

VIRGINIA PREMIER MEDICAID PRIOR AUTHORIZATION DETAIL

January 2023

GENERAL DISCLAIMER:

Virginia Premier does not recognize the use of drug samples to meet clinical criteria requirements for prior drug use for drugs covered under the pharmacy benefit or drugs administered in the physician office or other outpatient setting. A physician's statement that samples have been used cannot be used as documentation of prior drug use.

Non-Preferred products are subject to service authorization which requires trial and failure of two preferred 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

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

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 90 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

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- If member daily MME greater than 90, 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
- 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 90, 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

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the lowest possible effective doses of both opioids and benzodiazepines per the Board of Medicine Opioid Prescribing Regulations, AND

- ONE OF THE FOLLOWING:
 - FOR Long acting agent (Arymo ER, Hysingla ER, Morphabond ER, Zohydro, Xtampza): 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

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

• **Authorization period**

- 6 months based on diagnosis
 - Cancer pain
 - Sickle cell disease
 - Palliative care
 - End-of-life care
 - Hospice patient
- 3 months based on diagnosis
 - HIV/AIDS
 - Chronic back pain
 - Arthritis
 - Fibromyalgia
 - Diabetic Neuropathy
 - Postherpetic Neuralgia
 - Other pain

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

- **Sample Physician/Patient Agreement:**
<https://www.drugabuse.gov/sites/default/files/files/SamplePatientAgreementForms.pdf>
- **Tapering Guidelines for Opioids and Benzodiazepines:**
<http://www.oregonpainguidance.org/app/content/uploads/2016/05/Opioid-and-Benzodiazepine-Tapering-flow-sheets.pdf>

ACCRUFER (FERRIC MALTOL)

- For patients with iron deficiency anemia, consider the following criteria:
 - Age ≥ 18 years
 - Determine cause of iron deficiency anemia and treatment plan
 - Current diagnosis of iron deficiency anemia as defined by:
 - Hb 9.5–12.0 g/dl for women
 - Hb 9.5–13.0 g/dl for men
 - Ferritin < 30 µg/l
 - Prior OTC oral iron supplementation trial for at least 3 months
- For patients with iron deficiency anemia and non-dialysis dependent CKD:
 - Age ≥ 18 years
 - Current diagnosis of iron deficiency anemia as defined by:
 - Hb 8–11.0 g/dL
 - Ferritin < 25 µg/L
 - TSAT < 25%
 - Prior OTC oral iron supplementation trial for at least 3 months

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**

Authorization: 12 months

Last Revision: 1/1/2023

ACTEMRA (TOCILIZUMAB)

- Prescribed by a Rheumatologist, AND
- Negative tuberculosis test or received treatment if tested positive, AND
- Absolute neutrophil count (ANC) > 2000/mm³, 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

- 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
 - Giant cell arteritis (GCA)
- ≥2 years of age:
 - Systemic Juvenile Idiopathic Arthritis (SJIA) or Polyarticular juvenile rheumatoid arthritis, AND
 - Tried/failed/intolerance to glucocorticoids or methotrexate OR
 - Cimeric antigen receptor (CAR) T-cell induced severe or life-threatening cytokine release syndrome

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:
 - ANC at least 500/mm³
 - Platelet count at least 50,000/mm³ (50 x 10⁹/L, 5 x 10⁸/L 50,000/ml, 50 K/μL)
 - Transaminases (ALT, AST) not greater than 5x ULN

LAST REVISION: 7/1/21

References

1. Actemra. In:DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
2. American College of Rheumatology 2010 Arthritis and Rheumatism. September 2010;62(9):2569-2581.
3. Tocilizumab, In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.

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.

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

- 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

1. Actiq prescribing information. Cephalon, Inc. February 2007.
2. Mystakidou D, Datsouda E, Parpa E, Vlahos L. Oral transmucosal fentanyl citrate: Overview of pharmacological and clinical characteristics. *Drug Delivery* 2006;13:269-276.
3. Virginia Premier
4. Model guidelines for the use of controlled substances for the treatment of pain. The Federation of State Medical Boards of the United States. Available at: <http://www.medsch.wisc.edu/painpolicy/domestic/model.htm>. Accessed September 20, 2006.
5. Landy SH. Oral transmucosal fentanyl citrate for the treatment of migraine headache pain in outpatients: A case series. *Headache* 2004;44:762-766.
6. Shaiova L, Wallenstein D. Outpatient management of sickle cell pain with chronic opioid pharmacotherapy. *J Natl Med Assoc* 2004 96(7):984-986.
7. Sharar SR, Carrougher GJ, Selzer K, et al. A comparison of oral transmucosal fentanyl citrate and oral oxycodone for pediatric outpatient wound care. *J Burn Care Rehabil* 2002;23(1):27-31.
8. Lichtor JL, Sevarino FB, Joshi GP, et al. The relative potency of oral transmucosal fentanyl citrate compared with intravenous morphine in the treatment of moderate to severe postoperative pain. *Anesth Analg* 1999;89(3):732-738.
9. Facts and Comparisons. Clinisphere Version ISBN 1-57439-036-8. St. Louis, MO: Facts and Comparisons; October, 2002. Accessed November, 2002.
10. DiPiro J, Talbert R, Yee G, Matzke G, Wells B, Posey L. *Pharmacotherapy*. 5th Ed. Stamford, Ct: Appleton & Lange 2002.

ACTHAR HP AND CORTROPHIN (REPOSITORY CORTICOTROPIN)

INFANTILE SPASMS

- Diagnosis of Infantile Spasms **AND**
- Prescribed by a Neurologist **AND**
- Patient is less than 2 years of age **AND**
- Approval granted for a **MAXIMUM** of 30-day supply at which time dosage should be tapered according to the following schedule:
 1. Initial dose: 75U/m² IM twice daily for 2 weeks, then tapered at 30 U/m² IM in the morning for 3 days; 15 U/m² IM in the morning for 3 days; 10 U/m² IM in the morning for 3 days; and 10 U/m² IM every other morning for 6 days (3 doses).

NOTE: If Acthar or Cortrophin was started in-patient please provide date started and dose/day.

NEPHROTIC SYNDROME

- Diagnosis of Nephrotic Syndrome with at least **ONE** of the following: Focal Segmental glomerulosclerosis **OR** Membranous Nephropathy **AND**
- Prescribed by a nephrologist **AND**
- Member must have tried and failed both a corticosteroid **AND** a calcineurin inhibitor taken concurrently with in the past year **AND**
- Member must have tried and failed either a high dose corticosteroid or a calcineurin inhibitor independently for a minimum of 90 days within the last year

Approval will be for a period of 6 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

Renewal will require documented labs containing proteinuria showing improvement. (increase in baseline proteinuria with 3 months of paid claims of high dose steroid)

SYMPTOMATIC SARCOIDOSIS

- Member must have a diagnosis of sarcoidosis **AND**
- Active pulmonary symptoms OR extra pulmonary symptoms only **AND**
- Member must have tried and failed or contraindicated to systemic corticosteroids **AND**
- Member must have tried and failed or contraindicated to at least one immunomodulators **AND**
- Member must have tried and failed or contraindicated to at least one TNF inhibitor **AND**
- Documentation of worsening disease on any of the above mentioned items including pulmonary imaging/function tests or noncaseating granulomas showed worsening of disease while on steroid, immunomodulator, and TNF inhibitor.

Approval will be for a period of 3 months

Renewal will require documentation of clinically significant improvements.

