. Early Virological Response (EVR)
10. Liver Function Tests

EXCLUSIONS

Do not approve coverage of peginterferon, ribavirin, Intron A, interferon alfacon, Incivek, and Victrelis for the treatment of Hepatitis C in the following instances:

1. When the above criteria have not been met.
2. Members < 3 years of age for peginterferon
3. When known contraindications to interferon or ribavirin therapy are documented
4. Members < 18 years of age for Victrelis® and Incivek®
5. Members who have failed previous therapy with Victrelis® or Incivek®-based regimens

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
6. Hypersensitivity to interferon alpha or any other component of the product
7. Decompensated liver disease

Coverage of ribavirin is not recommended in the following circumstances:

1. Hypersensitivity to ribavirin or any components of the tablet.
2. Women who are pregnant.
3. Men whose female partners are pregnant.
4. Patients with hemoglobinopathies.
5. Patients with a history of significant or unstable cardiac disease.
6. Creatinine clearance < 50ml/min.
7. Coverage is not recommended

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
37. Schwarz KB, Gonzalez-Peralta RP, Murray KF et al. The combination of ribavirin and peginterferon is superior to peginterferon and placebo for children and adolescents with chronic hepatitis C. Gastroenterology. 2011; 140:450-458.e1.

**RITUXAN (RITUXIMAB)**

- Non-Hodgkin's Lymphoma, OR
- Autoimmune hemolytic anemia, OR
- B-cell lymphoma, OR
- Chronic lymphoid leukemia, OR
- Evans syndrome refractory to immunosuppressive therapy, OR
- Chronic Graft-versus-host disease refractory to steroids, OR
- CD20-positive Hodgkin's disease, OR
- Idiopathic thrombocytopenic purpura, OR
- Untreated, induction therapy Mantle cell lymphoma, in combination with anthracycline-based regimen, OR
- Refractory Steroid-dependent or steroid-resistant nephrotic syndrome, OR
- Severe pemphigus vulgaris, OR
- Post-transplant lymphoproliferative disorder, OR
- Primary Sjögren's syndrome, OR
- Systemic lupus erythematosus refractory to immunosuppressive therapy, OR
- Waldenström macroglobulinemia, OR
- Moderate to severe active rheumatoid arthritis with at least four of the following symptoms:
  - Morning stiffness.
  - Arthritis of three (3) or more joint areas.
  - Arthritis of hand joints.
  - Symmetric arthritis.
  - Rheumatoid nodules.
  - Serum rheumatoid factor.
  - Radiographic changes, AND
  - Tried/failed/intolerance to at least one (1) of the following DMARDs:
    - Methotrexate
    - Cyclosporine
    - Azathioprine
    - Penicillamine

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Cuprimine
• Sulfasalazine
• Leflunomide
• gold sodium thiomalate
• Aurolate
• Aurothioglucose
• Solganal
• Auranofin
• Ridaura
• Hydroxychloroquine AND
  ▪ has had a previous tried/failed/intolerance to at least one of the following:
    ▪ Enbrel
    ▪ Humira

Reauthorization/continuing therapy:
• RA: The provider must show an improvement in clinical symptoms that may include
  improvement in tender and swollen joint count, mobility, stiffness or delay in progression
  of disease.

References

1. American College of Rheumatology 2008 Recommendations for the Use of Nonbiological
   and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. Arthritis &
   antibody treatment in 6 patients with therapy-refractory chronic graft-versus host disease.
   Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington,
   treatment of refractory immune-mediated thrombocytopenia in a patient with chronic graft-

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at
least 30 days upon receipt of documentation demonstrating that approval


RYZOLT (TRAMADOL HYDROCHLORIDE) EXTENDED-RELEASE

PA criteria for FDA age indications. Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Patient must have moderate to moderately severe pain
- Must have tried and failed immediate release tramadol.
- Must be unable to take tramadol on a consistent regular schedule every 6 hours.

Contraindication:
- hypercapnia, severe bronchial asthma, or significant respiratory depression, in unmonitored settings or without resuscitative equipment
- hypersensitivity to opioids
- hypersensitivity to tramadol hydrochloride or any other components of the product
- situations where opioids are contraindicated, including acute intoxication with alcohol, hypnotics, narcotics, centrally acting analgesics, opioids, or psychotropic drugs; may worsen CNS and respiratory depression

Not approved if:
- Patient does not meet the above stated criteria.
- Patient has any contraindications to the use of Ryzolt or tramadol.

References

1. Virginia Premier

SABRIL (VIGABATRIN)

- Prescribed by a neurologist, AND
- Adjunct therapy for Refractory complex partial seizures, AND
  - ≥ 18 years of age, AND
  - Tried/failed/intolerance to two formulary anticonvulsants, AND
  - Prescriber confirmation that potential benefit outweighs the potential risk of vision loss, AND
  - Vision tested at baseline before beginning treatment and will be tested every 3 months thereafter, OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Infantile spasms, AND.
  o > 1 month to ≤2 years of age, AND.
  o Prescriber confirmation that potential benefit outweighs the potential risk of vision loss, AND
  o Vision tested, when possible, at baseline before beginning treatment and will be tested every 3 months thereafter.

Reauthorization/continuing therapy:
• Demonstrate clinical benefit, AND
• Confirmation of vision test within the last 3 months

References


SAMSCA (TOLVAPTAN)

• Hypervolemic Hyponatremia, OR
• Euvolemic Hyponatremia, OR
• Hyponatremia in Heart Failure, AND
• Tried/failed/intolerance to fluid restriction, AND
• Treatment was or will be initiated and titrated in a hospital setting with close serum monitoring, AND
• Patient is able to sense and respond appropriately to thirst, AND
• Patient is not Anuric

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


SANCUSO (GRANISETRON) PATCH

PA criteria for FDA age indications. Criteria for use (bullet points below are all inclusive unless otherwise noted):
- Postoperative nausea and vomiting
- Postoperative nausea and vomiting; Prophylaxis
- Radiation-induced nausea and vomiting; Prophylaxis
- Radiation-induced nausea and vomiting; Treatment and Prophylaxis
- Patient’s receiving chemotherapy.
- Tried and failed or intolerant to at least one oral 5-HT3 antagonists:
  - generic granisetron, generic ondansetron, Aloxi, Anzemet.
- Tried and failed or intolerant to Emend.
- Patient unable to tolerate oral dosage forms.

Contraindication:
- Patients with a known hypersensitivity to the drug or to any of its components.

Not approved if:
- Patient does not meet the above-stated criteria.
• Patient has any contraindications to the use of Sancuso.

References

1. Virginia Premier

**SAVAYSA (EDOXABAN)**
• To reduce the risk of stroke and systemic embolism in non-valvular atrial fibrillation; **OR**
• Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5-10 days of initial therapy with a parenteral anticoagulant, **OR**
• Diagnosis of Pulmonary Embolism, **AND**
• Documentation that Creatinine Clearance is **NOT** ≥ 95 mL/min calculated by Cockroft-Gault

**SAVELLA (MILNACIPRAN HYDROCHLORIDE)**
• Fibromyalgia confirmed by a rheumatologist or neurologist, **AND**
• Tried/failed/intolerance to Gabapentin and at least 1 tricyclic antidepressant; **AND**
• No presence of End-stage renal disease or contraindication to use of Savella.

Caution
• Can increase blood pressure and heart rate
• Serotonin syndrome has been reported with SNRIs and SSRIs. Concomitant use of serotonergic drugs such as triptans, tramadol and drugs that inhibit serotonin reuptake, including Savella, is not recommended
• Seizures have been reported in patients who take Savella. Prescribe with caution in patients with a history of seizure.

Monitoring
• Blood Pressure
• Worsening of depressive symptoms and/or emergence of suicidal ideation and behavior or unusual changes in behavior in patients with depression or other psychiatric disorders taking Savella

Contraindications
• Patients taking Monoamine Oxidase Inhibitors (MAOI) or within 14 days of discontinuing treatment with an MAOI.
• Narrow Angle Glaucoma
• Hypersensitivity to FD&C Yellow No. 5 (tartrazine).

Not approved if:
• Being used for depression.
• Patient has End Stage Renal Disease.

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


SAXENDA (LIRAGLUTIDE)

CRITERIA FOR USE:
1. Member is 18 years of age or older, AND
2. Member currently has a BMI ≥ 30 kg/m² OR
2. Member has a BMI ≥ 27 kg/m² for those with risk factors besides obesity (e.g. diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea, AND
3. Member is currently engaged in behavioral modification and on a reduced calorie diet, AND
4. Member has had a trial and failure, intolerance, or contraindication to at least one (1) of the following:
   a. Adipex-P (Phentermine)
   b. Belviq
   c. Contrave
   d. Qsymia
   e. Xenical

RENEWAL:
1. Member has lost at least 4% or baseline bodyweight

Approval Duration:
4 months

Notes:
Change in body weight with Saxenda should be evaluated every 16 weeks after initiation of medication. If the patient has not lost ≥ 4% of baseline body weight, Saxenda should be discontinued because it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
**Dosing:**
Chronic weight management: SubQ: Initial: 0.6 mg once daily for one week; increase by 0.6 mg daily at weekly intervals to a target dose of 3 mg once daily. If the patient cannot tolerate an increased dose during dose escalation, consider delaying dose escalation for one week. If the 3 mg daily dose is not tolerated, discontinue use as efficacy has not been established at lower doses.

**SENSIPAR (CINACALCET)**

**POLICY**

I. **INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. **FDA-Approved Indications**
   1. Secondary hyperparathyroidism in adult patients with chronic kidney disease (CKD) on dialysis
   2. Hypercalcemia in adult patients with parathyroid carcinoma
   3. Hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy

B. **Compendial Use**
   1. Tertiary hyperparathyroidism in post-kidney transplant patients not receiving dialysis

All other indications are considered experimental/investigational and are not a covered benefit.

II. **INITIAL CRITERIA FOR APPROVAL**

A. **Secondary Hyperparathyroidism with CKD on Dialysis**
Authorization of 12 months may be granted for the treatment of secondary hyperparathyroidism in a member with chronic kidney disease on dialysis who has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

B. **Primary Hyperparathyroidism**
Authorization of 12 months may be granted for the treatment of primary hyperparathyroidism in a member who is not able to undergo parathyroidectomy and has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

C. **Tertiary Hyperparathyroidism in Post-Kidney Transplant Patients Not Receiving Dialysis**
Authorization of 12 months may be granted for the treatment of tertiary hyperparathyroidism in a member who has had a kidney transplant, is not receiving dialysis, and has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
D. Parathyroid Carcinoma
Authorization of 12 months may be granted for the treatment of parathyroid carcinoma in a member who has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

III. CONTINUATION OF THERAPY
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. APPENDIX
Corrected calcium = measured total calcium + 0.8(4.0 – serum albumin)

V. REFERENCES

SGLT2 (FARXIGA/INVOKANA)
Criteria for use (bullet points below are all inclusive unless otherwise noted):
- Must be clinically diagnosed with type 2 diabetes.
- Must have tried and failed or had an inadequate response to metformin (HgbA1c signifies control, A1c greater than or equal to 7.6% qualifies for approval and A1c >9% does not require trial of metformin); OR
- Patient is intolerant to Metformin
- 18 years of age or older

Contraindication:
- History of serious hypersensitivity reaction to Invokana
- Severe renal impairment, ESRD, or on dialysis.

Not approved if:
- Have any contraindications to the use of Invokana
- Does not meet the above stated criteria.

Authorization
Initial – 6 months, Renewal – 12 months

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
SILENOR (DOXEPIN)

- PA criteria for FDA age indications.

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
  - Clinically diagnosed insomnia.
  - Treatment failure on one of these products (oxazepam, temazepam, lorazepam, alprazolam, diazepam, flurazepam, trazodone).
  - Treatment failure on zolpidem.
  - Underlying physical or psychological conditions (including addiction, depression, anxiety, sleep apnea, restless leg syndrome, circadian issues, pain, GERD, etc.) have been ruled out or are being adequately treated.
  - Failed/intolerant to Doxepin concentrate.

Contraindication:
- Hypersensitivity to doxepin, any of its inactive ingredients, or other dibenzoxepines.
- Co-administration with monoamine oxidase inhibitors (MAOIs).
- Individuals with untreated narrow angle glaucoma.
- Individuals with severe urinary retention.

Not approved if:
- Does not meet the above-stated criteria.
- Have any contraindications to the use of doxepin.

References
1. Virginia Premier

SIMPONI (GOLIMUMAB)

STEP THERAPY ALERT:
Humira and Enbrel are the preferred drugs. Member must have tried/failed Humira AND Enbrel first unless contraindicated.

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Coverage of golimumab is recommended in those who meet one of the following criteria:

FDA-Approved Indications

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
1. **Adults with rheumatoid arthritis.**
   i. Approve if the patient has tried one DMARD (brand or generic; oral or injectable) for at least 2 months, [this includes patients who have tried other biologic DMARDs for at least 2 months]
   AND
   ii. the patient will be receiving MTX in combination with golimumab.

   **Note:** Patients are not required to use MTX concurrently with golimumab if there are contraindications to MTX or the patient has a history of intolerance to MTX.

2. **Psoriatic arthritis (PsA).**
   Golimumab is FDA-approved for PsA and can be used alone or in combination with MTX or other non-biologic DMARDs. In clinical trials, golimumab was effective in patients with active PsA despite therapy with a NSAID or DMARD.

3. **Ankylosing spondylitis (AS).**
   Golimumab is FDA-approved for AS and can be used alone or in combination with MTX or other non-biologic DMARDs.

### Other Uses with Supportive Evidence

**Patient has been started golimumab. (Grandfathered)**
Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications).

**EXCLUSIONS**
Coverage of golimumab is not recommended in the following circumstances:

1. **Golimumab should not be given in combination with a TNFα antagonist (e.g., adalimumab, certolizumab pegol (Cimzia®), etanercept, infliximab), anakinra, rituximab, abatacept, or tocilizumab (Actemra).**
   Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.

2. **Plaque psoriasis without psoriatic arthritis.**
   Golimumab has been studied in patients with psoriatic arthritis who had plaque psoriasis. Plaque psoriasis improved in these patients with a PASI-75 being attained by 40% of patients on golimumab 50 mg every 4 weeks and by 58% in the golimumab 100 mg group at week 14. Golimumab is FDA-approved in patients with psoriatic arthritis, but not in patients with plaque psoriasis without psoriatic arthritis. Prospective, controlled trials are needed to determine safety and efficacy in plaque psoriasis. The other TNFα antagonists, adalimumab, etanercept and infliximab are FDA-approved for the treatment of plaque psoriasis.

3. **Asthma.**
   In a double-blind trial, 309 patients with uncontrolled, severe asthma despite high-dose inhaled corticosteroids and long-acting beta-2 agonists were randomized to golimumab 50, 100, or 200 mg or to placebo for 52 weeks. No significant differences were observed for change in percent-predicted FEV₁ or severe exacerbations through week 24. Unfavorable risk-benefit profile led to early discontinuation of study agent administration after the week 24 database lock.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
4. Ulcerative colitis.
Phase III trials are underway studying golimumab SC for induction of remission and maintenance in adults with moderately to severely active ulcerative colitis.