OTHER CONDITIONS (Multiple Sclerosis, Rheumatic disorders, collagen diseases, allergic/ophthalmic states)

- Member must have a diagnosis of the conditions mentioned above **AND**
- Member must have tried and failed a 3-month consecutive course of high dose steroids concurrently with immunosuppressants within the past year. (Documentation attached which shows no improvement in symptoms while on high dose corticosteroids and immunosuppressant agent concurrently).

Approval will be for a period of 3 months

Renewal will require documentation of clinically significant improvements.

ACZONE (DAPSONE)

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

- Patient must be 9 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.

ADBRY (TRALOKINUMAB-IDRM)

Initial therapy:

1. Member has a diagnosis of moderate to severe atopic dermatitis; **AND**
2. Member is at least 18 years of age; **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

3. Member has documentation of trial and failure of 8 weeks of EACH
 - a. 1 topical corticosteroid of medium to high potency (ie. mometasone, fluocinolone) **AND**
 - b. 1 topical calcineurin inhibitor (tacrolimus or pimecrolimus) **AND**
4. Member has documentation of trial and failure of Dupixent **AND**
5. Member has documentation of trial and failure of Eucrisa

Renewal therapy:

1. Confirmation of clinical improvement in signs and symptoms of atopic dermatitis; **AND**
2. Documentation of current disease severity

Approval Duration: 12 months

Quantity Limit:

4 prefilled syringes for initial 28 days, followed by 2 prefilled syringes per 28 days

LAST REVISION: 1/1/2023

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:

Requests for continuing 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
- Use with nitrates or nitric oxide donors in any form
- 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:
 - Pregnancy
 - Use with nitrates or nitric oxide donors in any form
 - Use with phosphodiesterase (PDE) inhibitors

References:

- 1.) Adempas [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; March 2015.
- 2.) Ghofrani H, Galie N, Grimminger F, Grunig E, Humbert M, et al (PATENT-1 Study Group). Riociguat for the treatment of pulmonary arterial hypertension. NEJM 2013; 369 (4):330-340.

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 **AND**
- 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)

RENEWAL

Requests for continuing 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 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

Reviewed: 1/1/2023

AEMCOLO (RIFAMYCIN)

CRITERIA FOR USE

- 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:

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

- Sutent (sunitinib); OR
- Nexavar (sorafenib), OR
- Patient has a diagnosis of Waldenström’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

1. Afinitor. In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
2. Everolimus. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology – Breast Cancer. NCCN Web site. Available from: <http://www.nccn.org/>.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology – Kidney Cancer. NCCN Web site. Available from: <http://www.nccn.org/>.
5. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology – Neuroendocrine Tumors. NCCN Web site. Available from: <http://www.nccn.org/>.
6. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology – Pancreatic Cancer. NCCN Web site. Available from: <http://www.nccn.org/>.
7. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology – Soft Tissue Sarcoma. NCCN Web site. Available from: <http://www.nccn.org/>.

ANTI-MIGRAINE NON-PREFERRED (AIMOVIG, EMGALITY 100 MG SYRINGE, REYVOW, QULIPTA, UBRELVY, TRUDHESA)

Initial

- Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria **AND**
- Patient must have tried and failed preferred products: For preventative treatment of migraine: Emgality pen or Emgality syringe 120mg **AND** Ajovy Autoinjector **OR** For acute treatment of migraine: Nurtec ODT **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**

Requests for continuing 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 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**
- **Trudhesa** – a cardiovascular evaluation has been completed.

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: 3 months, Continuation: 12 months

LAST REVISION: 1/1/23

ANTI-MIGRAINE PREFERRED (EMGALITY PEN AND SYRINGE 120 MG, AJOVY, NURTEC ODT)

- Diagnosed with migraine with or without aura or a medically accepted indication; **AND**
- Trial and failure of 2 generic triptans.

If the above ST criteria is not met for preferred anti-migraine products, please review with the below PA criteria. Reviews can be approved if EITHER the ST or the PA criteria have been met.

Initial

- Diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria **AND**
- Patient must have tried and failed preferred products: For preventative treatment of migraine: Emgality pen or Emgality syringe 120mg **AND** Ajovy Autoinjector **OR** For acute treatment of migraine: Nurtec ODT **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**

Requests for continuing 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 is utilizing prophylactic intervention modalities (e.g. behavioral therapies, physical therapy, or life-style modifications) **AND**
- Member has tried and failed \geq 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**

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

LAST REVISION: 9/6/2022

ALFERON N (INTERFERON ALFA-N3)

- \geq 18 years of age, AND
- External condylomata 25 (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

1. Alferon N. In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
2. Friedman-Kien AE, Eron LJ, Conant M, et al. Natural interferon alfa for treatment of condylomata acuminata. JAMA. 1988 Jan;259(4):533-8.
3. Interferon Alfa-N3. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.

ALOXI (PALONOSETRON)

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

References

1. Aloxi. In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

Requests for continuing 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. American Society of Health-System Pharmacists Therapeutic Guidelines on the Pharmacologic Management of Nausea and Vomiting in Adult and Pediatric Patients Receiving Chemotherapy or Radiation Therapy or undergoing Surgery. Am J Health Syst Pharm.1999;56:730-764.
3. Kris MG, Hesketh PJ, Somerfield MR, et al. American Society of Clinical Oncology (ASCO) Treatment Guidelines for the Use of Anti-emetics in Chemotherapy and Radiation Update 2006. J Clin Oncol. 24:2932-2947.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology – AntiemesisV3.2011. NCCN Web site. Available from: <http://www.nccn.org/>.
5. Palonosetron. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.

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.
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.

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

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

1. Ampyra prescribing information. Acorda. November 2012.
2. Goodman AD, Brown TR, Cohen JA, et al. Dose comparison trial of sustained release fampridine in multiple sclerosis. *Neurology* 2008;71:1134-1141.
3. Goodman AD, Brown TR, Krupp LB, et al. Sustained release oral fampridine in multiple sclerosis. *Lancet* 2009;373:732-738.
4. FDA. Medical review of fampridine. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022250s000_MedR.pdf
5. National Multiple Sclerosis Society Disease Management Consensus Statement-Recommendations from the MS Information Sourcebook; 2007 Update. National Multiple Sclerosis Society. Available at: <http://www.nationalmssociety.org/for-professionals/healthcare-professionals/publications/expert-opinion-papers/download.aspx?id=8>.
6. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002; 58(2)169-78.
7. Avonex prescribing information. Biogen Idec, Inc. November 2012.
8. Betaseron prescribing information. Bayer HealthCare Pharmaceuticals Inc. June 2012.
9. Copaxone prescribing information. Teva Neurosciences, Inc. July 2011.
10. Rebif prescribing information. Serono, Inc./Pfizer Inc. November 2012.
11. Ampyra™, Symptomatic Medicine Approved by FDA to Improve Walking for People with All Types of MS, Available at www.Nationalmssociety.org
12. Andrew D Goodman, et al. Sustained-release oral fampridine in multiple sclerosis: a randomized, double-blind, controlled trial. *Lancet* 2009; 373:732-38

AKLIEF (TRIFAROTENE)

1. Patient has a diagnosis of acne vulgaris 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. Patient is 9 years of age or older AND
3. Patient has tried and failed at least 2 other formulary alternative products such as
 - a. Benzoyl peroxide
 - b. Clindamycin
 - c. Clindamycin phosphate/benzoyl peroxide
 - d. Sodium sulfacetamide
 - e. Erythromycin gel
 - f. Erthromycin-Benzoyl
 - g. Differin OTC
 - h. Tretinoin gel or cream

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 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 psychosocial treatment and psychosocial treatment will continue with parent/guardian involvement for the duration of medication therapy (**NOTE: Not applicable if a Psychiatrist**). **AND**
- A family assessment has been performed (including parently psychopathology and treatment needs) and have family functioning and parent child relationship has been evaluated.

Authorization: 6 months

Last revision: 1/1/2023

References

1. Virginia Premier

ANZEMET (DOLASETRON 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

1. Anzemet. In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

Requests for continuing 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. American Society of Health-System Pharmacists Therapeutic Guidelines on the Pharmacologic Management of Nausea and Vomiting in Adult and Pediatric Patients Receiving Chemotherapy or Radiation Therapy or undergoing Surgery. Am J Health Syst Pharm.1999;56:730-764.
3. Dolasetron Mesylate. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.co>.
4. Kris MG, Hesketh PJ, Somerfield MR, et al. American Society of Clinical Oncology (ASCO) Treatment Guidelines for the Use of Anti-emetics in Chemotherapy and Radiation Update 2006. J Clin Oncol. 24:2932-2947.
5. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology – AntiemesisV3.2011. NCCN Web site. Available from: <http://www.nccn.org/>.

ARCALYST (RILONACEPT)

Treatment of cryopyrin-associated periodic syndromes (CAPS)

- Prescribed by a Rheumatologist or Immunologist, AND
- ≥ 12 years of age, AND
- Cryopyrin-Associated Periodic Syndromes (CAPS) disorder:
 - Familial Cold Autoinflammatory Syndrome, OR
 - 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).

Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

- Member has a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA); **AND**
- Member is at least 10kg; **AND**
- Member has a loss-of-function IL1RN mutations; **AND**
- Member has trial and failure of anakinra (Kineret) **AND**
- Arcalyst is not being used concomitantly with anakinra (Kineret®); **AND**
- Prescribed by a specialist such as immunologist

Treatment of recurrent pericarditis (RP)

- Member has a diagnosis of recurrent pericarditis; **AND**
- Member is 12 years of age or older; **AND**
- Documentation provided to support member has trial and failure standard of care such as NSAIDs and corticosteroids **AND**
- Documentation provided to support member has trial and failure of anakinra (Kineret)

LAST REVISION: 7/1/21

References

1. Arcalyst. In:DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
2. Hoffman, HM, Throne ML, Amar NJ, et al. Efficacy and safety of rilonacept (Interleukin-1 Trap) in patients with cryopyrin-associated periodic syndromes. Arthritis and Rheumatism. 2008;58(8): 2443-2452.
3. Lachmann, HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al. Use of canakinumab in the cryopyrin-associated periodic syndrome. N Engl J Med. 2009;360:2416-2425.

Requests for continuing 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. Rilonacept. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.

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:
 - 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.

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. Aredia. In:DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
2. MacLaughlin EJ and Raehl CL. ASHP therapeutic position statement on the prevention and treatment of osteoporosis in adults. Am J Health-Syst Pharm. 2008;65:343-57.
3. Management of osteoporosis in postmenopausal women: 2010 position statement of the North American Menopause Society. Menopause. 2010;17(1):25-54.
4. Pamidronate Disodium. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
5. Qaseem A, Snow V, Shekelle P, et al for the Clinical Efficacy Assessment Subcommittee of the American College of Physicians. Pharmacologic treatment of low bone density or osteoporosis to prevent fractures: A clinical practice guideline from the American College of Physicians. Ann Intern Med. 2008;149:404-15.

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
- Patient is 18 years of age or older
AND
- Patient has failed a multi-drug regiment 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 **AND**
- Arikayce will be prescribed in conjunction with a multi-drug antimycobacterial regimen

Authorization: 12 months

Last Revision: 1/1/2023

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

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

- 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
- Pregnancy
- Current leflunomide treatment

Not approved if:

- Does not meet the above stated criteria.
- Have any contraindications to the use of teriflunonide.

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

AUVI-Q (EPINEPHRINE)

Requests for continuing 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 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 (chart notes/medical record documenting trial and failure history required):
 - Epinephrine Auto-Injector (generic EpiPen)
 - EpiPen
- ***OR***
- 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

Last updated: 1/1/2023

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
- Unresectable or metastatic hepatocellular carcinoma, in combination with atezolizumab, for patients who have not yet received prior systemic therapy, OR
- 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 AND
 - Quantity does not exceed 1.25mg per eye per 28 days, 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, AND
 - Quantity does not exceed 1.25mg per eye per 28 days OR
- Proliferative diabetic retinopathy, AND
 - Will be undergoing vitrectomy AND
 - Quantity does not exceed 1.25mg per eye per 28 days 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

- Macular edema secondary to retinal vein occlusion AND
Quantity does not exceed 1.25mg per eye per 28 days OR
- Diabetic macular edema AND
Quantity does not exceed 1.25mg per eye per 28 days 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

1. Arevalo JF, Sanchez JG, Wu L, et al. Primary intravitreal bevacizumab for diffuse diabetic macular edema. *Ophthalmology*. August 2009;116(8):1488-1497.
2. Avastin. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
3. Bashshur ZF, Haddad ZA, Schakal A, et al. Intravitreal Bevacizumab for Treatment of Neovascular Age-related Macular Degeneration: A One-year Prospective Study. *Am J Ophthalmol*. 2008;145: 249-256.
4. Bevacizumab. In: G.K. McEvoy et al. (Eds.), *American Hospital Formulary Service Drug Information*. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
5. Breast Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
6. Brouzas D, Charakidas A, Moschos M, et al. Bevacizumab (Avastin.) for the management of anterior chamber neovascularization and neovascular glaucoma. *Clinical Ophthalmology*. 2009;3:685-688.
7. Central Nervous System Cancers. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
8. Colon Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
9. Costagliola C, Cipollone U, Rinaldi M, et al. Intravitreal bevacizumab (Avastin.) injection for neovascular glaucoma: a survey of 23 cases throughout 12-month follow-up. *Br J Clin Pharmacol*, 2008;66(5):667-673.
10. di Lauro R, De Ruggiero P, di Lauro R, di Lauro MT, Romano MR. Intravitreal bevacizumab for surgical treatment of severe proliferative diabetic retinopathy. *Graefes Arch Clin Exp Ophthalmol*. 2010;248:785-791.
11. Escudier B, Pluzanska A, Koralewski P, et al. Bevacizumab plus interferon alfa-2a for treatment of metastatic renal cell carcinoma: a 34-week, double-blind phase III trial. *Lancet*. 2007;370:2103-2111.
12. Hurwitz H, Fehrenbacher L, et al. Bevacizumab plus Irinotecan, Fluorouracil, and Leucovorin for Metastatic Colorectal Cancer. *N Engl J Med*. 2004;350: 2335-2342.
13. Kidney Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
14. Kook D, Wolf A, Kreutzer T, et al. Long-term effect of intravitreal bevacizumab (Avastin) in patients with chronic diffuse diabetic macular edema. *Retina, the Journal of Retinal and Vitreous Diseases*. 2008; 28(8): 1053-1060.
15. Ladewig MS, Karl SE, Hamelmann V, et al. Combined intravitreal bevacizumab and photodynamic therapy for neovascular age-related macular degeneration. *Graefes Arch Clin Exp Ophthalmol*. 2008;246:17-25.
16. Melichar B, Koralewski P, Ravaud, A, et al. First-line bevacizumab combined with reduced dose interferon-2a is active in patients with metastatic renal cell carcinoma. *Annals of Oncology*, doi:10.1093/annonc/mdn161.
17. Moraczewski AL, Lee RK, Palmberg PF, et al. Outcomes of treatment of neovascular glaucoma with intravitreal bevacizumab. *Br J Ophthalmol*, 2009;93:589-593.
18. Ovarian Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.