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

SOLARAZE (DICLOFENAC) TRANSDERMAL GEL

- PA criteria for FDA age indications.
Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
  - Must have clinically diagnosed actinic keratosis.
  - Failed or not a good candidate to receive liquid nitrogen cryotherapy which is the treatment of choice for single or a few scattered small, thin, or shallow lesions.
  - Failed or not a good candidate for surgical curettage.
    Note: usually for isolated, thick AK’s particularly on the dorsal arms or hands, and in patients who are immunocompromised.
  - Failed/ intolerant to topical 5 fluorouracil.
    Note: for multiple AK’s
Contraindications:
  - Hypersensitivity to diclofenac, benzyl alcohol, polyethylene glycol monomethyl ether 350 and/or hyaluronate sodium.
Not Approved if:
  - Patient does not meet the above stated criteria.
  - Patient has any contraindications to the use of Solaraze
Special Considerations:
  - Complete healing of the lesion or optimal therapeutic effect may not be evident for up to 30 days after the completion of therapy.
  - Exposure to sunlight and the use of sunlamps should be avoided.

References
1. Virginia Premier

SOLIRIS (ECULIZUMAB)

1. Paroxysmal nocturnal hemoglobinuria (PNH) confirmed by HAM test of flow cytometry, with at least 10% PNH type III red cells, AND
2. Patient has been vaccinated against meningococcal infection (at least 2 weeks prior to treatment, if not previously vaccinated), AND
3. Patient has one of the following:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

a) Transfusion dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of Soliris due to documented hemoglobin < 7 g/dL (without anemic symptoms), or <9 g/dL (with symptoms from anemia) and has platelet counts of at least 30,000/microliter prior to initiation of Soliris treatment, OR

1. History of thromboembolism, pulmonary hypertension, renal insufficiency, or other end organ complications from PNH, OR

1. Atypical hemolytic uremic syndrome without serious unresolved Neisseria meningitidis infection, OR

1. Diagnosis of Myasthenia Gravis (gMG), AND

2. Patient is 18 years of age or older, AND

3. Patient has tried and failed therapy with immunosuppressive therapy, defined as continued disease symptoms such as difficulties seeing, walking, talking, swallowing and breathing

References


SOLODYN (MINOCYCLINE) EXTENDED-RELEASE

• PA criteria for FDA age indications.
Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
  • Clinically documented inflammatory lesions of non-nodular moderate to severe acne.
  • Must be 12 years of age or older.
  • Failed/intolerant to topical combinations.
  • Intolerant to an excipient in the immediate release minocycline

Contraindications:
  • Hypersensitivity to any of the tetracyclines

Not Approved if:
  • Lesions are non-inflammatory.
  • Have any contraindications to the use of Solodyne.
  • Does not meet the above stated criteria.

Special Considerations:
  • There is no evidence that Solodyne is superior to its generic minocycline for treating acne. For patients who require antibiotic treatment generic minocycline is a less expensive option.

Duration of Therapy: 12 weeks (safety beyond this point has not been established).

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
SONATA (ZALEPLON)

- FDA age indications
- Must have tried and failed Zolpidem, Rozerem and sedative benzodiazepines
- Should not be prescribed in quantities exceeding a 1-month supply and no refills allowed.

References

1. Virginia Premier

SORIATANE (ACITRETIN)

Criteria for use for (bullet points below are all inclusive unless otherwise noted):
- Must be used for treatment of moderate to severe Psoriasis
- Trial and failure, intolerance, or contraindication to, 90 day trial of Methotrexate
- Trial and failure, intolerance, or contraindication to, 90 day trial of high dose topical steroid (i.e. betamethasone augmented, halobetasol)
- Prescribed by, or in consultation with, a Dermatologist
- Maximum of 2 capsules per day
- For continuation of therapy, requires documentation of a positive response to therapy

Approval Duration

Initial: 3 months
Renewal: 1 year

References

Virginia Premier

SPRAVATO (esketamine)

CRITERIA FOR USE

- Patient must have a diagnosis of Treatment Resistant Depression (TRD)
  AND
- Patient must be 18 years of age or greater
  AND
- Patient has tried/failed or intolerant to at least 2 medications in the Selective Serotonin Reuptake Inhibitor (SSRI) drug class (a trial is considered at least 4 consecutive weeks of therapy)
  AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Patient has tried/failed or intolerant to at least 2 medications in the Serotonin-Norepinephrine Reuptake inhibitors (SNRI) drug class (a trial is considered at least 4 consecutive weeks of therapy)  
  AND  
• Patient has tried/failed or intolerant to at least 1 medication from an alternative anti-depressant drug class (MAO-I, Tricyclic, alpha-2 receptor antagonist)  
  AND  
• If patient is 65 years of age or older they are being prescribed the appropriate initiation dose of 28mg

Criteria for Renewal
• Patient continues to meet initial criteria  
  AND  
• Prescriber attests patient has had a positive response to therapy

Not approved if:
• Does not meet above criteria  
• Any contraindication to treatment

Quantity Limit:
• 1st month 8/28 days  
• Maintenance (starting month 2) 4/28 days

Approval Duration: Initial – 3 months; Renewal – 6 months

SPINRAZA (NUSINERSEN)
• **Note: covered through pharmacy benefit only at specified pharmacies, all other claims through Medical Benefit  
• Partially approve, move to client queue, and send email to Adam at AHarbert@envisionrx.com, to be forwarded to client for review by Medical Directors.

1. The treatment of Spinal Muscular Atrophy (SMA) in patients who meet all of the following criteria:
   a. For initial therapy, all of the following:
      (1) One of the following:
         (a) Diagnosis of spinal muscular atrophy type I, II, or III by a neurologist with expertise in the diagnosis of SMA.
         (b) Diagnosis of spinal muscular atrophy type I, II, or III by a physician in consultation with a neurologist with expertise in the diagnosis of SMA.  
         AND  
      (2) Submission of medical records (e.g., chart notes, laboratory values) confirming both of the following:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval:

(a) The mutation or deletion of genes in chromosome 5q resulting in one of the following:
   i. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13).
   OR
   ii. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2])
   AND

(b) Patient has at least 2 copies of SMN2

AND

(3) Patient is not dependent on either of the following:
   (a) Invasive ventilation or tracheostomy
   (b) Non-invasive ventilation for at least 6 hours per day
   AND

(4) Submission of medical records (e.g., chart notes, laboratory values) of the baseline exam of at least one of the following exams (based on patient age and motor ability) to establish baseline motor ability:
   (a) Hammersmith Infant Neurological Exam (HINE) (infant to early childhood)
   (b) Hammersmith Functional Motor Scale Expanded (HFMSX) (1,9,13-14
   (c) Upper Limb Module (ULM) Test (Non ambulatory)1,9,
   (d) Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)1,8
   AND

(5) One of the following:
   (a) Spinraza is prescribed by a neurologist with expertise in the treatment of SMA
   (b) Spinraza is prescribed by a physician in consultation with a neurologist with expertise in the treatment of SMA
   AND

(6) Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.

AND

(7) Spinraza dosing for SMA is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg for each loading dose.

AND

(8) Initial authorization will be for no more than 4 loading doses

Continuation of Therapy
For continuation therapy, all of the following:

(1) One of the following
   (a) Diagnosis of spinal muscular atrophy type I, II, or III by a neurologist with expertise in the diagnosis of SMA.
   (b) Diagnosis of spinal muscular atrophy type I, II, or III by a physician in consultation with a neurologist with expertise in the diagnosis of SMA.
   AND

(2) Submission of medical records (e.g., chart notes, laboratory values) confirming both of the following:
   (a) The mutation or deletion of genes in chromosome 5q resulting in one of the following:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

i. Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13).

OR

ii. Compound heterozygous mutation (e.g., deletion of SMN1 exon 7[allele 1] and mutation of SMN1 [allele 2])

AND

(b) Patient has at least 2 copies of SMN2

AND

(3) Patient is not dependent on either of the following:
(a) Invasive ventilation or tracheostomy
(b) Non-invasive ventilation for at least 6 hours per day

AND

(4) Submission of medical records (e.g., chart notes, laboratory values) with the most recent results (< 1 month prior to request) documenting a positive clinical response from pretreatment baseline status to Spinraza therapy as demonstrated by at least one of the following exams:
(a) HINE milestones:
   i. One of the following:
      (i) Improvement or maintenance of previous improvement of at least 2 point (or maximal score) increase in ability to kick
      (ii) Improvement or maintenance of previous improvement of at least 1 point increase in any other HINE milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp.

   AND

   ii. One of the following:
      (i) The patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement).
      (ii) Achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk).

   OR

(b) HFMSE: One of the following:
   i. Improvement or maintenance of previous improvement of at least a 3 point increase in score from pretreatment baseline
   ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

   OR

(c) ULM: One of the following:
   i. Improvement or maintenance of previous improvement of at least a 2 point increase in score from pretreatment baseline
   ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

   OR

(d) CHOP INTEND: One of the following:
   i. Improvement or maintenance of previous improvement of at least a 4 point increase in score from pretreatment baseline
   ii. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so

   AND

(5) One of the following:
(a) Spinraza is prescribed by a neurologist with expertise in the treatment of SMA

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
(b) Spinraza is prescribed by a physician in consultation with a neurologist with expertise in the treatment of SMA

AND

(6) Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures.

AND

(7) Spinraza dosing for SMA is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 12mg every 4 months, starting 4 months after the last loading dose.

AND

(8) Reauthorization will be for no more than 3 maintenance doses (12 months). Spinraza is not proven or medically necessary for spinal muscular atrophy without chromosome 5q mutations or deletions.

I. Length of Authorization
Coverage will be provided annually and may be renewed.

II. Dosing Limits
A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   - Loading: 1 vial on D1, D15, D29, and D59
   - Maintenance: 1 vial (5ml) every 112 days

B. Max Units (per dose and over time) [Medical Benefit]:
   - Loading: 12 mg (1-vial-5ml) on D1, D15, D29, and D59
   - Maintenance: 12 mg (1-vial-5ml) every 112 days

Store refrigerated at 2°C to 8°C; warm to room temperature prior to administration

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

SPORANOX (ITRACONAZOLE)

- PA criteria for FDA age indications.
- MUST fail generic first.

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
- Patient has an invasive, systemic fungal infection
  Or
- Patient has clinically documented onychomycosis of the finger nails
  Or
- Patient has clinically documented onychomycosis of the toe nails and:
  - is diabetic or immunosuppressed/immunocompromised
    Or
  - patient is in acute pain due to the onychomycosis with signs of associated soft tissue inflammation
    Or
  - For dermal fungal infections (not including onychomycosis) where topical antifungal agents are considered first line therapy:
    - Patient must have failed/intolerant to both an OTC and Rx topical antifungal agent used for an appropriate length of time
    Or
    - Patient has an extensive infection involving areas too large to reasonably use a topical agent
    Or
    - Patient has a chronic, recalcitrant infection
    Or
    - Patient is immunocompromised

Contraindications:
- Congestive heart failure
- Concomitant administration of itraconazole with drugs metabolized by CYP3A4: oral midazolam, pimozide, quinidine, dofetilide, tirazolam, lovastatin, and simvastatin.

Duration of Therapy:
- Toenail onychomycosis -12 weeks
- Fingernail onychomycosis – 5 weeks (2 treatment pulses for 1 week separated by 3 weeks)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
SPRIX (KETOROLAC TROMETHAMINE) INTRANASAL

***Partially approve the EOC and submit to the PA Hub External queue. Send an e-mail to Adam @ aharbert@rxoptions.net and the “CC” the CDPharmacist e-mail distribution box, noting the EOC # and requested indication for use.

PA criteria for FDA age indications.
Criteria for use (bullet points below are all inclusive unless otherwise noted):
  • The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
  • Clinically documented acute pain
  • Failed/intolerant to generic NSAID’s
  • Failed/intolerant to Celebrex (Celebrex requires a PA)
  • Failed/intolerant to VPHP preferred opioids including morphine sulfate, Fentanyl patches
  • Failed/intolerant to generic ketorolac tromethamine tablets (ketorolac tablets requires a PA)
  • Maximum combined duration of use of any form of ketorolac is not to exceed 5 days
  • Total daily dose of Sprix not to exceed 126mg (1 bottle per day)

Not approved if:
  • Patient is less than 18 years of age
  • Patient has high risk of GI bleed
  • Patient has any risk of bleed potential, including CVA, TIA
  • Patient needs medication for a longer period than 5 days

Duration of therapy: Maximum of 5 days

References
1. Virginia Premier

STELARA (USTEKNINUMAB)

STEP THERAPY ALERT:
Humira and Enbrel are the preferred drugs. Member must have tried/failed Humira AND Enbrel first unless contraindicated.

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Coverage of ustekinumab is recommended in those who meet one of the following criteria:

**FDA-Approved Indications**

1. **Plaque psoriasis in adults.**
   Authorization can be given for patients who meet all of the following criteria a, b, c, and d:

   a. Ustekinumab is prescribed by a dermatologist or in consultation with a dermatologist and

   b. Patient has minimum BSA involvement with plaque psoriasis of ≥ 5%.

   Exceptions can be made to the requirement for ≥ 5% BSA involvement in the following instances (i or ii):

   i. Patients with plaque psoriasis of the palms, soles, head and neck, nails, intertriginous areas or genitalia are not required to have a minimum BSA involvement OR

   ii. The patient who meets all four of the following conditions (bullet points) is not required to have a minimum BSA involvement:

       • Patient has had an inadequate response to a 3-month trial of either topical therapy OR localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light (PUVA) and

       • Patient has had an inadequate response to a 3-month trial of systemic therapy with one of the following: MTX, cyclosporine, or acitretin (Soriatane®) or has contraindications to all of these and

       • Patient has tried a tumor necrosis factor (TNF) antagonist [adalimumab (Humira®), etanercept, infliximab (Remicade®)] and

       • Patient has significant disability or impairment in physical or mental functioning, according to the treating physician.

   Note: Patients who meet the criteria under 1bii are not required to meet 1c below.

   **AND**

   c. Patient has tried systemic therapy or phototherapy for 3 months with one of the following: acitretin (Soriatane®), cyclosporine, methotrexate, or phototherapy with UVB or PUVA for psoriasis. Rarely, a patient may have contraindications to nearly all of these other therapies and patients will be evaluated by a pharmacist and/or a physician on a case-by-case basis to determine a coverage recommendation for the client. (Due to its toxicity, ustekinumab therapy should be reserved for patients who have not responded well or are intolerant to other standard systemic therapy. In addition, the National Psoriasis Foundation Clinical Consensus, states that there currently are no prognostic factors that ascertain which therapies will be most efficacious and least toxic.)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
AND

d. Patient has tried adalimumab, etanercept, or infliximab for plaque psoriasis.