Requests for continuing 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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21. Small Cell Lung Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
22. Yang, JC, Haworth L, Sherry RM, et al. A randomized trial of bevacizumab, an antivascular endothelial growth factor antibody, for metastatic renal cancer. *N Engl J Med*. 2003;349: 427-434.
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AVSOLA, REMICADE (INFLIXIMAB)

CRITERIA FOR USE

Treatment of Crohn's Disease:

- Member has a diagnosis of Crohn's disease; AND
- Member is 6 years of age or older; AND
- Member has tried and failed Humira and Inflectra.

Treatment of Ulcerative Colitis:

- Member has a diagnosis of ulcerative colitis; AND
- Member is 6 years of age or older; AND
- Member has tried and failed Humira and Inflectra.

Treatment of Rheumatoid arthritis:

- Member has a diagnosis of moderately to severely rheumatoid arthritis; AND
- Member is 18 years of age or older; AND
- Member has tried and failed Renflexis and Humira or Enbrel.

Treatment of Ankylosing Spondylitis:

- Member has a diagnosis of active rheumatoid arthritis; AND
- Member is 18 years of age or older; AND
- Member has tried and failed Inflectra and Humira or Enbrel.

Treatment of Psoriatic Arthritis:

- Member has a diagnosis of psoriatic arthritis; AND
- Member is 18 years of age or older; AND
- Member has tried and failed Inflectra and Humira or Enbrel.

Treatment of Plaque Psoriasis:

- Member has a diagnosis of chronic, severe (extensive and/or disabling) plaque psoriasis; AND
- Member is 18 years of age or older; AND
- Member has tried and failed Inflectra and Humira or Enbrel.

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

Approval Duration

- Initial – 12 months
- Renewal – 12 months

LAST REVISION: 1/1/2023

AYVAKIT (AVAPRITINIB)

CRITERIA FOR USE

- 1) Prescriber attests to a documented diagnosis of unresectable or metastatic GIST (gastrointestinal stromal tumor)
AND
- 2) Age is 18 years or older
AND
- 3) Prescribed by or in consultation with an oncologist
AND
- 4) Tumors must harbor PDGFRA exon 18 mutations including PDGFRA D842V mutations
AND
- 5) Must have ECOG performance status of 0 to 2

Authorization duration: 6 months

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

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

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
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.

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

- 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.
 - Patient is being treated for substance abuse (including treatment with buprenorphine or buprenorphine-naloxone).

References

1. Virginia Premier

BENLYSTA (BELIMUMAB)

- Confirm member has a diagnosis of moderate to severe systemic lupus erythematosus (SLE); **AND**
- Member is 5 years of age and older **AND**
- Member has tried three of the following and is receiving standard therapy on two therapies for SLE such as glucocorticoids, antimalarial agents (hydroxychloroquine, chloroquine), and/or immunosuppressive agents (including cyclophosphamide, cyclosporine, tacrolimus, leflunomide, methotrexate, azathioprine, or mycophenolate) and had an intolerance or inadequate response; **AND**
- Member is auto-antibody positive, defined as, ANA titer greater than or equal to 1:80 OR anti-dsDNA greater than or equal to 30 IU/mL; **AND**
- Symptoms involve the musculoskeletal and mucocutaneous system; **OR**
- Confirm member has a diagnosis of lupus nephritis; **AND**
- Member is 5 years of age or older **AND**
- Member is receiving standard therapy for SLE such as glucocorticoids, antimalarial agents (hydroxychloroquine, chloroquine), and/or immunosuppressive agents (including cyclophosphamide, cyclosporine, tacrolimus, leflunomide, methotrexate, azathioprine, or mycophenolate) and had an intolerance or inadequate response

AND

- Member is not taking Saphnelo with Benlysta concurrently; **AND**
- Member does not have severe active central nervous system (CNS) lupus; **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 or in consultation with a specialist such as rheumatologist or nephrologist

Renewal Approval:

SLE:

- Prescriber has documented clinical benefit from therapy (e.g. reduction in SELENA-SELDAI score, decrease in steroid therapy, decrease in symptoms)

Lupus Nephritis:

- Prescriber provides clinical documentation of renal disease stabilization (i.e eGFR improvement or improvement in proteinuria) or improvement with Benlysta **AND** (2) Prescriber attests that patient continues to receive standard of care therapy

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/23

BEOVU (BROLUCIZUMAB-DBLL)

1. Patient has a diagnosis of Neovascular (wet) age-related macular degeneration (wet AMD) or Diabetic Macular Edema **AND**
2. Member must have tried and failed Avastin (bevacizumab) OR Lucentis (ranibizumab)
3. 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

BESREMI (ROPEGINTERFERON ALFA-2B-NJFT)

Initial therapy:

1. Member must have a diagnosis of polycythemia vera (PV); **AND**
2. Prescriber confirms that the member is at high risk for PV (i.e. greater than 60 years of age or history of thrombosis)
3. Member is 18 years of age or older; **AND**
4. Prescribed by or in conjunction with a hematologist
5. Member has documented resistance or contraindication to hydroxyurea (HU):
 - Need for phlebotomy to keep hematocrit less than 45% after 3 months on 2 g/day of HU OR
 - Platelet count >400 × 10⁹/L and white blood count >10 × 10⁹/L after 3 months on 2 g/day of HU 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

- Reduction of splenomegaly <50% after 2 g/day of HU OR
- Absolute neutrophil count <1.0 × 10⁹/L or platelet count <100 × 10⁹/L or hemoglobin <10 g/dL OR
- Presence of HU side effects at any dose of HU

Renewal therapy:

1. Prescriber attests to stabilization or improvement in lab parameters in relation to thrombosis risk.

Approval Duration: 1 year

LAST REVISION: 5/1/22

BONIVA (IBANDRONATE) SYRINGE

- Osteoporosis or high risk of osteoporosis with any ONE of the following:
 - BMD T-score worse than -2.5 SD (DEXA [Dual Energy X-ray Absorptionmetry] measured T-scores), OR
 - History of osteoporotic fractures (i.e. vertebral, hip, compression fractures), 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 or generic ibandronate

Requests for continuing 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

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BOTOX (ONABOTULINUMTOXINA)

- Dystonia, Spasticities, and Neuro-ophthalmological 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:
 - i. Persistent pain
 - ii. Interference with nutritional intake
 - iii. 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
 - Lower limb spasticity caused by cerebral palsy in patients 2 years of age and older, 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:

Requests for continuing 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 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
- 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, **AND**
 - Member has had trial and failure of topical antiperspirants, **AND**
 - Member has had trial and failure of at least **ONE** anticholinergic drug during the last six months, **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

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- 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 at least ONE of each of any 3 of the following preventive therapy classes:
 - ACEIs/ARBs
 - Beta-blockers,
 - Calcium channel blockers,
 - Anticonvulsants,
 - Antidepressants,
 - Injectable CGRP inhibitor or oral CGRP inhibitors indicated for migraine prevention, OR
- Backache:
 - Tried/failed/intolerance to oral therapy:
 - Muscle relaxant (e.g., baclofen), OR
 - NSAIDs, OR
- Benign prostatic hyperplasia:
 - Tried/failed/intolerance to oral therapy:
 - Alpha-blocker, AND
 - 5-alpha-reductase inhibitor, OR
- Excessive salivation (Sialorrhea):
 - Tried/failed/intolerance to oral therapy:
 - Glycopyrrolate, OR
- Epicondylitis, OR
- Fibromyalgia:
 - Tried/failed/intolerance to oral therapy:
 - Gabapentin, OR
 - Lyrica, AND
 - Cymbalta, OR
- Tourette Syndrome, OR
- Tardive dyskinesia, OR
- Whiplash injury to neck

Reauthorization Criteria:

Chronic Migraine Prophylaxis:

- Member has experienced positive response to therapy, demonstrated by a reduction in headache frequency (supporting chart notes must be attached); **AND**
- Use of acute migraine medications have decreased since the start of Botox; **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

- Botox wil **NOT** be used in combination with another CGRP inhibitor indicated for migraine prevention.

LAST REVISION: 8/1/2022

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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

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BREXAFEMME (IBREXAFUNGERP)

- Diagnosed with a medically accepted indication; **AND**
- Trial and failure of any one of the following: oral fluconazole, terconazole, or miconazole.

LAST REVISION: 11/1/21

BRUKINSA (ZANUBRUTINIB)

Initial

For the treatment of mantle cell lymphoma (MCL)

1. Patient has a diagnosis of mantle cell lymphoma (MCL) AND
2. Patient is 18 years of age or older AND
3. Patient has received at least 1 prior therapy for the treatment of mantle cell lymphoma (MCL) AND
4. Documented failure to achieve response with prior therapy AND
5. Prescriber agrees to monitor for bleeding and malignancies, CBC for cytopenias and for cardiac arrhythmias AND
6. No prior exposure to a different BTK inhibitor
7. Prescribed by or in consultation with an oncologist/hematologist.

For the treatment of Marginal zone lymphoma

1. Patient has a diagnosis of marginal zone lymphoma; AND
2. Patient is 18 years of age or older; AND
3. Patient has received at least one anti-CD20-based regimen; AND
4. Prescribed by or in consultation with an oncologist/hematologist

For the treatment of Waldenstrom's macroglobulinemia (WM)

1. Patient has a diagnosis of Waldenstrom's macroglobulinemia (WM); AND
2. Patient is 18 years of age or older; AND
3. Prescribed by or in consultation with an oncologist/hematologist

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

Reauthorization

1. Prescriber attests to no disease progression or unacceptable toxicity AND
2. Patient continues to meet initial criteria

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

BUPRENORPHINE (GENERIC BUPRENEX, 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>)
- 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

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

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
 - Urine 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 of buprenorphine per day. Doses over 24mg per day cannot be approved.
 - **Quantity Limits**
 - Buprenorphine SL Tab 2 mg – 12 tabs per day
 - Buprenorphine SL Tab 8mg – 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

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.

BYLVAY (ODEVIXIBAT)

Initial 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

- Confirm member has a diagnosis of progressive familial intrahepatic cholestasis (PFIC); AND
- Member is 3 months of age or older; AND
- Diagnosis is confirmed by molecular genetic testing and it does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-3 ; AND
- There is presence of moderate to severe pruritus; AND
- Member does not have history of liver transplant; AND
- Member does not have history of biliary diversion surgery within the past 6 months; AND
- Member does not have clinical evidence of decompensated cirrhosis; AND
- Member has concurrent use or previous trial of at least one systemic medication, ursodiol, rifampicin, or cholestyramine; AND
- Prescribed by or in consultation with a specialist such as hepatologist or gastroenterologist.

Renewal Approval:

- Documentation that the member is tolerating therapy and there has been an improvement in pruritus and reduction in serum bile acid

Quantity Limit: 150 capsules per 30 days

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

CABLIVI (CAPLACIZUMAB-YHDP)

CRITERIA FOR USE

- 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

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

CALQUENCE (ACALABRUTINIB)

- Diagnosis of Mantle cell lymphoma (MCL); **AND**
- Member is 18 years of age or older; **AND**
- Member does not have severe hepatic impairment **AND**
- Member has received at least one prior therapy; **AND**
- Calquence will be used as a single agent; **AND**
- Prescriber agrees to do a baseline CBC and monitor monthly during therapy; **AND**
- Prescriber agrees to monitor for malignancies; **AND**
- Prescriber agrees to monitor for bleeding

OR

- Diagnosis of Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL); **AND**
- Member is 18 years of age or older; **AND**
- Member does not have severe hepatic impairment **AND**
- Calquence will be used as either a single agent **OR** in combination with Gazyva (obinutuzumab) as first-line therapy for CLL or SLL; **AND**
- Prescriber agrees to do a baseline CBC and monitor monthly during therapy; **AND**
- Prescriber agrees to monitor for malignancies; **AND**
- Prescriber agrees to monitor for bleeding

LAST REVISION: 1/1/23

CAMZYOS (MAVACAMTEN)

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

INITIAL:

- Clinically diagnosed with Obstructive Hypertrophic cardiomyopathy (oHCM); **AND**
- Member is 18 years of age or older; **AND**
- Prescribed by or in conjunction with a cardiologist; **AND**
- Prescriber attests to oHCM with symptomatic NYHA class II-III diagnosis; **AND**
- Prescriber attests patient has a LVEF greater than or equal to 55%; **AND**
- Prescriber confirms that patient has not undergone septal reduction therapy within 6 months prior to Camzyos initiation; **AND**
- Member is not taking concurrent dual therapy with beta blocker and calcium channel blocker or monotherapy with disopyramide.

RENEWAL:

- Prescriber attests to improvement in pVO₂ since initiation of therapy and a reduction or stabilization in NYHA class; **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

- Prescriber attests to improvement in symptoms.

Initial approval: 9 months

Renewal: 12 months

Please note Quantity Limits Apply: 30 tablets per 30 days

LAST REVISION: 10/1/22

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CAPLYTA (LUMATEPERONE)

Initial

1. Patient has a diagnosis of schizophrenia OR
2. Patient has a diagnosis of depressive episodes associated with bipolar I or II disorder AND
3. Patient is 18 years of age or older AND
4. Prescriber is a psychiatrist or prescribing in consultation with a psychiatrist AND
5. Trial of and inadequate response or intolerance to 2 of the generic alternatives, unless contraindicated or clinically significant adverse effects are experienced:
 - a. Risperidone
 - b. Olanzapine
 - c. Quetiapine
 - d. Ziprasidone
 - e. Aripiprazole AND
6. Quantity is not exceeding 30 capsules per 30 days

Reauthorization

1. Continuation of prior therapy with confirmed claims history OR
2. Prescriber attestation for new plan members that the patient is continuing therapy

LAST REVISION: 8/1/22

CARIMUNE NF (IMMUNE GLOBULIN, HUMAN INTRAVENOUS)

- Primary immune deficiency:
 - Common Variable Immunodeficiency (hypogammaglobulinemia), 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

- 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
- 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
- Renal Transplant rejection, OR
- Respiratory syncytial infection, OR
- Sepsis, OR
- Uveitis, OR
- Von Willebrand disorder, or
- Idiopathic (immune) thrombocytopenic purpura, 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

- 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,

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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

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CARISOPRODOL TABLET (SOMA)

- 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)
- 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
2. SOMA. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