2. **Psoriatic arthritis without plaque psoriasis.**
   Patients with plaque psoriasis also may have psoriatic arthritis. If so, they may receive ustekinumab if they meet the criterion 1 for plaque psoriasis above or criterion 2 for patients who have already been started on ustekinumab.

3. **Moderate to Severely Active, Crohn’s Disease**
   - Must be 18 years of age or older
   - Must have tried and failed or been intolerant to, therapy with at least two (2) of the following:
     - Corticosteroids (i.e. prednisone, prednisolone, methylprednisolone)
     - 5-Aminosalicylates (i.e. sulfasalazine, Dipentum)
     - 6-Mercaptopurine (6-MP) and/or azathioprine
     - Methotrexate (MTX)
   - Must have tried and failed, or been intolerant to, therapy with Humira
   - The dose must be within the standard dosing limits, required as below:
     - **Induction Therapy**
       - Induction infusion is based on weight as below:
         - 55kg or LESS: 260 mg IV infusion as a single dose over 1 hour
         - 56kg to 85 kg: 390 mg IV infusion as a single dose over 1 hour
         - 86 kg or MORE: 520 mg IV infusion as a single dose over 1 hour
     - **Maintenance Therapy**
       - 90 mg subcutaneously starting 8 weeks after the initial Intravenous induction dose, then given 90mg subcutaneously every 8 weeks thereafter

**Other Uses with Supportive Evidence**

**Patient has been started on ustekinumab.** (Grandfathered)
Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications).

**EXCLUSIONS**

Coverage of ustekinumab is *NOT* recommended in the following circumstances:

1. **Ustekinumab should not be given in combination with a TNFα antagonist (e.g., adalimumab [Humira®], certolizumab pegol [Cimzia®], etanercept [Enbrel®], golimumab [Simponi™], infliximab [Remicade®], anakinra [Kineret®], or alefacept (Amevive®).**
   Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
2. **Children or adolescents ≤ 18 years of age.**
   Safety and efficacy in pediatric patients have not been established.

3. **Multiple sclerosis.**
   In a Phase II double-blind trial, 249 adult patients with relapsing-remitting multiple sclerosis were randomized to one of four different ustekinumab SC doses or placebo for 19 weeks. No statistically significant or clinically meaningful differences in the cumulative number of new lesions on serial cranial magnetic resonance imaging (MRI) through Week 23 between any of the ustekinumab dosage groups and placebo were observed.

**Other indications.** Exceptions not recommended. Case reports have documented some efficacy in the treatment of pityriasis rubra pilaris and variable efficacy for treatment of palmoplantar pustulosis with ustekinumab. Controlled clinical trials are needed to evaluate the safety and efficacy of ustekinumab in conditions not mentioned in the authorization criteria.

**References**


**STRI BhILD (ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE)**

**Duplicate therapy:**
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

References

1. Virginia Premier

SUBLOCADE (BUPRENORPHINE, EXTENDED RELEASE)

Initial

- Clinically diagnosed with opioid use disorder
  - FDA approved indication is for treatment of opioid use disorder only, NOT pain management.
- Must be 16 years of age or older
- Patient has been initiated on transmucosal buprenorphine-containing product followed by a dose adjustment for a minimum of 7 days
- Prescriber is enrolled in SUBLOCADE REMS PROGRAM (WWW.SUBLOCADEREMS.COM) and will comply with the REMS requirements
- Patient must be participating in psychosocial counseling (individual or group) at least once per week
- Must provide name and phone number of behavioral health care provider that is providing counseling
- Prescriber must have reviewed the Virginia Controlled Substance Database Prescription Monitoring Program (PMP) before the initiation of therapy (https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx)
  - Must provide date of last opioid prescription
  - Must provide date of last benzodiazepine prescription
- Prescriber must confirm that the patient is NOT concurrently taking any stimulant medication
- Patient must not be taking a Benzodiazepine concurrently (if patient is taking, approve for one month only and prescriber must resubmit)

Maintenance

- Clinically diagnosed with opioid dependence
  - FDA approved indication is for treatment of opioid dependence only, NOT pain management.
- Must be 16 years of age or older
- Patient must be participating in psychosocial counseling (individual or group) at least once to twice per month
- Prescriber must review the PMP Web Site on the date of the request for maintenance therapy
- Prescriber must confirm that patient is NOT concurrently taking any of the following medications during Maintenance (These medications will not be allowed to be prescribed or taken concurrently with buprenorphine containing drugs)
  - Benzodiazepines, Tramadol (Ultram), Carisoprodol (Soma), other opiates, or stimulants

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Prescriber must provide a tapering plan and document medical reasoning for co-prescribing these substances (may authorize up to a maximum of 3 months for tapering)
- Prescriber must check random urine drug screens
  - Urine drug screens must check for buprenorphine, norbuprenorphine, methadone, oxycodone, benzodiazepines, amphetamine/methamphetamine, cocaine, heroin, and other prescription opiates
- Prescriber must provide the last 2 urine drug screens (with at least 1 of these screenings within the past month)
  - Drug screens must be positive for buprenorphine/norbuprenorphine and negative for all other substances
  - If a drug screen is negative for buprenorphine/norbuprenorphine and/or positive for another substance, written documentation of steps being taken to address patient’s possible diversion of buprenorphine and/or ongoing use of other substances including intensifying the counseling that patient is receiving and/or considering referral to higher level of care (such as intensive outpatient, partial hospitalization, or residential treatment) MUST be provided
  - A 1x, 30 day supply will be allowed for failure of (positive) drug screens/UDS medical records/chart notes for the drugs listed above. Another prior authorization request would be needed for the next authorization and must include a new clean drug screen/UDS medical record/chart note (from the last EOC submission), otherwise will result in denial of request for continued therapy.

- Quantity Limits
  - Initial: Sublocade 300mg subcanteoulsy every month times first 2 months
  - Maintenance: Sublocade 100mg subcutaneously every month
- Authorization
  - Initial: 3 Months
  - Renewal: 6 months

SUPARTZ (HYALURONIC ACID DERIVATIVES, INTRA-ARTICULAR)

_Euflexxa is the preferred drugs. Member must have tried/failed Euflexxa first unless contraindicated._

- Osteoarthritis of the knee, AND
- Tried/failed/intolerance to mild analgesic therapy (e.g. acetaminophen) OR tried/failed/intolerance to generic NSAIDs or COX-2 Inhibitors.
- Tried/failed/intolerance to the following:
  - Intra-articular corticosteroid injection (relief <6-8 weeks)
  - Physical therapy, AND
- Must not have large effusions of the knee, AND
- No infections or skin diseases in the knee area, AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

References


SUPPRELIN LA (HISTRELIN)
Criteria for use (bullet points below are all inclusive unless otherwise noted):

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Clinically diagnosed with central precocious puberty
- Age of ≥ 2 years old
- Diagnosis has been confirmed by one of the following:
  - Measurement of blood concentration of total sex steroid (estrogen/testosterone)
  - Measurement of Leuteinizing Hormone and Follice-Stimulating Hormone with a Gonadotropin Releasing Hormone analog
  - Assessment of bone age versus chronological age
- Previous trial and failure with Lupron Depot (Failure is described as the inability to suppress physical signs of puberty)

Criteria for continuation of therapy:

- Height and weight regressed to a more normal linear pattern
- Secondary Sex characteristics do not progress
- Duration of therapy should last until onset of puberty (Girls ~ Age 11, Boys ~ Age 12)

Not approved if:

- Patient does not meet above listed criteria
- Being used to treat conditions other than FDA indicated uses
- Patient has any contraindications.

References
1. Virginia Premier

**SUSTIVA (EFAVIRENZ)**

Duplicate therapy:

- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

References
1. Virginia Premier.

**SUTENT (SUNITINIB)**

- Prescribed by Oncologist, AND
  - Gastrointestinal Stromal Tumor (GIST) and GIST is unresectable and/or metastatic malignant, AND
  - Disease progression while trying or intolerance to Gleevec drug regimen, OR
- Metastatic (advanced) renal cell carcinoma and the carcinoma is surgically unresectable, OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
- Chordoma, OR
- Metastatic (advanced) thyroid cancer, AND
  - The patient has tried and failed or intolerant to vandetanib and cabozantinib, OR
- Metastatic breast cancer previously treated with an anthracycline and a taxane, AND
  - No clinical manifestations of congestive heart failure, AND.
  - Patient will NOT be treated with interferon alfa (Roferon-A, Pegasys, Intron-A, Peg-Intron) or interleukin-2 (Proleukin) therapy in combination with Sutent treatment, AND
  - If the patient is female and of childbearing years (12 – 45 years of age), she is NOT pregnant, has NO plans for pregnancy and has been educated on the potential dangers of Sutent therapy in pregnancy.

Reauthorization/continuing therapy:
- If the patient has received previous Sutent therapy, he/she has no evidence of disease progression (tumor growth) since initiating Sutent therapy.

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


SYMDEKO (TEZACAFTOR/IVACAFTO)

Initial:
- Diagnosis of Cystic Fibrosis (CF); AND
- **ONE** of the following:
  - Documentation confirming patient is homozygous for the F508del mutation in the CFTR gene
    - OR –

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Documentation confirming the patient has at least one of the following mutations in the CFTR gene that is responsive to Symdeko:

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<td>F1052V</td>
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- Patient is at least 6 years of age or older
- Prescribed by, or in consultation with, a Pulmonologist
- Must NOT be taken concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator

Renewal
- Patient continues to meet criteria for initial therapy, AND
- Documentation of one of the following while on Symdeko therapy:
  - Improved lung function
  - Stable lung function

Authorization
- Initial – 6 months
- Renewal – 12 months

**SYMLIN/SYMLIN PEN (PRAMLINTIDE ACETATE)**

Exclude Members from targeting if they have a history of antidiabetic drugs (GPI27):
- Type 1 or Type 2 Diabetes, AND
- Patient uses both basal insulin and short-acting insulin or uses an insulin pump, AND
- Failure to achieve adequate glycemic control:
  - Hbg A1C level greater than 7% or marked day-to-day variability in glucose levels

**References**


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

SYNAGIS (PALIVIZUMAB)

RSV Season: 10/1 through 3/31

INDICATION and USAGE: Prevention of RSV for children <2yo at high risk of RSV disease.

- Respiratory syncytial virus (RSV) prophylaxis with palivizumab (Synagis®) may be considered medically necessary in the following infants and children to a maximum of five monthly doses:
  - Prematurity
    - Infants who are younger than 12 months of age at the start of RSV season and are born before **29 weeks 0 days** gestation, **or**
    - Infants who are less than 6 months of age at the start of RSV season and are born 28 weeks 0 days to 32 weeks 0 days gestation age, **or**
    - Infants who are less than 6 months of age at the start of RSV season and are born between 32 weeks 1 day and 35 weeks 6 days gestational age, **AND**
    - Prescriber attests that they have performed a RSV-relative risk scale assessment (including childcare attendance, school-aged siblings, twin or greater multiple gestation, young chronological age at the start of RSV season and parental smoking) and has determined patient is at high-risk for RSV disease complicated by hospitalization, **or**
  - Chronic Lung Disease (CLD)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
- Preterm infants younger than 24 months at the start of RSV season who develop chronic lung disease (CLD) or bronchopulmonary dysplasia (BPD) defined as:
  - BPD - Oxygen requirement at 36 weeks gestational age or at 28 days of age regardless of birth gestational age
  - CLD – Infant who has developed an oxygen requirement or other pulmonary condition requiring treatment or close medical observation
  - Infants with CLD/BPD who are less than 24 months of age at start of RSV season who have required intervention or maintenance therapy for their BPD/CLD within 6 months of the start of RSV season (the administration of Synagis in a previous month is sufficient to qualify for administration in a qualified month)
- Infants and children between 12 and 24 months of age who have CLD of prematurity and continue to require supplemental oxygen, diuretic therapy or chronic corticosteroid therapy within six months before the anticipated RSV season.
- **Heart Disease**
  - Infants who are 12 months of age or younger with hemodynamically significant Congenital Heart Disease (CHD). Those children with CHD who are most likely to benefit from immunoprophylaxis include those with:
    - acyanotic heart disease who are receiving medication to control congestive heart failure (documentation required) and will require cardiac surgical procedures; or
    - moderate to severe pulmonary hypertension; or
    - cyanotic heart disease (if recommended by a pediatric cardiologist).
  - Additionally, children younger than 24 months who undergo cardiac transplantation during the RSV season may be considered for prophylaxis.
- **Immune prophylaxis for RSV is considered not medically necessary** for:
  - Infants and children with hemodynamically insignificant heart disease including but not limited to:
    - secundum atrial septal defect,
    - small ventricular septal defect,
    - pulmonic stenosis,
    - uncomplicated aortic stenosis,
    - mild coarctation of the aorta, and
    - patent ductus arteriosus.
  - Lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure.
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.

- **Note**: Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that involve cardiopulmonary bypass, for children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a post-operative dose of palivizumab (15mg/kg) should be considered after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months.

- **Neuromuscular disease, congenital airway anomaly or pulmonary abnormality**
  - Infants under 12 months of age with neuromuscular disease, congenital anomalies of the airway or pulmonary abnormalities that impair the ability to clear secretions from the upper airway because of ineffective cough.

- **Immunocompromised**
  - Infants and children, who are 24 months of age or younger, who are profoundly immunocompromised because of chemotherapy or other conditions during the RSV season.

- **Cystic Fibrosis (CF)**
  - Infants with CF who are younger than 12 months of age with clinical evidence of CLD and/or nutritional compromise.

- **Genetic Disease**
  - Infants who are less than 12 months of age or younger at the start of RSV season, who are clinically diagnosed with Down’s Syndrome
  - Children 12-24 months of age with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile.

- **Dosage and Administration**
  - The recommended dose of Synagis is 15mg/kg body weight administered intramuscularly. Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (>24 weeks) of serum palivizumab concentrations above the desired level for most children, administration of more than 5 monthly doses is not recommended within the continental United States. For qualifying infants who require 5 doses, a dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
in February, which will provide protection for most infants through March. Qualifying infants born during the RSV season may require fewer doses.

- **Discontinuation of Synagis**
  - If any infant or young child receiving monthly Synagis prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season (<0.5%).

- ***Miscellaneous Information**
  - The clinical reviewer, in his or her professional judgment, will override criteria when the requested item is medically necessary. In addition, because there is no definite evidence for the treatment of patients undergoing stem cell transplant or infants and children with Cystic Fibrosis, the approval of Synagis for these patients will be done on a case by case basis by the clinical reviewer.

**References**

7. Virginia Premier Health Plan

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

**SYNVISC/SYNVISC-ONE (HYALURONIC ACID DERIVATIVES, INTRA-ARTICULAR)**

*Euflexxa is the preferred drugs. Member must have tried/failed Euflexxa first unless contraindicated.*

- Osteoarthritis of the knee, AND
- Tried/failed/intolerance to mild analgesic therapy (e.g. acetaminophen) OR tried/failed/intolerance to generic NSAIDs or COX-2 Inhibitors.
- Tried/failed/intolerance to the following:
  - Intra-articular corticosteroid injection (relief <6-8 weeks)
  - Physical therapy, AND
- Must not have large effusions of the knee, AND
- No infections or skin diseases in the knee area, AND
- Trial and failure, intolerance, or contraindication to Euflexxa

**References**


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


TCALONE (CALCIPOTRIENE/BETAMETHASONE DIPROPIONATE)

- PA criteria for FDA age indications. FDA Approved Uses: Topical treatment of psoriasis vulgaris in adults 18 years of age and older for up to 4 weeks.

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
- Must have clinically documented psoriasis vulgaris
- Must be 18 years of age or older
- Tried and failed calcipotriene cream or solution and betamethasone (as separate products) simultaneously
  Or
- Inability (other than convenience or non-compliance) to use two separate medications

Cautions:
- Should not be applied to the face, axillae, or groin
- Should not be used in the presence pre-existing skin atrophy at treatment site
- Treatment of more than 30% body surface area is not recommended
- Maximum weekly dose should not exceed 100gm
- Hypercalcemia has been observed. Discontinue Taclonex if serum calcium exceeds normal range until normal calcium levels are restored. The effects of Taclonex on calcium metabolism beyond 4 weeks is not known.
- May produce reversible HPA axis suppression
- Limit exposure to natural or artificial sunlight

Monitoring:
- Serum calcium
- HPA axis suppression
- Skin infections

References
1. Virginia Premier

TAFINLAR (dabrafenib; BRAF-inhibitor)
- Patient must be >= 18 years old; AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Prescribed by an Oncologist or Hematologist; AND
• A diagnosis of unresectable or metastatic melanoma; AND
• BRAF mutation V600E; AND
• Confirmation of mutation by FDA-approved test, AND
• No Wild-BRAF mutation; AND
• Eastern Cooperative Oncology Group (ECOG) Performance Status 0 – 1; AND
  o Fully active, able to carry on all pre-disease performance without restriction
  o Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g., light house work, office work)
  o Ambulatory and capable of all self care but unable to carry out any work activities; up and about more than 50% of waking hours
  o Capable of only limited self care, confined to bed or chair more than 50% of waking hours
  o Completely disabled: cannot carry on any self care; totally confined to bed or chair
• Baseline ECG, electrolytes, & bilirubin assessed prior to initiation of therapy and within acceptable limits; AND
• Performed dermatologic evaluation; AND
• No concomitant BRAF-inhibitor or MEK-inhibitor, or ipilimumab therapy.

References
1. Virginia Premier

**TALTZ (IXEKIZUMAB)**

**Usual dose**: 160mg (two 80mg injections) SubQ week 0, followed by 80mg SubQ at weeks 2, 4, 6, 8, 12 followed by 80mg SubQ every 4 weeks

**Criteria for approval (bullet points below are all inclusive unless otherwise noted):**

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- Must be 18 years of age or older
- Must be clinically diagnosed with moderate to severe plaque psoriasis
- Must be a candidate for phototherapy or systemic therapy
- Must have tried and failed or intolerant to at least one corticosteroid
- Must have tried and failed or intolerant to methotrexate
- Must have tried and failed or intolerant to Enbrel and Humira
- Must have a negative tuberculosis test or received treatment if tested positive

**Criteria for continuation of therapy:**

- Patient responding to treatment
- Patient tolerating treatment

**Caution:**

- Increased risk of serious infections. If a serious infection develops, discontinue Taltz until the infection resolves.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
- Onset or exacerbation of inflammatory bowel disease.
- Hypersensitivity reactions: if an anaphylactic or other serious allergic reaction occurs, discontinue Taltz immediately and initiate appropriate therapy.

**Contraindication**
- Taltz is contraindicated in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients.

**Special considerations:**
- Patients may not receive live vaccinations.

**Approval Duration:**
- Initial: 3 months
- Renewal: 12 months

**TARCEVA (ERLOTINIB)**

Criteria for Use for NSCLC: (bullet points below are all inclusive unless otherwise noted)

(approved for 3 month period only)
- Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC), AND
- Failure to at least one prior chemotherapy regimen.

Notes: Results from two multicenter, placebo-controlled, randomized, Phase III trials conducted in first line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum-based chemotherapy and its use are not recommended in this setting., OR
- Clinically documented locally advanced, unresectable or metastatic pancreatic cancer, AND
- Must be used in combination with gemcitabine, OR
- Chordoma

**Contraindications:**
- None stated

**Not Approved if:**
- The patient does not meet the above stated criteria.

**References**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

References

TARGRETIN (BEXAROTENE)

APPROVAL CRITERIA
Targretin (bexarotene) may be approved when the following criteria have been met:

- Patient has a diagnosis of cutaneous T-cell lymphoma; AND
- Patient has received at least one prior therapy including but not limited to:
  - Topical mechlorethamine or topical carmustine; OR
  - Psoralen + ultraviolet A (PUVA); OR
  - Methotrexate; OR
  - Bexarotene; OR
  - Denileukin; OR
  - Isotretinoin; OR
  - Pentostatin; OR
  - Fludarabine; OR
  - Cladarabine; OR
  - Photophoresis (extra-corporeal photochemotherapy), OR
- Patient has a diagnosis of Mycosis Fungoides (NCCN), OR
- Patient has a diagnosis of Sezary syndrome (NCCN)


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.


**TASIGNA (NILOTINIB)**

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
- Clinically diagnosed with chronic phase or accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia, AND
  - Must be 18 years of age or older, AND
  - Failed or intolerant to therapy with imatinib (Gleevec), OR
- Clinically diagnosed with Gastrointestinal stromal tumor (GIST), AND
  - Failed or intolerant to imatinib and sunitinib (Sutent), AND
  - Must be 18 years of age or older, OR
- Newly-diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, AND
  - Failed or intolerant to therapy with Imatinib, AND
  - Patient is 1 year of age or older

Criteria for Continuation of Therapy:
- Patient responding to treatment without disease progression

Cautions:
- Capsules contain lactose- do not use in patients with galactose intolerance, severe lactase deficiency, or glucose-galactose malabsorption syndromes
- Caution should be exerted when patients are on concurrent drugs that prolong the QT interval as Tasigna can also prolong the QT interval resulting in Torsades de pointes, which can result in seizure, syncope, and death
- Use in caution in patients with pancreatitis as Tasigna may cause dose limiting elevations of serum lipase and amylase
- Tasigna may cause hepatotoxicity and dose-limiting elevations in bilirubin, AST, ALT, and phosphatase
- Tasigna should be used in caution in patients with hepatic impairment as metabolism of the drug is mostly hepatic (Tasigna has not been studied in patients that have AST or ALT levels greater than 2.5 times the upper limit of normal or greater than 5 times the upper limit of normal if disease related or in patients with bilirubin greater than 1.5 times the upper limit of normal
- Myelosuppression (grade 3 or 4 thrombocytopenia, neutropenia, or anemia) may occur with treatment
- Electrolyte abnormalities (hypophosphatemia, hypokalemia, hyperkalemia, hypocalcemia, hyponatremia) may occur with treatment

Monitoring and does adjustments:
- CBC with differential (every 2 weeks for the first 2 months and then monthly thereafter)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Electrolytes (baseline and periodic)
- Hepatic function- AST, ALT, bilirubin, and alkaline phosphatase should be monitored at baseline and periodically thereafter
- Serum lipase (baseline and periodic)
- Bone marrow assessments
- ECG (baseline, 7 days after initiation of treatment or dosage adjustments, then periodic)

**Dose Adjustments for QT Prolongation**

- ECGs with a QTc > 480 msec
  1. Withhold Tasigna, and perform an analysis of serum potassium and magnesium, and if below lower limit of normal, correct with supplements to within normal limits. Concomitant medication usage must be reviewed.
  2. Resume within 2 weeks at prior dose if QTcF returns to <450msec and to within 20 msec of baseline.
  3. If QTcF is between 450 msec and 480 msec after 2 weeks reduce the dose to 400 mg once daily.
  4. If, following dose-reduction to 400 mg once daily, QTcF returns to >480 msec, Tasigna should be discontinued.
  5. An ECG should be repeated approximately 7 days after any dose adjustment.

- Dose Adjustments for Neutropenia and Thrombocytopenia
  - Chronic Phase or Accelerated Phase CML at 400 mg twice daily
    1. ANC* < 1.0 x 10⁹/L and/or platelet counts < 50 x 10⁹/L
      1. Stop Tasigna, and monitor blood counts
      2. Resume within 2 weeks at prior dose if ANC >1.0 x 10⁹/L and platelets >50 x 10⁹/L
      3. If blood counts remain low for > 2 weeks, reduce the dose to 400 mg once daily

- **Contraindications:**
  - Do not use in patients with hypokalemia, hypomagnesemia, or long QT syndrome.

**Not Approved if:**

- Does not meet the above stated criteria, OR
- Have any contraindications to the use of nilotinib, OR.
- Patients with the BCR-ABL mutation T315I, as data suggests that Tasigna is not effective against this mutation, OR
- Patients with galactose intolerance, severe lactase deficiency, or glucose-galactose malabsorption syndromes

**Special Considerations:**

- FDA’s approval of Tasigna includes a black box warning for possible life-threatening heart problems that may lead to an irregular heartbeat and possible sudden death.
- The effectiveness of Tasigna is based on hematological and cytogenetic (chromosome related) response rates. So far, no controlled trials have shown a clinical benefit, such as improvement in disease related symptoms or increased survival.
- Imatinib Resistance/failure
- Failure to achieve a complete hematologic response (CHR) after 3 months or loss of CHR, or a failure to achieve a cytogenetic response (CyR) after 6 months or loss of CyR, or a failure to achieve a major cytogenetic response (MCyR) after 12 months of treatment or loss of MCyR
- Imatinib Intolerance
requests for continuing therapy that were approved by a previous health plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Grade 3 or 4 adverse events that persist despite optimal supportive care,
- or grade 2 or higher adverse events that persist for longer than a month,
- or grade 2 or higher adverse events that recur more than 3 times despite optimal supportive care

Please note: Initial fill will be limited to a 14 days supply

References

TAVALISSE (FOSTAMATINIB DISODIUM HEXAHYDRATE)

I. Length of Authorization
   a. Coverage is provided for six months and may be renewed.

II. Dosing Limits
   a. Quantity Limit (max daily dose) [Pharmacy Benefit]: – 100 mg tablets – 2 tablets per day – 150 mg tablets – 2 tablets per day
   b. Max Units (per dose and over time):
      • 300 mg daily

III. Initial Approval Criteria - Coverage is provided in the following conditions:
   a. Chronic immune (idiopathic) thrombocytopenia (ITP)
      • Patient aged 18 years or older; AND
      • Patient has previously failed any of the following treatments for ITP:
         1. Patient has failed previous therapy with corticosteroids; OR
         2. Patient has failed previous therapy with immunoglobulins; OR
         3. Patient has had a splenectomy; OR
         4. Patient has failed previous therapy with a thrombopoietin receptor agonist (e.g., eltrombopag, romiplostim, etc.); AND
      • The patient is at increased risk for bleeding as indicated by platelet count (within the previous 28 days) of less than 30 x 10⁹ /L (30,000/mm³); AND
      • Tavalisse is not being used to attempt to normalize platelet count.

IV. Renewal Criteria - Coverage can be renewed based upon the following criteria:
   a. Chronic immune (idiopathic) thrombocytopenia (ITP)
      • Patient continues to meet the criteria identified in section III; AND

Requests for continuing therapy that were approved by a previous health plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hepatotoxicity (abnormal liver enzymes), hypertension, severe diarrhea and severe neutropenia, etc.; AND
• Disease response indicated by the achievement and maintenance of a platelet count of at least $50 \times 10^9 / L$ as necessary to reduce the risk of bleeding and/or the patient has demonstrated a documented decrease in requiring rescue treatment with platelet transfusions.

References

TAZORAC (TAZAROTENE)
• Acne vulgaris, AND
  o Tried/failed/intolerance to topical tretinoin, OR
• Plaque psoriasis, AND
  o Applied to < 20% of Body Surface Area, AND
  o Tried/failed/intolerance to two topical corticosteroids (e.g., clobetasol, fluocinonide, mometasone, triamcinolone), AND
• If female and able to bear children (e.g., no hysterectomy, not reached menopause, has achieved menses), patient has a negative pregnancy test prior to initiation of treatment, and prescriber confirmation that discussed with the patient the potential risks of fetal harm and importance of birth control while using Tazorac.