CELEBREX (CELECOXIB) STEP THERAPY

- History of a trial of a minimum of two (2) different non-COX2 NSAIDs within the past year; **OR**
- Concurrent use of anticoagulants (i.e. warfarin, heparin, etc), methotrexate, or oral corticosteroids; **OR**
- History of previous GI bleed or conditions associated with GI toxicity risk factors (i.e. PUD, GERD, etc); **OR**
- Specific indication for Celebrex for which preferred drugs are not indicated

Authorization Dates: 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

LAST REVIEWED: 1/1/2023

CHENODAL (CHENODIOL)

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

References

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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

CIBINQO (ABROCITINIB)

- Diagnosis of moderate to severe atopic dermatitis; **AND**
- Member is 18 years of age or older; **AND**
- Prior documented trial and failure (or contraindication) of 1 topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) and 1 topical calcineurin inhibitor (tacrolimus or pimecrolimus); **AND**
- Inadequate response to a 3-month minimum trial of at least 1 immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc); **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

- Inadequate response (or is not a candidate) to a 3-month minimum trial of phototherapy (e.g., psoralens with UVA light [PUVA], UVB, etc.) provided member has reasonable access to photo treatment.
- Prescriber attests that Cibinco will not be used in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Quantity Limits apply:

- 30 tablets per 30 days

References

1. Virginia Premier Health Plan

LAST REVISION: 7/1/22

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

- 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))
- **Plaque psoriasis, moderate to severe**
 - Prescriber attests to a documented diagnosis of plaque psoriasis AND
 - Individual is 18 years of age or older AND
 - Plaque psoriasis must involve greater than or equal to 5% of the body surface area (BSA) OR Patients with plaque psoriasis involving the palms, soles, head and neck, nails, intertriginous areas or genitalia OR
 - Three of the following, Patient has had an inadequate response to 3-month trial of either topical therapy OR localized phototherapy with ultraviolet B (UVB) or oral methoxsalen plus UVA light [PUVA] for psoriasis OR Patient has had an inadequate response to a 3-month trial of systemic therapy (i.e. MTX, cyclosporine, acitretin [Soriatane]) OR Patient has significant disability or impairment in physical or mental functioning, according to the treating physician. AND
 - Individual has had an inadequate response to TWO preferred biologic therapies in the previous 180 days. (Current preferred biologics include – Enbrel (etanercept) and 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))
- **Non-Radiographic Axial Spondyloarthritis (nraxSpA):**
 - Individual is 18 years of age or older with active non-radiographic axial spondyloarthritis AND
 - Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as NSAIDs or nonbiological DMARDs such as sulfasalazine) AND
 - Individual has had an inadequate response to, is intolerant of, or has a contraindication to Humira.
- **Criteria for continuation 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

- 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**

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- 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

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COMPOUNDED 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

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

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 \$100.

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.)

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:

Requests for continuing 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. Requested compound contains any of the following ingredients which are available as over-the-counter products:

Cetyl Myristoleate	Coenzyme Q10	Methylcobalamin	Hyaluronic Acid
Nicotinamide	Methyltetrahydrofolate	Ibuprofen	Lipoic acid
Beta Glucan	Ubiquinol	Chrysin	Glutathione
Lactobacillus	Vitamin E	Ascorbic Acid	Melatonin

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 by NOT LIMITED TO the following:

Ketamine	Morphine	Hydrocodone
Gabapentin	Nabumetone	Meloxicam
Flurbiprofen (topical ophthalmic use not included)	Oxycodone	Amitriptyline
Ketoprofen	Cyclobenzaprine	Pentoxifylline
Diclofenac	Baclofen	Orphenadrine
Tramadol	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 topical fluticasone formulations

OR

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

hydroquinone	PracaSil TM-Plus
Chrysaderm Night Cream	Acetyl hexapeptide-8
Chrysaderm Day Cream	PCCA products
Tocopheryl Acid Succinate	Lipopen Ultra

4 active ingredients:

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

5 active ingredients:

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

- 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 Health Plan

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 alfa-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
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

Requests for continuing 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. WBC $\geq 3000/\text{mm}$
5. Platelets $\geq 70,000/\text{mm}$
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

Class A	5-6 points	Well compensated liver disease	
Class B	7-9 points	Significant functional compromise	
Class C	10-15 points	Uncompensated liver disease	
Parameters			
Points Assigned	1 point	2 points	3 points
Encephalopathy	None	Minimal	Advanced coma
Ascites	None	Easily controlled	Poorly controlled
Serum Bilirubin	$< 2\text{mg/Dl}$	$2-3\text{ mg/Dl}$	$> 3\text{ mg/Dl}$
Serum Albumin	$> 3.5\text{ g/Dl}$	$2.8-3.5\text{ g/Dl}$	$< 2.8\text{ g/Dl}$
INR	INR < 1.7	INR $1.7-2.3$	INR > 2.3

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 $< 50\text{ml/min}$.
7. Coverage 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

References

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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

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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.
38. Gonzalez-Peralta RP, Kelly DA, Haber B et al. Interferon alfa-2b in combination with ribavirin for the treatment of chronic hepatitis C in children: efficacy, safety, and pharmacokinetics. *Hepatology.* 2005; 42:1010-8.

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 $\leq 35\%$
- 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:

1. Corlanor [Prescribing Information]. Thousand Oaks, California. Amgen, Inc. April 2015.
2. Yancy CW, Jessup M, Bozkurt B, et al; American College of Cardiology Foundation; American Heart Association Task Force on Practice Guidelines. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2013;62(16):e147-e239.
3. Swedberg K, Komajda M, Böhm M, Borer JS, Ford I, Tavazzi L. Rationale and design of a randomized, double-blind, placebo-controlled outcome trial of ivabradine in chronic heart failure: the Systolic Heart Failure Treatment with the I(f) Inhibitor Ivabradine Trial (SHIFT). *Eur J Heart Fail.* 2010;12(1):75-81.

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)

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

- Treatment of adults with active ankylosing spondylitis (AS)
- Treatment of active nonradiographic axial spondyloarthritis in adults with objective signs of inflammation
- Treatment of active enthesitis-related arthritis (ERA)
- Treatment of active juvenile psoriatic arthritis (JPsA)

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, unless diagnosed with active enthesitis-related arthritis (ERA) or active juvenile psoriatic arthritis (JPsA)

Plaque psoriasis

- Must be clinically diagnosed with moderate to severe plaque psoriasis
- Must be 6 years of age or older
- 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)

Requests for continuing 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 tried and failed or been intolerant to Enbrel AND Humira

Active non-radiographic axial spondyloarthritis

- Patient has objective signs of inflammation
- Must have tried and failed or been intolerant to at least two NSAID, unless contraindicated
- Prescriber must be utilizing maintenance dose of 150mg every 4 weeks
- Must have tried and failed or been intolerant to Humira

Active Enthesitis-Related Arthritis (ERA)

- Must be clinically diagnosed with active ERA
- Member must be 4 years of age or older
- Must have tried and failed or been intolerant to Enbrel AND Humira

Active Juvenile Psoriatic Arthritis (JPsA)

- Must be clinically diagnosed with JPsA
- Member must be 2 years of age or older
- Must have tried and failed or been intolerant to Enbrel AND Humira

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

Requests for continuing 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 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

LAST REVISION: 5/1/22

References:

Virginia Premier.