References
6. Webster GF et al. Efficacy and tolerability of once-daily tazarotene 0.1% gel versus once-daily tretinoin 0.025% gel in the treatment of facial acne vulgaris: a randomized trial. Cutis 2001;67(6 Suppl):4-9

**TEGSEDI (INOTERSEN)**

**CRITERIA FOR USE**

- Used for the treatment of hereditary transthyretin amyloidosis-associated polyneuropathy

**AND**

- Documentation is provided that the patient has a pathogenic TTR mutation
  **AND**
- Patient must be 18 years of age or greater
  **AND**
- Prescribed by or in consultation with a neurologist
  **AND**
- Documentation of one of the following; baseline polyneuropathy disability (PND) score of less than or equal to IIIb; OR baseline FAP stage 1 or 2; OR baseline neuropathy impairment (NIS) score of greater than or equal to 10 and less than or equal to 130
  **AND**
- Patient has clinical signs and symptoms of the disease, confirmed by submitted clinical documentation (chart notes, prescriber statement, etc.)
  **AND**
- Patient is will not be receiving Tegsedi in combination with Oligonucleotide agents

**Renewal**

- Patient continues to meet above criteria
  **AND**
- Documentation the patient has received a positive clinical response to Tegsedi therapy
  **AND**
- Prescribed by or in consultation with a neurologist

**Quantity Limit**

- 4 syringe/month

**Approval Duration:** Initial - 6 months, Renewal – 12 months

**References:**

Tegsedi [package insert]. Ionis Pharmaceuticals, Inc: Carlsbad, CA; October 2018


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

TEKTURNA (ALISKIREN)

• PA criteria for FDA age indications.
Criteria for Use: (bullet points below are all inclusive unless otherwise noted):
  • Clinically diagnosed mild to moderate hypertension.
  • Failed / intolerant to thiazide diuretics.
  • Failed / intolerant to ace inhibitors
  • Failed/ intolerant to ARBs.
  • Failed/ intolerant to beta blockers
  • Failed / intolerant to calcium channel blockers
  • Must have tried and failed two drug combinations
Cautions:
  • Experience with the use of aliskiren in patients with severe renal impairment is limited and therefore, caution is warranted
• Drug interactions:
  o Irbesartan (Avapro) - 50% reduction in aliskiren concentrations
  o Atorvastatin (Lipitor)- 50% increase in aliskiren concentrations
  o Ketoconazole (Nizoral) - 80% increase in aliskiren concentrations
  o Furosemide (Lasix)- reduced blood concentration levels of furosemide
Contraindications:
  • None reported at this time.
Not Approved if:
  • Does not meet the above stated criteria

References
1. Virginia Premier

TERSI (SELENIUM SULFIDE) FOAM

• PA criteria for FDA age indications.
Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
  • Clinically diagnosed seborheic dermatitis
  • Failed other OTC topical treatments.
  • Failed/intolerant to selenium sulfide lotion prescription strength (Selsun)
Contraindications:
  • Allergy to any component of the product
Not Approved if:
  • Above criteria not met
  • Being used to treat tinea versicolor since this condition is not a covered benefit.
  • Patient has any contraindications to the use of selenium sulfide.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

**THALOMID (THALIDOMIDE)**

**APPROVAL DURATION:** 6 months  
**APPROVAL CRITERIA:** Thalomid may be approved if the diagnosis is ONE of the following:

I. Acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL);  
   -OR-

II. As maintenance therapy for prevention and suppression of the cutaneous manifestations of erythema nodosum leprosum (ENL);  
   -OR-

III. Individuals with a diagnosis of multiple myeloma (including systemic light chain amyloidosis) (NCCN)  
   -OR-

IV. Waldenstrom’s Macroglobulinemia (NCCN)  
   -AND-

- Must be administered in compliance with all of the terms outlined in the S.T.E.P.S* program.
- Must be prescribed by a physician that is registered with the S.T.E.P.S program.
- Women of childbearing age must meet all of the following conditions:
  - Alternative therapies have failed or are considered inappropriate.
  - Understands and can reliably carry out instructions
  - Must be capable of complying with the mandatory contraceptive measures, pregnancy testing, patient registration, and patient survey as described in the S.T.E.P.S program.
  - Has received both oral and written warnings of the hazards of taking thalidomide during pregnancy and exposing a fetus to the drug.
  - Has received both oral and written warnings about the need to use two forms of contraception or continuous abstinence from sexual contact and she acknowledges in written of her understanding of this.
  - Has a negative pregnancy test within 24 hours prior to beginning therapy.
  - For patients between 12 and 18 years of age, her parent or legal guardian must agree to the above.
- Men who are sexually mature must meet all of the following conditions:
  - Alternative therapies have failed or are considered inappropriate.
  - Understands and can reliably carry out instructions
  - Must be capable of complying with the mandatory contraceptive measures, pregnancy testing, patient registration, and patient survey as described in the S.T.E.P.S program.
  - Has received both oral and written warnings of the hazards of taking thalidomide and exposing a fetus to the drug.

References

1. Virginia Premier
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

- Has received both oral and written warnings about the presence of thalidomide in semen. The need to use a latex condom during any sexual contact with women of childbearing potential, even if he has undergone a vasectomy.
- For patients between 12 and 18 years of age, his parent or legal guardian must agree to the above. • Patient must be 12 years of age or older since the safety and effectiveness has not been established in children under 12 years of age.

Criteria for Continuation of Use:
- Women of childbearing age must have pregnancy testing done once weekly during the first 4 weeks of treatment and then once every 4 weeks if the menstrual cycle is regular and once every 2 weeks if the menstrual cycle is irregular and the results must be negative each time.
- White blood cell count and differential should be monitored. If ANC decreases to below 750/mm³ while on treatment, consideration should be given to discontinuing therapy if neutropenia persists.

Contraindications:
- Pregnant women
- Women capable of becoming pregnant (see number 4 under guidelines for criteria).
- Hypersensitivity to the use of thalidomide.
- ANC < 750/mm³

Cautions:
- The use of thalidomide in multiple myeloma results in an increased risk of venous thromboembolic events. This risk significantly increased when used in combination with standard chemotherapeutic agents including dexamethasone.

Not approved if:
- Patient is pregnant.
- Patient does not meet the above stated criteria.
- Patient has any contraindications to the use of thalidomide.

Dosing/Regimen:
- Erythema nodosum leprosum (ENL) - 100 mg up to a maximum of 400 mg once daily or in divided doses.
- Multiple myeloma - 200 mg once daily with dexamethasone 40 mg daily on days 1-4, 9-12, and 17-20 every 28 days.

Authorization and Limitations:
If the above criteria are met initial authorizations is 6 months. Physicians must provide updates on disease progression. If disease progression is noted therapy may not be continued. Based on the maximum daily dose the following quantities will be limited to: 1 capsule per day. The quantity is limited to a maximum of a 30 day supply per fill.

The above criteria is based on the following reference(s):
1. Thalomid package insert. Summit, New Jersey: Celgene

* System for Thalidomide Education and Prescribing Safety (S.T.E.P.S) - Because of the toxicity and in an effort to make the chance of fetal exposure to thalidomide as negligible as

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
possible, thalidomide is approved by the FDA. Under this restricted distribution program, only prescribers and pharmacists registered with the program are allowed to prescribe and dispense the product. In addition, patients must be advised of, agree to, and comply with the requirements of the S.T.E.P.S program in order to receive product.

*Any suspected fetal exposure to Thalomid must be reported immediately to the FDA via the MedWatch number at 1-800-FDA-1088 and also to Celgene Corporation.*

**TOPICAL ANDROGEN AGENTS**

**Initial Criteria:**
- Patient is MALE AND
- Patient is at least 18 years of age
- Patient has a diagnosis of primary or secondary hypogonadism
- Patient does not have a history of prostate or male breast carcinoma;
- Prescriber must submit at least **TWO** separate serum testosterone levels (each drawn in the morning) that indicate level is below normal range (300 – 1,000 ng/dL within the past 6 months)

**Renewal Criteria:**
- Patient has been compliant with treatment based on refill history; AND
- Prescriber has submitted a serum testosterone level within normal range within past 12 months

**TOPICAL LIDOCAINE**
- Being used for topical anesthesia of the skin and mucous membranes, AND
- Patient has a clinical trial and failure to **ALL** of the following:
  - Lidocaine 4% cream (Aspercreme 4%)
  - Lidocaine 5% ointment
  - Lidocaine 2% gel
  - Lidocaine 5% patch

**TOPIRAGEN, TOPAMAX, TOPIRAMATE ER**
- The patient has a diagnosis of:
  - Adjunct treatment for Lennox-Gastaut syndrome, OR
  - Migraine prophylaxis, OR
  - Partial seizure, OR
  - Tonic-clonic seizure, OR
  - Tried/failed/intolerance to topiramate; AND
  - Must have a documented inadequate response, intolerance, or contraindication to topiramate IR by chart notes.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
If the member has been stabilized on the medication, the provider must submit a form or chart notes, or the patient has claims history for the medication within the the previous 90 days.

References

TRELSTAR (TRiptorelin PAMOATE)
- Prostate cancer, AND
  - Tried/failed/intolerance or documented unacceptable for orchiectomy or estrogen, OR
- Metastatic prostatic carcinoma or stage B2-C prostatic, OR
- Endometriosis:
  - Tried/failed/intolerance to at least two of the following:
    - oral contraceptive
    - medroxyprogesterone
    - danazol, AND
  - Tried/failed/intolerance to Leuprolide, OR
- Uterine Leiomyoma (uterine fibroids), AND
  - Tried/failed/intolerance to Leuprolide, OR
- Central precocious puberty, AND
  - Tried/failed/intolerance to Leuprolide

References


**TREXIMET (SUMATRIPTAN SUCCINATE/NAPROXEN SODIUM)**

PA criteria for FDA age indications.

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- Clinically diagnosed migraine headaches
- Failed/ intolerant to 2 FCHP preferred alternative triptan products used alone
- Failed treatment with sumatriptan and naproxen as separate products used at the same time
- 18 years of age or older
- Treatment is for 5 headaches a month or less. If requested quantities are greater than the manufacturer recommendation, the request must be submitted with documentation as to why larger quantities are required, including all applicable criteria as indicated in the “Excess Quantity Limit criteria”.

**Contraindication:**
- History, symptoms, or signs of ischemic cardiac, cerebrovascular, or peripheral vascular syndromes.
- Other significant underlying cardiovascular diseases
- Coronary artery bypass graft (CABG) surgery
- Uncontrolled hypertension.
- Within 24 hrs of ergot-type drugs or concurrent administration of MAO-A inhibitors or within 2 weeks of discontinuing MAOIs or within 24 hours of another 5-HT1 agonist
- Basilar headaches or hemiplegic migraine
- Hepatic impairment
- Allergy to naproxen/asthma, nasal polyps, urticaria, and hypotension associated with nonsteroidal anti-inflammatory drugs
- Hypersensitivity to sumatriptan or naproxen or any of Treximet’s components

Available dosage forms: tablet containing sumatriptan (85 mg) and naproxen sodium (500 mg) (packs of 9 tablets

**References**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
1. Virginia Premier

**TRINTELLIX (VORTIOXETINE)**

**Criteria for use (bullet points below are all inclusive unless otherwise noted):**
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- **Must be 18 years of age or older**
- **Clinically diagnosed major depressive disorder.**
- Failed or intolerant to at least one generic SSRI (Citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine HCl immediate-release, sertraline).
  - **AND**
  - Failed or intolerant to at least one SNRI (duloxetine, venlafaxine, desvenlafaxine, Fetzima)
  - **AND**
  - Viibryd

**Criteria for continuation of therapy:**
- Patient is tolerating and responding to medication and there continues to be a medical need for the medication. Renew yearly.

**Contraindication:**
- Hypersensitivity to vortioxetine or any components of the Brintellix formulation.
- Must not be used concomitantly with an MAOI or within 14 days of stopping an MAOI. Do not use MAOI's within 21 days of stopping treatment with Brintellix.
- Do not start Brintellix in a patient who is being treated with linezolid or IV methylene blue.

**Not approved if:**
- Patient has any contraindications to the use of Brintellix.
- Patient does not meet the above stated criteria.

**Description:** Brintellix (vortioxetine) inhibits reuptake of serotonin (5-HT). It also has agonist activity at the 5-HT1A receptor and antagonist activity at the 5-HT3 receptor. The mechanism of the antidepressant effect of vortioxetine is not fully understood, but is thought to be related to its enhancement of serotonergic activity in the CNS through inhibition of the reuptake of serotonin (5-HT). It also has several other activities including 5-HT3 receptor antagonism and 5-HT1A receptor agonism. The contribution of these activities to vortioxetine’s antidepressant effect has not been established.

- **FDA-approved uses:** treatment of major depressive disorder
- **Available dosage forms:** 5, 10, 15, and 20mg tablets
- **Usual dose:** Starting dose is 10mg once daily up to a maintenance dose of 20mg once daily.

- **Duration of therapy:** Renew yearly, If the below criteria are met authorization will be given for 1 year.
- Quantities will be limited to 1 tablet per day (30 tablets per month)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

References

1. Virginia Premier

**TRIZIVIR (ABACAVIR SULFATE/LAMIVUDINE/ZIDOVUDINE)**

Duplicate therapy:
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

References

1. Virginia Premier

**TROKENDI XR (TOPIRAMATE)**

- The patient has a diagnosis of:
  - Adjunct treatment for Lennox-Gastaut syndrome, OR
  - Partial seizure, OR
  - Tonic-clonic seizure, AND
  - Must have a documented inadequate response, intolerance, or contraindication to topiramate IR, topiramate ER, and Qudexy XR by chart notes.
  - If the member has been stabilized on the medication, the provider must submit a form or chart notes, or the patient has claims history for the medication within the previous 90 days.

References

1. Virginia Premier

**TRUVADA (EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE)**

Duplicate therapy:
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

References

1. Virginia Premier

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

**TYSABRI (NATALIZUMAB)**

- Multiple Sclerosis, AND
  - Tried/failed/intolerance to Avonex, Betaseron, Copaxone, or Rebif, OR
- Moderate to severe Crohn’s Disease, AND
  - Patient does not have perforation, abscess, or obstruction, AND
  - Tried/failed/intolerance to Humira or Remicade

**References**


TYVASO (TREPROSTINIL)

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Clinically diagnosed with pulmonary arterial hypertension WHO Group 1. The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient's medical records
- Patients with NYHA class III
- Prescribed by a pulmonologist or cardiologist
- Patient is not smoking cigarettes
- Must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test.
- Must have tried and failed sildenafil
- Must have tried and failed either bosentan or ambrisentan
- Must have baseline 6 minute walking distance
- QL of 28 ampules or 81.2 mls /28 days

Criteria for continuation of therapy:

- Patient tolerating treatment
- By 12 weeks the patient must show an increase in exercise ability, demonstrated by a 20 meter improvement in 6 minute walking distance

References:

1.) Tyvaso [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp.; April 2013

ULTOMIRIS (RAVULIZUMAB-cwvz)

CRITERIA FOR USE

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Patient must have diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by HAM test of flow cytometry, with at least 10% PNH type III red cells
  
  AND

• Patient must be 18 years of age or greater
  
  AND

• Patient must be vaccinated against meningococcal infection (at least 2 weeks prior to treatment, if not previously vaccinated)

• Documented baseline value for serum lactate dehydrogenase (LDH)
  
  AND

• Patient must have one of the following: Transfusion dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation due to documented hemoglobin < 7 g/dL (without anemic symptoms), or <9 g/dL (with symptoms from anemia) and has platelet count of at least 30,000/microliter prior to initiation of treatment, or history of thromboembolism, pulmonary hypertension, renal insufficiency, or other end organ complications from PNH, or atypical hemolytic uremic syndrome without serious unresolved Neisseria meningitides infection
  
  AND

• Patient has tried/failed or intolerant to Soliris

### UPTRAVI (SELEXIPAG)

• Diagnosis of pulmonary arterial hypertension, WHO Group I

• NYHA Functional Class II-III

• Prescribed by or in conjunction with a cardiologist or pulmonologist

• ≥ 18 years of age

• Must have trial and failure or intolerance to Sildenafil (Revatio) or Adcirca (tadalafil) AND Letairis (ambrisentan)

• Patient does not have severe hepatic impairment or currently breastfeeding.

References


### ULESFIA, OVIDE & LINDANE

• Indications:

• **Lindane (shampoo):** Treatment of head lice (Pediculosis humanus capitis), crab lice (Pthirus pubis), and their ova only in patients who have failed or cannot tolerate other approved therapies. **The CDC recommends this agent not be used in infants and children less than 2 years old.**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
- **Ovide (lotion):** Indicated for patients infested with Pediculus humanus capitus (head lice and their ova) of the scalp hair in patients ≥ 6 years old.

- **Ulesfia (lotion):** Indicated for the topical treatment of head lice infestation in patients 6 months of age and older. Ulesfia does not have ovicidal activity.