1)

CRESEMBA (ISAVUCONAZONIUM)

- Individual is 18 years of age or older **AND**
- Individual initiated treatment in an inpatient setting and requires continued treatment of invasive aspergillosis or mucormycosis in an outpatient setting

OR

- Individual is 18 years of age or older **AND**
- Individual has a diagnosis of invasive aspergillosis **AND**
- Has treatment failure/intolerance of
 - Voriconazole **OR**
 - Liposomal amphotericin B

OR

- Individual is 18 years of age or older **AND**
- Individual has diagnosis of invasive mucormycosis **AND**
- Treatment failure/intolerance of Amphotericin B

AND (for all patients)

- Laboratory and clinical documentation of causative organism(s) **AND**
- Baseline liver function tests and monitoring during the course of therapy with dose adjustments based on liver function severity

CRYSVITA (BUROSUMAB-TWZA)

- Patient has a documented diagnosis of X-linked hypophosphatemia **AND**
- **Patient is at least 6 months of age 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

Requests for continuing 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

- Serum Fibroblast growth factor 23 level greater than 30pg/mL by Kainos assay, test and results must be provided for documentation

OR

- **Patient has a documented diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)**

AND

- Patient is at least 2 years of age

AND

- The diagnosis is associated with phosphaturic mesenchymal tumors that are not curative or resectable
- 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

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 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

- Crysvida 10mg/ml vial - 1 vial every 14 days
- Crysvida 20mg/ml vial - 1 vial every 14 days
- Crysvida 30mg/ml vial - 3 vials every 28 days

APPROVAL DURATION: Initial - 3 mos. Continuation - 12 mos.

CUMULATIVE MED GREATER THAN 90

INITIAL

1. Diagnosis of Active Cancer pain, Sickle Cell Disease, or patient receiving palliative care or hospice care; **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. 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**
10. If patient is using CONCOMITANT BENZODIAZEPINE AND OPIOID THERAPY:
 - a. Both medications must be prescribed for a medically accepted indication

Requests for continuing 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. 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

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

Requests for continuing 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. FDA Safety Information on Extended Release – Long Acting Opioid Analgesics. Available: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm396503.htm>. Accessed: August 7, 2014.
2. Berland D, Rodgers P. Rationale use of opioids for management of chronic nonterminal pain. Am Fam Physician 2012 Aug 1;86(3):252-8.
3. Use of Opioids for the treatment of chronic pain. A statement from the American Academy of Pain Medicine. Available at <http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf>. Accessed July 13, 2015.

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
 - 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

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

- 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.

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

- Dose of penicillamine in cystinuria should limit 73ysteine 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:

1. Cuprimine [Package Insert]. Whitehouse Station, NJ: Merck & Co., Inc.; 2004.
2. Depen [Package Insert]. Somerset, NJ: Meda Pharmaceuticals Inc.; 1988.
3. Penicillamine. In DRUGDEX®. Micromedex Solutions Website. <http://www.micromedexsolutions.com>. Accessed March 10, 2014.
4. Penicillamine: Pediatric drug information. In UptoDate. UptoDate Website. <http://www.uptodate.com>. Accessed March 10, 2014.
5. Cystine Stones. In UptoDate. UptoDate Website. <http://www.uptodate.com>. Accessed March 11, 2014.
6. Wilson disease. In UptoDate. UptoDate Website. <http://www.uptodate.com>. Accessed March 10, 2014.
7. Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology recommendation for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care & Research*. 2012; 64(5):625-39.
8. DeBerardinis RJ, Coughlin CR, and Kaplan P. Penicillamine therapy in pediatric cystinuria: experience from a cohort of American children. *J Urol*. 2008; 180(6):2620-3.
9. Roberts EA, Schilsky ML, and the American Association for the Study of Liver Diseases (AASLD). Diagnosis and treatment of Wilson disease: An update. *Hepatology*. 2008; 47(6):2089-2111.
10. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis & Rheumatism*. 2008; 59(6):762-84.

CYSTAGON (CYSTEAMINE BITARTRATE)

- Nephropathic cystinosis, **AND**
- Condition confirmed:
 - By leukocyte 73ysteine measurements greater than normal (nl range normal values are <0.2 nmol half-cystine/mg protein), OR
 - By DNA testing (two mutations in the CTNS gene; the only gene).

References

1. Barbaro G, Di Lorenzo G, Belloni G, et al. Interferon alpha-2b and ribavirin in combination for patients with chronic hepatitis C who failed to respond to, or relapsed after, interferon alpha therapy: a randomized trial. *Am J Med* 1999; 107: 112-8.
2. Cystagon. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
3. Cysteamine Bitartrate. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
4. Davis GL, Esteban-Mur R, Rustgi V, et al. Recombinant interferon alfa-2b alone or in combination with ribavirin for retreatment of relapse of chronic hepatitis C. *N Engl J Med* 1998; 339: 1493-9.
5. Dore GJ. The impact of HIV therapy on co-infection with hepatitis B and hepatitis C viruses. *Curr Opin Infect Dis*. 2001;14(6):749-755.

Requests for continuing 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. Kleta R, Kaskel F, Dohil R, et al. Consensus Statement: First NIH/Office of Rare Diseases Conference on Cystinosis: past, present, and future. *Pediatric Nephrology*; April 1, 2005
7. The Cystinosis Research Organization. Cystinosis. Available from <http://www.cystinosis.org/filemanager/file/Cystinosis%20Article%20Library/Genetics/cystinosis%20gene%20review.pdf>

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

DARAPRIM (PYRIMETHAMINE)

INITIAL:

Diagnosis of Toxoplasmosis – prophylaxis:

- Member has a diagnosis of HIV/AIDS; **AND**
- Member has a CD4 count < 100 cells/mm³; **AND**
- Positive test for Toxoplasmosis gondii IgG antibodies; **AND**
- Intolerance to first line agent trimethoprim/sulfamethoxazole (documentation submitted of intolerance); **OR**

Diagnosis of Toxoplasmosis – treatment:

- Diagnosis by an infectious disease specialist, neurologist, or HIV specialist; **AND**
- Member has a diagnosis of HIV/AIDS with CD4 count < 100; **AND**
- Member has headache, fever, and neurological symptoms (confusion, motor weakness); **AND**
- Submission of positive serum testing for Toxoplasmosis gondii IgG antibodies; **AND**
- Clinical documentation submitted identifying one or more mass lesions by CT/MRI

Diagnosis of Toxoplasmosis – chronic maintenance therapy:

- Member has completed at least 6 weeks of active treatment for AIDS-related toxoplasmosis (verified by pharmacy claims); **AND**
- CT/MRI documents improvement in ring-enhancing lesions prior to initiating maintenance therapy; **AND**
- Member has documented improvement in clinical symptoms

All other MAI including Pneumocystitis pneumonia and Cystoisporiasis:

- Member has a diagnosis or exposure to HIV; **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 intolerance to ALL the following drug regimens supported by attached clinical documentation:
 - Trimethoprim/sulfamethoxazole
 - Dapsone
 - Atovaquone

Daraprim is no longer recommended for the treatment/prophylaxis of malaria according to the CDC guidelines for the Treatment of Malaria in the United States and will NOT be approved for malaria.

LAST REVISION: 8/1/2022

References

1. [Virginia Premier](#)

DAYVIGO (LEMBOREXANT)

Initial

1. Patient has a diagnosis of insomnia AND
2. Patient is 18 years of age or older AND
3. Trial and inadequate response or intolerance to 2 generic covered generic alternatives, unless contraindicated or clinically significant adverse effects are experienced (i.e. zolpidem, eszopiclone, zaleplon, ramelteon etc) AND
4. Maximum dose of 10mg per day is not exceeded

Reauthorization:

1. Prescriber attests to therapeutic benefit of therapy AND
2. Patient is tolerating therapy

Duration of approval: Initial 6 months; reauthorization 6 months

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

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

- 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
 - 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:

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

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 77ulticen 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:
 - GERD symptoms and disease
 - Hypersecretory GI disease
 - Duodenal ulcers
 - On high dose steroids or NSAID and have failed therapy with H2antagonists,**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

- 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.