- **Quantity Limits**

  - **LINDANE** Shampoo: 1% (Quantity Limit 60ml)
  - **OVIDE® (malathion)** Lotion: 0.5% (Quantity Limit 60ml)
  - **ULESFIA™ (benzyl alcohol)** Lotion: 5% (Quantity Limit 48oz)

- **PA CRITERIA FOR APPROVAL:**
  - Diagnosis of pediculus capitus (head lice and its eggs).
  - Age appropriateness and Documented trial and failure of a first line agent (permethrin or pyrethrin/piperonyl butoxide) within the previous 45 days, but no earlier than 21 days after the original fill.

  - If the above conditions are met, the request will be approved. If the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.

- **PA CRITERIA FOR RENEWAL:**
  - Ovide and Ulesfia can be approved for a second treatment if live lice are present 7-9 days after the initial treatment.

  - If the above condition is met, the request will be approved for a maximum of 2 treatments in a 30 day period. If the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.

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**VANTAS (HISTRELIN)**

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Clinically diagnosed with advanced prostate cancer
- 18 years of age or older
- Male

Criteria for continuation of therapy:

- Testosterone continues below castration level

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**VASCEPA (ICOSAPENT ETHYL)**

Criteria for Use:

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.

Clinically diagnosed hypertriglyceridemia with a baseline triglyceride (TG) level > 500mg/dl AND

Must already be on an appropriate lipid lowering diet and should continue during treatment with Vascepa AND

Failed / intolerant to Niaspan (niacin ER), AND

Failed/ intolerant to at least one fibric acid derivative such as: Antara (fenofibrate) micronized, Tricor (fenofibrate), or Lopid (gemfibrozil), OR

Patient taking a statin and is unable to take a fibric acid derivative or niacin due to an increased risk of myopathy

VENTAVIS (ILOPROST)

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Clinically diagnosed with pulmonary arterial hypertension WHO Group 1. The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- Patients with NYHA class III-IV
- Prescribed by a pulmonologist/cardiologist
- Patient is not smoking cigarettes
- Must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test.
- Must have tried and failed sildenafil
- Must have tried and failed either bosentan or ambrisentan
- Ventavis is primarily an outpatient therapy initially administered under the care of a healthcare professional

Criteria for continuation of therapy:

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication
- Patient has improved exercise capacity or a delay in clinical worsening

References:


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
VERDESO (DESONIDE) FOAM

• PA criteria for FDA age indications. FDA Approved Uses: Mild to moderate atopic dermatitis in patients 3 months of age or older.
Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
  • Clinically documented mild to moderate atopic dermatitis.
  • Failed/intolerant to desonide (DesOwen) cream, ointment or lotion.
  • Failed/intolerant to other intermediate potent topical corticosteroids such as fluocinolone, fluticasone, traimcinolone or mometasone.

Contraindications:
  • Patients who are hypersensitive to desonide or to any ingredient in the preparation.

Not approved if:
  • Patient does not meet the above stated criteria.
  • Patient has any contraindications to the use of topical corticosteroids.

References
1. Virginia Premier

VERZENIO (ABEMACICLIB)

• Patient is taking Verzenio in one of the following indications:
  o in combination with fulvestrant for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy; or
  o as monotherapy for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
  o in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer
  • Prescribed by an oncologist
  • Patient is 18 years of age or older
  • If patient is a female of child-bearing age, member is NOT pregnant or breast feeding

Authorization Dates:
  • 12 months

VFEND (VORICONAZOLE)

• PA criteria for FDA age indications.
FDA Approved Uses: treatment of:
  - invasive aspergillosis,
  - Fungal infections due to Scedosporium apiospermum, Fusarium spp.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- esophageal candidiasis
- candidemia in non-neutropenic patients and,
- the following Candida infections:
  - disseminated infections in skin and abdomen,
  - kidney,
  - bladder wall and,
  - wounds.

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
• Clinically documented fungal infection invasive aspergillosis, Scedosporium apiospermum, or Fusarium spp that is susceptible to voriconazole.
  o Fungal culture and other relevant laboratory studies (including histopathology) need to be obtained to isolate and identify causative organisms.
  • Failed/ intolerant to at least one other antifungal therapy.
  Or
• Clinically documented esophageal candidiasis, candidemia or wound infection due to candida.
  o Must have failed or is intolerant to oral fluconazole.

Contraindications:
• Hypersensitivity to voriconazole or its excipients.
• Coadministration with terfenadine, astemizole, cisapride, pimozide, or quinidine can lead to QT prolongation or Torsade de Pointes.
• Coadministration with sirolimus can lead to increased sirolimus levels.
• Coadministration with rifampin, carbamazepine and long-acting barbiturates can lead to decreased voriconazole levels. • Coadministration with rifabutin can increase rifabutin levels and voriconazole levels can be decreased.
• Coadministration with ergot alkaloids can result in ergotism.

Not approved if:
• The patient has any contraindications to the use of voriconazole.
• The patient does not meet the above stated guidelines for approval.

References
1. Virginia Premier

VIAGRA (SILDENAFIL CITRATE)
• Prescribed by a pulmonologist
• Pulmonary Arterial Hypertension (PAH) diagnosis only. (Only this diagnosis will be approved).

References
1. Virginia Premier

VIBERZI (ELUXADOLINE)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Must have diagnosis of diarrhea predominant Irritable Bowel Syndrome **AND**
• Must be 18 years old or over **AND**
• Must have failed conventional therapies including: Dietary changes (including fiber), or stress reduction, or behavioral changes **AND** any ONE of the following medications:
  a. Anti-diarrheals (i.e. Loperamide, diphenoxylate/atropine); **OR**
  b. Antispasmodics (hyoscyamine, dicyclomine); **OR**
  c. Tricyclic antidepressants (despiramine, imipramine)
  **AND**
• The member does not have severe (Child-Pugh C) hepatic impairment; **AND**
• Must be prescribed by a gastroenterologist; **AND**
• Other gastrointestinal medical conditions that could explain the symptoms have been ruled out; **AND**
• Must have tried and failed Xifaxan

**For Continuation of therapy**
• Patient must be responding to treatment and tolerating treatment; **AND**
• Patient must continue to follow dietary and physical activity recommendations

**Approval Duration:**
• 6 months

**Caution:**
• Sphincter of Oddi Spasm and Pancreatitis

**Contraindications:**
• Biliary Duct Obstruction
• Sphinicter of Oddi dysfunction
• Alcoholism
• History of Pancreatitis
• Severe Hepatic Impairment
• History of severe constipation or mechanical GI obstruction

**References**

**VIIBRYD (VILAZODONE HYDROCHLORIDE)**

• PA criteria for FDA age indications. FDA-approved uses: treatment of major depressive disorder in adults.
  Criteria for use (bullet points below are all inclusive unless otherwise noted):
  • The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
    • Must be 18 years of age or older

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• Clinically diagnosed major depressive disorder.
• Failed or intolerant to at least one generic SSRI.
• Failed or intolerant to at least one SNRI or any other anti-depressant from a different class.
Contraindication:
• Must not be used concomitantly with an MAOI or within 14 days of stopping an MAOI. Allow 7 days after stopping Viibryd before starting an MAOI.
Not approved if:
• Patient has any contraindications to the use of Viibryd.
• Patient does not meet the above stated criteria.

References

1. Virginia Premier

**VIMOVO (NAPROXEN/ESOMEPRAZOLE)**

***Partially approve the EOC and submit to the PA Hub External queue. Send an e-mail to Adam @ aharbert@rxoptions.net and the “CC” the CDPharmacist e-mail distribution box, noting the EOC # and requested indication for use.

• Diagnosed with rheumatoid arthritis or osteoarthritis, or other chronic diseases associated with pain, **AND**
• Predisposition to gastric ulcer, **AND**
• Failed/intolerant to Celecoxib*, **AND**
• Failed/intolerant to preferred formulary proton pump inhibitors and any formulary Naproxen, **AND**
• Intolerance to naproxen delayed-release and **Nexium 24Hr OTC used simultaneously for 90 days**. (both are formulary)**

Or

• Inability to use two separate medications-Specifically documented.

*Celecoxib requires a prior authorization. Please place a PA for Celecoxib for patient in lieu of Vimovo.

Not approved if:
• Does not meet the above stated criteria

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
1. Virginia Premier

**VIVITROL (NALTREXONE) INJ**

Criteria for use for alcohol dependence (bullet points below are all inclusive unless otherwise noted):
- Patient must be 18 years old or over
- Patient must have already abstained from drinking alcohol.
- Must be part of a comprehensive treatment program for alcohol dependence that should include a psychosocial support system.
- Failed/intolerant to oral naltrexone
- Failed/intolerant to Campral
  - Campral requires a prior authorization and the criteria that must be met for approval.

Criteria for use for opioid dependence (bullet points below are all inclusive unless otherwise noted):
- Patient must be 18 years old or over
- Patient must be opioid free for a minimum of 7-10 days
- Patient must not have a current need for opioid analgesics
- Must be part of a comprehensive treatment program for opioid dependence that should include a psychosocial support system.
- Failed/intolerant to oral naltrexone
- Failed/intolerant to Suboxone and Subutex

**Contraindications:**
- Should not be administered to patients in opioid withdrawal.
- Acute hepatitis or liver failure.
- Patients allergic to naltrexone, or any inactive ingredient of Vivitrol powder or diluent.
- **Not approved if:**
  - Does not meet the above stated criteria.
  - Have any contraindications to the use of Vivitrol.

**Special considerations:**
- Alternative to daily doses of oral naltrexone.
- Expected to work the same as oral naltrexone.
- No head to head trials with other medications for alcohol dependence.
- No head to head trials with other medications for opioid dependence.
- High incidence of nausea that may decrease with subsequent doses.
- Patients at risk of opioid overdose after stopping therapy and restarting prior opioid dose.
  - Patients are advised to wear a medical alert bracelet so they get proper pain management in case of an emergency. If an opioid must be used in the ER or hospital, the dose must be carefully titrated to give enough to overcome the naltrexone, but not too much to cause respiratory depression."** The patient does not meet the above stated guidelines for approval.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

References

1. Virginia Premier

VORICONAZOLE (GENERIC VFEND)

PA criteria for FDA age indications.

- FDA Approved Uses: treatment of:
  - invasive aspergillosis,
  - Fungal infections due to Scedosporium apiospermum, Fusarium spp.
  - esophageal candidiasis
  - candidemia in non-neutropenic patients and
  - the following Candida infections:
    - disseminated infections in skin and abdomen,
    - kidney,
    - bladder wall and,
    - wounds.

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)

- Clinically documented fungal infection invasive aspergillosis, Scedosporium apiospermum, or Fusarium spp that is susceptible to voriconazole.
  - Fungal culture and other relevant laboratory studies (including histopathology) need to be obtained to isolate and identify causative organisms.
    - Failed/ intolerant to at least one other antifungal therapy.
  Or
    - Clinically documented esophageal candidiasis, candidemia or wound infection due to candida.
  - Must have failed or is intolerant to oral fluconazole.

Contraindications:

- Hypersensitivity to voriconazole or its excipients.
- Coadministration with terfenadine, astemizole, cisapride, pimozide, or quinidine can lead to QT prolongation or Torsade de Pointes.
- Coadministration with sirolimus can lead to increased sirolimus levels.
- Coadministration with rifampin, carbamazepine and long-acting barbiturates can lead to decreased voriconazole levels.
- Coadministration with rifabutin can increase rifabutin levels and voriconazole levels can be decreased.
- Coadministration with ergot alkaloids can result in ergotism.

Not approved if:

- The patient has any contraindications to the use of voriconazole.
- The patient does not meet the above stated guidelines for approval.

References

1. Virginia Premier
VRAYLAR (CARIPRAZINE)

- Clinically diagnosed with Schizophrenia or Manic or Mixed episodes associated with bipolar 1 disorder; AND
- Patient is 18 years of age or older
- Patient has had a trial and failure, inadequate response, or contraindication to therapy with two (2) of the following alternatives:
  - Risperidone
  - Olanzapine
  - Quetiapine
  - Ziprasidone
  - Aripiprazole (PA required)
- Not approved if:
  - Patient has any contraindications to the use of Vraylar.
  - Patient does not meet the above stated criteria.
  - Patient has dementia-related psychosis.
- Special considerations:
  - Black box warning:
    - Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo.

References

1. Virginia Premier

WEIGHT LOSS

Prior Authorization – (Duration of Approval – 6 months per authorization, 3 months interval for Qsymia®)

A prior authorization request will be required for all prescriptions for the anti-obesity medications listed below. These requests will be approved when the following criteria are met:

_Xenical®, Qsymia®, Belviq, Alli®, phentermine, diethylpropion, phendimetrazine, benzphetamine_

Initial Therapy

Documentation of the following:

1. Body Mass index (BMI) > 30 kg/m²; OR Body Mass Index > 27 kg/m² and at least one of the following high risk factors:
   - Obstructive Sleep Apnea
   - Coronary Heart Disease
   - Type 2 Diabetes
   - Atherosclerotic disease; AND

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
2. Inability to meet target weight loss goal despite lifestyle modifications including dietary changes and participating in a structured exercise program for at least 2 months; AND

Continuation of Therapy

*Xenical*, Belviq, Alli®, phentermine, diethylpropion, phendimetrazine, benzphetamine

Documentation of the following:

1. Continued coverage (up to 12 months) may be authorized for members who provide documentation of weight loss of at least 5% during the first 12 weeks of treatment; AND

2. The member continues to practice lifestyle modifications including dietary changes and participates in a structured exercise program.

Note: The Plan will not approve use of any of the above anti-obesity medications for more than a total of 24 months.

Limitations Virginia Premier will *not* approve coverage for anti-obesity agents in the following instances:

- When the above criteria are not met.
- Member under 18 years of age
- Member has contraindications to the use of agent.
- When the total duration of use of the medication is > 24 months.

References


2. Product Information. Adipex –P UpToDate® accessed July 2012

3. Product Information Xenical® UpToDate® accessed July 2012


**XELODA (CAPECITABINE)**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

- Dukes’ C, Stage II, or Stage III Colon Cancer, OR
- Metastatic Colorectal Carcinoma (Colon Cancer or Rectal Cancer), OR
- Adenocarcinoma of the Distal Esophagus or Gastroesophageal Junction, OR
- Advanced/metastatic Gastric Cancer, AND
  - Xeloda is being used as a component of modified ECF (epirubicin, cisplatin or oxaliplatin, and capecitabine) protocol, OR
- Locoregional disease as capecitabine-based chemoradiation for unresectable disease in medically fit patients, OR
- Hepatobiliary Cancer:
  - Extrahepatic Cholangiocarcinoma, OR
  - Gallbladder Cancer, OR
  - Intrahepatic Cholangiocarcinoma, OR
- Islet Cell Tumors and requires management of bone metastases or unresectable liver and lung metastases, OR
- Pancreatic Adenocarcinoma, OR
- Metastatic or Recurrent Breast Cancer, OR
- Brain metastases if active against primary breast tumor, OR
- Ovarian Cancer

References

XENAZINE (TETRABENAZINE)

Please route to client queue, and forward to Adam Harbert at aharbert@envisionrx.com to be forwarded to the VPHP medical directors for review.

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- Confirmed diagnosis of chorea associated with Huntington’s disease.
- Required information is needed to complete review which includes clinical notes from the patient’s medical records including any applicable labs and/or tests, supporting the diagnosis.
- Must have tried and failed at least two of the following: amantadine, an antipsychotic (fluphenazine, haloperidol, risperidone, ziprasidone, quetiapine or olanzapine), riluzole, or a benzodiazepine.
- Must be prescribed by a neurologist that treats Huntington’s disease.
- For doses greater that 50 mg/day, CYP2D6 genotyping is required.
- If approved, Xenazine will be approved for 3 months at a time.

Criteria for continuation of therapy:
- Signs and symptoms of chorea must be decreased.
- Patient must not show signs of worsening depression.

References

XEOMIN (INCOBOTULINUMTOXINA)

Criteria for use (bullet points below are all inclusive unless otherwise noted):
The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Prescribed by a dermatologist, neurologist, ophthalmologist, or physiatrist AND
- Must be greater than 18 years of age, AND
- Must have at least one of the following conditions:
  - Cervical dystonia, OR

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
• Upper limb spasticity, Poststroke
• Spasmodic torticollis, AND

• **No contraindications:**
  • Pregnancy, OR
  • Sensitivity or allergic reaction to other botulinum toxins, OR
  • Contraindications to the use of dapsone, AND
• Not being used for treatment of glabellar rhytids, AND
• Tried/fail or intolerance to Botox

**Not approved if:**
• Does not meet the above-stated criteria

**Caution:**
• Potency of units between different preparations of botulinum toxin products is not interchangeable

Available dosage forms: 50 unit and 100 unit single-use vials
Usual dose: Cervical dystonia – 120 units per treatment
Blepharospasm – 33 units per eye

**References**

1. Virginia Premier

**XEPI (OZENOXACIN)**

• Must have a documented diagnosis of impetigo due to Staphylococcus aureus or Streptococcus pyogenes; **AND**
• Patient is 2 months of age or older; **AND**
• Clinical trial and failure of Mupirocin ointment

**COVERAGE DURATION**

• 5 days

**EXCLUSION CRITERIA**

• Underlying skin disease
• Skin trauma
• Secondary infection or systemic signs and symptoms of infection

**XIAFLEX (COLLAGENASE CLOSTRIDIUM HISTOLYTICUM)**

• The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
1. Must have Dupuytren’s contracture with a palpable cord, functional impairment and fixed-flexion contractures of the metacarpophalangeal joint or proximal interphalangeal joint of 20 degrees or more (excluding the thumb).
2. Must be 18 years of age or older.
3. Xiaflex should only be administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren’s contracture. (orthopedic surgeon, hand surgeon, general surgeon, plastic surgeon, or rheumatologist)
4. Upon request, documentation of credentials supporting fellowship training in procedures of the hand must be made available.
5. Only one cord per session should be injected. If patient has other cords with contractures, treat each in sequential order.
6. Must not have had surgery on the primary joint within the past 90 days, OR
1. A diagnosis of moderate to severe Peyronie’s Disease (PD) with a palpable plaque and curvature of greater than 30 degrees, AND
2. The prescribing physician is a urologist, AND
3. Symptoms have persisted for greater than 12 months, AND
4. An inadequate response, contraindication, or intolerance to a trial (6 months or greater) of appropriate alternative treatments such as pentoxifylline or intralesional verapamil.
5. Approval is for 2 vials per 30 days, to a maximum of 8 vials

Criteria for continuation of therapy (Dupuytren's contracture):
- Injection may be repeated up to a maximum of 3 sessions per cord at 4 week intervals if reduction in primary joint contracture is not 0-5 degrees of full extension.
- Patient must follow-up within 24 hours following an injection for finger extension procedure if a contracture persists in order to qualify for more injections.
- If after the second injection there is no improvement the 3rd injection may not be approved.

Contraindication:
- None at this time.

Duration of therapy: Depends upon response to treatment and number of cords affected. Can be up to a maximum of 3 sessions per cord at 4 week intervals.

Not approved if:
- Does not meet the above stated criteria.

References
1. Virginia Premier

XIFAXAN (RIFAXIMIN)

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.

Traveler's Diarrhea:
- Patient must be >12 years of age AND must t/f fluoroquinolone and azithromycin before approving for treating traveler's diarrhea.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Hepatic encephalopathy:
- Must have clinically diagnosed condition of hepatic encephalopathy
- Treatment failure with nonabsorbable disaccharides (i.e. lactulose, lactitol). Or
- Intolerant/Contraindication to treatment with formulary nonabsorbable disaccharide

Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults
- Must have diagnosis of diarrhea predominant Irritable Bowel Syndrome AND
- Must be 18 years old or over AND
- Must have failed conventional therapies including: Dietary changes (including fiber), or stress reduction, or behavioral changes AND any ONE of the following medications:
  a. Anti-diarrheals (i.e. Loperamide, diphenoxylate/atropine); OR
  b. Antispasmodics (hyoscyamine, dicyclomine); OR
  c. Tricyclic antidepressants (despiramine, imipramine) AND
- One 550 mg tablet 3 times a day for 14 days. Patients who experience recurrence can be retreated up to two times with the same regimen.

Criteria for continuation of therapy:
Travelers Diarrhea: Discontinue therapy if patient has persistent or worsening symptoms after 24-48 hours

Duration of therapy: TD: 3 days , HE: varies-initial approval 6 months and may repeat for 6 months.

QUANTITY LIMITS

<table>
<thead>
<tr>
<th>Medication</th>
<th>Strength</th>
<th>Quantity Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xifaxan (rifaximin)</td>
<td>200mg tablets</td>
<td>9 tabs/30 days</td>
</tr>
<tr>
<td>Xifaxan (rifaximin)</td>
<td>550mg tablets</td>
<td>60 tabs/30 days</td>
</tr>
<tr>
<td>Xifaxan (rifaximin)</td>
<td>550 mg tablet</td>
<td>42 tabs/14 days</td>
</tr>
</tbody>
</table>

APPROVAL DURATION

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Strength</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatic Encephalopathy</td>
<td>550mg tablets</td>
<td>1 Year</td>
</tr>
<tr>
<td>Travelers’ Diarrhea</td>
<td>200mg tablets</td>
<td>1 Time Only</td>
</tr>
<tr>
<td>IBS-D</td>
<td>550mg tablets</td>
<td>14 days</td>
</tr>
</tbody>
</table>

Usual dose: TD: 200mg three times a day for 3 days
- HE: 550 mg twice a day (1100mg/day)
- IBS-D: 550mg three times daily for 14 days.

Hepatic Encephalopathy:
- A decrease in fasting serum ammonia levels from baseline
- Improvements in patient’s mental status

Contraindication:
- Hypersensitivity to rifaximin (or other rifamycins such as rifampin) or any component of the formulation.

Not approved if:
- Patient does not meet the above stated criteria
- Patient has any contraindications to the use of rifaximin.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
• E. coli is not suspected as the causative pathogen.
• Diarrhea is complicated by fever or bloody stool.
• Patient is being treated for dysentery.
• Diarrhea is associated with use of antibiotics.
• Hepatic encephalopathy patient has not attempted therapy with a formulary nonabsorbable disaccharide (as long as no contraindication exists).

References:
1.) Virginia Premier

XOLAIR (OMALIZUMAB)

Initial
• Moderate-to-severe persistent asthma in a member that is age 6 years old or older, AND
• Prescribed by an Allergist, or Immunologist, AND
• Prescriber attests that patient is symptomatic despite being compliant with a trial of combination controller therapy including at least a medium dose of inhaled corticosteroid and one of the following:
  o Long-acting beta agonist
  o Long-acting muscarinic antagonist
  o Leukotriene modifier
  o Theophylline
  AND
• Member exhibits any one (1) of the following signs of poor asthma control
  o Daily use of short-acting inhaled beta2-agonists; OR
  o Diurnal variation in peak expiratory flow (PEF) of greater than 30 %; OR
  o Forced expiratory volume in 1 second (FEV1) less than 60 % predicted; OR
  o PEF less than 80 % of personal best; OR
  o A total of at least 3 of the following events within the preceding 12 months due to acute asthma exacerbations while on controller medications:
    ▪ Hospital admissions;
    ▪ Treatments with high-dose injectable or oral corticosteroids;
    ▪ Visits to the emergency room or urgent care center
• Patient has had a positive skin test to a perennial aeroallergen, AND
• Prescriber attests that source of allergenic asthma trigger has been removed or addressed, AND
• Prescribed by an Allergist, Immunologist, or Pulmonologist
• Patient’s baseline IgE is between 30 to 700 IU/mL in adults OR 30-1300 IU/mL for pediatric patients between 6 and 12 years of age

Renewal
• Patient is tolerating treatment, AND
• Patient has disease stabilization or improvement in disease, documented by one or more of the following:
  o Decreased utilization of rescue medications,
  o Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids),

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval

- Improvement in lung function (increase in percent predicted FEV1 or PEF) from pre-treatment baseline
- Reduction in reported symptoms (e.g., decrease in asthma symptom score)

Authorization
- Initial – 6 months
- Renewal – 12 months

-OR-

Initial
- Members aged 12 and over with moderate to severe refractory chronic idiopathic urticaria
- Urticaria must be continuously or intermittently present for at least six weeks.
- Prescribed by an Allergist, Immunologist, or Dermatologist; AND
- Documented failure of, or contraindication to at least one medication from all of the following categories:
  - first generation H1 antagonist (brompheniramine, chlorpheniramine, diphenhydramine, doxylamine, hydroxyzine, meclizine, etc)
  - second generation H1 antagonist (cetirizine, desloratadine, fexofenadine, levocetirizine, or loratadine)
  - H2 antagonist (ranitidine, famotidine, cimetidine, nizatidine)
  - leukotriene inhibitor, and
  - immunosuppressive therapies (e.g. oral corticosteroids, cyclosporine, or anti-inflammatory agents); AND
- Evidence of an evaluation that excludes other medical diagnoses associated with chronic urticaria.

Renewal
- Patient is tolerating treatment
- Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)

Authorization
- Initial: 12 weeks
- Renewal: 12 months

Special Considerations
- Maximum of 300mg every 4 weeks for 12 weeks
- Contraindications: Severe hypersensitivity reaction to Xolair or any ingredient of Xolair
- Exclusions: when the above criteria is not met, or used in combination with mepolizumab (Nucala) or reslizumab (Cinqair), and when Xolair is contraindicated.

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval


**XTANDI (ENZALUTAMIDE)**

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
  - Clinically diagnosed with metastatic castration-resistant prostate cancer, AND
  - ECOG performance status ≤ 2, AND
  - Prostate-specific antigen (PSA) level obtained at time of treatment initiation
  - Approval will be for periods of 3 months or less

**Criteria for continuation of therapy:**

- PSA level measured at least once monthly, AND
- Patient responding to treatment without disease progression
- Disease progression defined as three increasing values for PSA or radiographically confirmed progression with or without a rise in the PSA level, AND
- Patient tolerating treatment

**Caution:**

- Seizures

**Contraindication:**

- Pregnancy

**Not approved if:**

- Does not meet above criteria, OR
- Has any contraindications to treatment with enzalutamide

**Special considerations:**

- Results from the double-blind, placebo-controlled trial indicate the benefit with enzalutamide is a 5.3 month delay in time to PSA progression, a 5.4 month delay in time to radiographic progression, and 3.4 month delay in time to first skeletal-related event.

**References**

1. Virginia Premier

**XYREM (SODIUM OXYBATE)**

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
- Patient must be clinically diagnosed with narcolepsy and have cataplexy or excessive daytime sleepiness that is substantial enough to warrant treatment
- For cataplexy, must have tried and failed/intolerant to tricyclic antidepressants or SSRIs
- For excessive daytime sleepiness, must have tried and failed/intolerant to at least one formulary/preferred stimulant treatment, such as methylphenidate or dextroamphetamine.
- Must be older than 16. (Safety and effectiveness not established in children under 16.)
- Patient and physician must adhere to all regulations of the XYREM REMS Program.
- Must be prescribed by a neurologist or a sleep specialist.
- Approval Duration: Initial-1 month, Renewal-3 months. (Patients are to be evaluated by physician no less frequently than every 3 months).
- Quantity limit of 540mL/30 days.

NOT APPROVED IF:
- Patient is being treated with sedative hypnotic agents, other CNS depressants, or using alcohol.
- Patient has succinic semialdehyde dehydrogenase deficiency (This rare disorder is an in-born error of metabolism and variably characterized by mental retardation, hypotonia, and ataxia.)
- Patient has a history of drug abuse.
- Patient has any contraindications to the use of Xyrem
- Patient does not meet above criteria.

Because of the risks of CNS depression, abuse, and misuse, Xyrem is available only through a restricted distribution program called the Xyrem Success= Program(R), using a centralized pharmacy. Prescribers and individuals must enroll in the program; call 1-866-XYREM88.

References
1. Virginia Premier

YERVOY (IPILIMUMAB)
- Patient must be >= 18 years old; AND
- Prescribed by an Oncologist or Hematologist; AND
- A diagnosis of unresectable or metastatic melanoma; AND
- BRAF mutation V600E; AND
- Confirmation of mutation by FDA-approved test, AND
- No Wild-BRAF mutation; AND
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0 – 1; AND
  - 0: Fully active, able to carry on all pre-disease performance without restriction
  - 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g., light house work, office work)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Contraindication:
- History of coronary artery disease or coronary vasospasm
- Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorder
- History of stroke, transient ischemic attack, or hemiplegic or basilar migraine
- Peripheral vascular disease
- Ischemic bowel disease
- Uncontrolled hypertension
- Recent use of another 5-HT1 agonist or use of an ergotamine-containing medication
- Use of monoamine oxidase-A inhibitor in past 2 weeks
- Hypersensitivity to sumatriptan or components of Zecuity
- Severe hepatic impairment
- Allergic contact dermatitis to Zecuity

Not approved if:

References
1. Virginia Premier

ZECUITY (SUMATRIPTAN TRANSDERMAL)

- Clinically diagnosed with Migraine; AND
- Prescribed by or in consultation with a Neurologist, AND
- Must be 18 years of age or older, AND
- There has been a trial and failure, intolerance or contraindication to 2 of the following preferred TRIPHTANS: zolmitriptan, rizatriptan, naratriptan, AND
- Tried and failed, intolerant to ALL of the following: Sumatriptan tablets, Sumatriptan Injection, Sumatriptan Nasal Spray, AND
- The request is for no more than 4 patches per 30 days

Continuation of therapy
- Patient is responding to treatment, AND
- Patient tolerating treatment

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

Special considerations:

- Zecuity is a single-use transdermal patch composed of a battery operated inotophoretic device and a drug reservoir card. Patient is required to assemble and activate the device.
- Patients with migraine who also have nausea, vomiting, or gastroparesis may not be able to take or absorb an oral triptan. Nasal sprays have a more rapid onset of action than oral (10-15 vs 30-60 minutes) but they can have unpleasant taste and they also depend on GI absorption of the significant portion of the dose that is swallowed. SubQ administered sumatriptan is fastest acting (~10 minutes) and most effective.

References


ZELBORAF (vemurafenib; BRAF-inhibitor)

- Patient must be >= 18 years old; AND
- Prescribed by an Oncologist or Hematologist; AND
- A diagnosis of unresectable or metastatic melanoma; AND
- BRAF mutation V600E; AND
- Confirmation of mutation by FDA-approved test, AND
- No Wild-BRAF mutation; AND
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0 – 1; AND
  - Fully active, able to carry on all pre-disease performance without restriction
  - Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (e.g., light house work, office work)
  - Ambulatory and capable of all self care but unable to carry out any work activities; up and about more than 50% of waking hours
  - Capable of only limited self care, confined to bed or chair more than 50% of waking hours
  - Completely disabled: cannot carry on any self care; totally confined to be or chair
- Baseline ECG, electrolytes, & bilirubin assessed prior to initiation of therapy and within acceptable limits; AND
- Performed dermatologic evaluation; AND
- No concomitant BRAF-inhibitor, MEK inhibitor, or ipilimumab therapy.

References

1. Virginia Premier

ZEMPLAR (PARICALCITOL)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.

- Secondary hyperparathyroidism, AND
- Intact Parathyroid Hormone (iPTH) > 240 pg/mL, AND
- Corrected serum calcium <10.5 mg/dL, AND
- Corrected Serum Ca x(times) Serum Phosphorus <70, AND
- Trail/failure/intolerance to calcitriol/Hectorol oral or injection therapy by demonstrating iPTH level Greater than180 pg/mL, AND
- Development of hypercalcemia (serum Calcium >11.5 mg/dL) despite adequate therapy and discontinuance of calcium based phosphate binders.

Reauthorization/Continuing treatment:
- iPTH >120 pg/mL (or 2 times the upper limit of normal), AND
- Corrected Serum calcium <11.5 mg/dL, AND
- Corrected Serum Ca x (times) Serum Phosphorus < 75

References


ZIAGEN (ABACAVIR)

Duplicate therapy:
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

References

1. Virginia Premier

ZIDOVUDINE (GENERIC RETROVIR)

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Duplicate therapy:
- FDA approved indication or off label use supported by clinical evidence and documented in an official compendium for drug utilization, AND
- Patient will be switching from one antiretroviral combination to an alternate product with the same active ingredient (i.e. Emtriva [emtricitabine] or Viread [tenofovir] to Truvada [emtricitabine/tenofovir] or vice versa)

References
1. Virginia Premier

ZOLADEX (GOSERELIN ACETATE)

- Hormone-receptor positive breast cancer in men and pre-menopausal women, OR
- Advanced breast cancer in pre- and peri-menopausal women, OR
- Prostatic carcinoma, OR
- Endometrial ablation or hysterectomy (preoperative adjunct), OR
- Endometriosis, Stage III or IV, OR
- Uterine fibroids (preoperative adjunct to surgical treatment), OR
- Precocious puberty, OR
- Dysfunctional uterine bleeding

References

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
ZOLINZA (VORINOSTAT)

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
- Patient must have a medical oncology consult, AND
- Clinically diagnosed cutaneous T-cell lymphoma (CTCL), AND
- Strict diagnostic criteria and demonstration of a T cell clonality or mutation, AND
- Progressive, persistent or recurrent disease on or following two systemic therapies.
  - Approved for 3 months at a time and can receive a 1 month supply at a time.

Criteria for Continuation of Therapy:
- Patient must have a follow up with medical oncology, AND
- Must have a clinical response* to treatment within 3 to 6 months of beginning treatment.
- Approved for 3 months initially,
  - If a response* is seen, Zolinza will be approved each time for an additional 3 months.
  - If no response** is seen, may be approved for an additional 3 months. Zolinza will not be re-approved if no response** after 6 months of treatment.
*Response- Objective measures for disease activity may include pruritis or decrease plaques or erythema.
**No response- Disabling pruritis and diffuse erythema may warrant a treatment change.

Cautions:
- Pulmonary Embolism and deep vein thrombosis have been reported.
- Dose related thrombocytopenia have occurred and may require dose modification or discontinuation.
- Gastrointestinal disturbances (nausea, vomiting, and diarrhea). Patients may require antiemetics, antidiarrheals and fluid and electrolyte replacement to prevent dehydration.

Monitoring:
- Blood cell counts and chemistry tests, including electrolytes, glucose and serum creatinine, every 2 weeks during the first 2 months of therapy and monthly thereafter.

Contraindications:
- None at this time.

Not Approved if:
- Does not meet the above stated criteria.

Special Considerations:
- Until more data are available, use should be reserved for patients with disease progressing or recurring on or following 2 systemic therapies.
- other treatment options:
  - PUVA
  - UVB therapy
  - Radiotherapy
  - Chemotherapy
  - Bexarotene
  - Interferon
  - Photopheresis

Clinical trials- 45% BSA involved, mean pruritis score was 8 (0-10)
- Median time to response was about 55 days. Rare cases took up to 6 months.
- Median time to progression was about 5 months.
- Response rates in studies were about 24%-30%.

Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval.
Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval. Act is a three part program specifically designed to assist patients in obtaining Zolinza, help with insurance reimbursement issues, and provide support for those qualified individuals lacking insurance coverage for Zolinza. To enroll in Act program patients should call 1-866-363-6379.

References


ZOMETA (ZOLEDRONIC ACID)

- History of osteoporotic fracture or low trauma fracture, OR
- Osteoporosis, with BMD T-score: < -2.5 SD from the mean, OR,
- BMD T-score between: -1 and -2.5 SD with the presence of one or more of the following:
  - Age > 50 years old
  - Postmenopausal status in women
  - Hypogonadal status in men
  - Currently taking certain medications that can decrease BMD:
    - Glucocorticoids (equivalent of >5mg/day of prednisone for > 3 months), cyclosporine, chemotherapy, anticonvulsants, aluminum salts, gonadotropin-releasing hormone agonists, heparin, lithium, high doses of thyroxine
  - Concurrent disease state that increases the risk of osteoporosis:
    - Hypogonadal diseases, endocrine disorders, nutritional and gastrointestinal disorders, rheumatic disorders, hematologic/oncologic disorders, organ transplantation, selected inherited disorders, chronic obstructive pulmonary disease, pregnancy and lactation, scoliosis, multiple sclerosis, sarcoidosis, amyloidosis, acromegaly, diabetes mellitus type 1, chronic liver disease, or states of immobilization.
  - Other risk factors:
- Vitamin D or calcium deficiency, alcohol intake (3 or more drinks per day), parental history of hip fracture, small frame or stature, early menopause, and low body mass index (BMI in kg/m2; BMI for healthy weight is between 18.5 to 24.9 kg/m2, current smoking, AND
- Tried/failed/intolerance to alendronate, and generic zolendronic acid.
- Paget's disease of bone with elevations in serum alkaline phosphatase (ALP) of ≥2 x ULN of the age-specific normal reference range with:
  - Symptomatic disease (bone pain, hearing loss, bone deformities, fractures, arthritis), AND
  - At risk of complications from Paget’s disease (e.g., osteoarthritis, heart failure, kidney stones, broken bones), AND
  - Concomitant treatment with calcium and vitamin D, AND
- Tried/failed/intolerance to alendronate and pamidronate, and generic zolendronic acid, OR
- Hypercalcemia of malignancy
  - Tried/failed/intolerance to generic zolendronic acid

References


Requests for continuing therapy that were approved by a previous Health Plan will be honored for at least 30 days upon receipt of documentation demonstrating that approval
ZOVIRAX (ACYCLOVIR) TOPICAL

Zovirax Cream Criteria for Use:

- Must have documented diagnosis of herpes labialis (cold sores).
- Must have documented trial and failure or intolerance to Abreva.

References


ZUBSOLV (BUPRENORPHINE/NALOXONE BUCCAL)

Subutex generic:

Criteria for Use: (bullet points below are all inclusive unless otherwise noted)
- Must have opioid dependence diagnosis.
  - FDA approved indication is for treatment of opioid dependence only, NOT pain management.
- Must be 16 years old or over
- For initial requests, the member must not have had Suboxone/buprenorphine therapy within the last 90 days per chart notes or claims history. These requests will be considered re-initiation requests.
- Prescriber Restriction: Suboxone/Subutex – The prescriber is a licensed physician who is treating the member and is qualified to prescribe this therapy according the DATA 2000 and SAMHSA. Physician must be listed on the Buprenorphine Physician Locator maintained by the Substance Abuse and Mental Health Services Administration (SAMSHA).
- The member has been referred or is participating in a substance abuse or behavioral health treatment program, behavioral health counseling, or an addictions recovery program. (During the initial course of treatment, referral and enrollment must be with a licensed Drug and Alcohol or behavioral health provider)
- The prescriber must sign and agree to the Suboxone/Buprenorphine Attestation Form
- Use of Zubsolv for maintenance therapy will be limited to patients who cannot tolerate Suboxone with medical documentation. Intolerance to Suboxone or naltrexone must be accompanied by documentation of the intolerance from the submission of a FDA Medwatch form (FDA Form 3500) to the FDA. Request must include a completed FDA Medwatch form with the EOC submission. The FDA Medwatch form can be obtained at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf
- When buprenorphine monotherapy is used for induction, it is recommended that it be used for no more than 2-7 days before switching to the buprenorphine/naloxone combination formulation (for patient who are not pregnant or breastfeeding).
- During the induction period, the patient should receive medication under the doctor’s supervision in the office. (Induction doses may be obtained through physician’s own supply or through a pharmacy.)
- Patient must not be using short or long acting narcotics concurrently with Suboxone/Subutex/Zubsolv/Bunavail.
- The maintenance dose of SUBOXONE sublingual film is generally in the range of 4/1 mg buprenorphine/naloxone to 24/6 mg buprenorphine/naloxone per day depending on

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- Dose reduction of CNS depressants, SUBUTEX, SUBOXONE Sublingual Film and SUBOXONE Sublingual Tablets, or both when both are being taken should be considered.
- Liver function should be monitored before and during treatment
- Once the diagnosis of opioid dependence has been confirmed, authorization will be given for a 7 days for the induction period if member is not pregnant or no medical records documenting intolerance. The member should transition to Suboxone treatment following Subutex induction.
- If the member is pregnant, breastfeeding or completed FDA Medwatch form documenting intolerance to naloxone or Suboxone (buprenorphine/naloxone), authorization will be given for a 180 day period. Renewal authorizations will be for a 180 day period, pending drug screen results** [See Coverage Renewal].

**Not approved if:**
- Patient has any contraindication to the use of buprenorphine or buprenorphine/naloxone
- Patient does not meet the above criteria.
- Patient is using short or long acting narcotics concurrently with Suboxone/Subutex/Zubsolv/Bunavail.

*Because of the potential for naloxone to precipitate withdrawal in both mother and fetus, pregnant and breastfeeding women who are deemed to be appropriate candidates for buprenorphine treatment should be inducted and maintained on buprenorphine monotherapy.

Envision to block all other opioids for the patient, when approving Zubsolv.

**Coverage renewal**, the member must remain compliant with the comprehensive treatment program, and the provider must have evaluated random drug screenings as per the individual treatment plan, and the member had consistent participation in a substance abuse or behavioral health treatment program, behavioral health counseling, or an addictions recovery program. Thus, copies of two (2) drug screen results, one (1) dated within the previous three (3) months must be provided for all renewal requests. Medical records/chart not es may be submitted instead of drug screen labs (same timeframe applies). The prescriber must submit an attestation that the member had consistent participation in a substance abuse or behavioral health treatment program, behavioral health counseling, or an addictions recovery program. For Suboxone and Subutex, the prescribing physician must document that the continuation therapy is an attempt at a step-down dose.

Positive drug screens – If either or both required drug screens are found to be positive for Opioids, Opiod-derivates, illicit Opiod-derivatives, carisoprodol, or meprobamate during the reauthorization request, the prescribing physician must acknowledge the positive drug screen and provide the steps being taken to address member’s non-compliance with program. A 1x, 30 day supply will be allowed for failure of (positive) drug screens/UDS medical records/chart notes for the drugs listed above. Another prior authorization request would be needed for the next authorization and must include a new clean drug screen/UDS medical record/chart note (from the last request), otherwise will result in denial of request for continued therapy.

Renewal authorizations will be for a 180 day period.

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**ZYMAXID (GATIFLOXACIN)**

- Bacterial Conjunctivitis, AND
- Tried/failed/intolerance/bacteria-unsusceptible to ciprofloxacin, or levofloxacin ophthalmic solution.

**References**

**ZYVOX (LINEZOLID)**

- Therapy is NOT being used for prophylaxis therapy, AND
- Infection is NOT a decubitus ulcer, AND
- Chart notes, lab values and susceptibility results that document that the pathogen is susceptible to Zyvox, other meds that the organism is susceptible to have been tried, the infection is a covered indication listed below, and the organism is a covered pathogen also listed below:
  - Infection caused by Vanco-Resistant Enterococcus faecium, nosocomial pneumonia infection caused by Staph aureus (MTH-susceptible and MTH-resistant strains) or S. pneumoniae (including multi-drug resistant strains [MDRSP]), AND
  - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, OR
  - Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, caused by Staph aureus (MTH-susceptible and MTH-resistant strains) OR S. pyogenes OR S. agalactiae, AND
  - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, AND
  - Patient does NOT have osteomyelitis, OR
  - Uncomplicated skin and skin structure infections caused by MTH-susceptible only –Staph aureus AND the pathogen is MTH-susceptible only, AND
    - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, OR
  - Bacteremia associated with intravascular line, AND
    - Confirmed ampicillin- and vancomycin-resistant Enterococcus faecalis/faecium, OR
  - Febrile neutropenia
  - Bone infection, AND
    - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, OR
  - Infective endocarditis, AND
    - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, AND
- Documented documented trial and failure or intolerance to the susceptible antibiotics, OR
- A first time Zyvox request to treat uncomplicated skin and skin structure infections caused by S. pyogenes, OR
- A first time Zyvox request to treat community-acquired pneumonia caused by S. pneumoniae (including multi-drug resistant strains [MDRS]), including cases with concurrent bacteremia, AND
  - Susceptibility report shows that the pathogen is not susceptible to any other antibiotics, OR
- A first time Zyvox request to treat community-acquired pneumonia caused by Staph aureus (MTH-susceptible strains only), AND the pathogen is MTH-susceptible, AND
  - Susceptibility report shows that the pathogen is NOT susceptible to any other antibiotics.

**References**


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