AND

- 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.

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)

- If request is for 2 different pancreatic enzymes the patient must be utilizing a feeding tube; **AND**
- Diagnosis of pancreatic insufficiency due to cystic fibrosis **OR** Diagnosis of pancreatic insufficiency due to chronic pancreatitis and a trial and failure of two (2) of the following preferred alternatives: Zenpep, Creon; **OR**
- Diagnosis of pancreatic insufficiency due to pancreatectomy and a trial and failure of two (2) of the following preferred alternatives: Zenpep, Creon. If request is for patient with Cystic Fibrosis, trial and failure of preferred alternatives not required (Zenpep, Creon, Pancrelipase are preferred)

DRONABINOL

Requests for continuing 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 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
- 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

DUPIXENT (DUPILUMAB)

APPROVAL DURATION: 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.

INITIAL

1. Must be at least 6 months of age or older **AND**
2. Must have a diagnosis of moderate to severe atopic dermatitis **AND**
3. Prior documented trial and failure of 30-days for each trial (or contraindication of):
 - a. One (1) topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) **OR**
 - b. One (1) topical calcineurin inhibitors (tacrolimus or pimecrolimus)

RENEWAL

1. Documentation (i.e., progress note) of positive clinical response will be required.

-OR- INITIAL

1. Patient is 6 years of age or older, **AND**
2. Diagnosis of moderate to severe asthma with an eosinophilic phenotype with eosinophil count ≥ 150 cells/mcL **OR** with oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months, **AND**
3. Prescribed by, or in consultation with an allergist or pulmonologist, **AND**
4. Will not be used in combination with Xolair, Nucala, Cinqair or Fasenra

RENEWAL

1. Patient has experienced an improvement in symptoms (reduction in exacerbation, reduction in oral glucocorticoids, or improvement in FEV1)
2. Patient continues to tolerate treatment

-OR- INITIAL

1. Diagnosis of chronic rhinosinusitis with nasal polyps, **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. 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 after 3 consistent months, intolerance, or contraindication to **ONE** medication from each of the following classes:
 - a. Nasal Corticosteroid spray
 - 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

-OR- INITIAL

1. Diagnosis of eosinophilic esophagitis, **AND**
2. Prescribed by or in consultation with an allergist or gastroenterologist **AND**
3. Member is 12 years of age or older and weighs at least 40 kg, **AND**
4. Inadequate response to all of the following:
 - a. High-dose proton pump inhibitor
 - b. Flovent or Flovent HFA swallowed

RENEWAL

1. Documentation (i.e., progress note) of positive clinical response will be required.

-OR- INITIAL

1. Member has a diagnosis of Prurigo Nodularis **AND**
2. Member is 18 years of age or older

LAST REVISION: 1/1/2023

DYSPORT (ABOBOTULINUMTOXINA)

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:
 - Cervical dystonia, **OR**
 - Spasmodic torticollis, **AND**
- No contraindications:
- Pregnancy, **OR**
- Sensitivity or allergic reaction to other botulinum toxins, **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

- Allergy to cow's milk protein, OR
- Contraindications to the use of dapsons, AND
- Not being used used for treatment of moderate to severe glabellar lines.

Not approved if:

- Does not meet the above-stated criteria

Caution:

- 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

ELAPRASE (IDURSULFASE)

- Hunter syndrome (mucopolysaccharidosis II)

References

1. Elaprase. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
2. Idursulfase. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.

ELMIRON (PENTOSAN)

COVERAGE DURATION: 3 months NOTE: The maximum dosage is 100 mg three times daily. Authorization will be for 3 months. If the member meets continuing therapy criteria following initial therapy, another 3 months may be approved. The clinical benefit of treatment beyond 6 months for patients whose pain has not improved is not known

- Diagnosis of interstitial cystitis; AND
- The requested medication is prescribed by (or in conjunction with) a urologist; 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

- There must be clinical documentation supporting a diagnosis of interstitial cystitis with lab results including both a negative urinalysis (urine test), AND a negative urine culture; AND
- For CONTINUING THERAPY, there must be documentation in the patient's chart notes or medical records that the patient has seen an improvement in symptoms (for example, a decrease in bladder pain).

EMFLAZA (DEFLAZACORT)

APPROVAL DURATION: Initial 6 months, Renewal 12 months.

APPROVAL CRITERIA

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

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.
2. Must be clinically diagnosed with Duchenne Muscular Dystrophy (DMD); **AND**
 - i. Diagnosis has been confirmed by documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
3. Patient must not have any *active* infection, including Tuberculosis and Hepatitis B Virus; **AND**
4. Patient is at least 2 years of age or older; **AND**
5. Serum creatinine kinase activity at least 10 times the Upper Limit of Normal (ULN) prior to initiating therapy; **AND**
6. 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 $\geq 10\%$ 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.
7. FOR CONTINUATION OF THERAPY
 - i. Physician has attested that the patient has had a positive clinical response to Emflaza therapy

LAST UPDATED: 6/1/2021

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. Product Information: EMFLAZA(TM) oral tablets, suspension, deflazacort oral tablets, suspension. Marathon Pharmaceuticals LLC (per FDA), Northbrook, IL, 2017.

EMPAVELI (PEGCETACOPLAN)

Initial Approval:

- Confirm member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); **AND**
- Member is 18 years of age or older; **AND**
- PNH diagnosis is confirmed by flow cytometry showing detectable GPI-deficient hematopoietic clones or a PNH clone size of at least 10%; **AND**
- Documented baseline value for serum lactate dehydrogenase (LDH)
- Member has received meningococcal vaccines at least 2 weeks before starting Empaveli; **AND**
- Member is transfusion-dependent with one of the following:
 - hemoglobin ≤ 7 g/dL OR
 - hemoglobin ≤ 9 g/dL and member is experiencing symptoms of anemia; **AND**
- Member has documented symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end organ damage); **AND**
- Member is receiving standard-of-care therapy concurrently upon initiation of therapy; **AND**
- Prescribed by or in consultation with a hematologist or oncologist, or immunology specialist.

Renewal Approval:

- Documentation of positive response to therapy, such as decrease in transfusions, increase in hemoglobin levels, normalization in LDH levels, etc., and tolerating therapy.

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 11/1/21

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:

Requests for continuing 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 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 (SSRI's, 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

ENHERTU (FAM-TRASTUZUMAB DERUXTECAN-NXKI)

Treatment of unresectable or metastatic HER2 positive breast cancer:

Initial

1. Patient has a diagnosis of unresectable and/or metastatic HER2 breast cancer **AND**
2. Patient is 18 years of age or older **AND**
3. Prescribed by or in consultation with an oncologist **AND**
4. Trial and inadequate response or intolerance to at least 2 prior anti-HER2 based regimens or 1 prior anti-HER2-based regimen in the neoadjuvant or adjuvant setting and disease recurrence developed within 6 months of completing the therapy **AND**
5. A documented ECOG score of 0-1 **AND**
6. Patient must not have any of the following:
 - a. Past cardiovascular events such as MI, CHF, unstable angina or serious cardiac arrhythmia
 - b. QTc prolongation
 - c. Clinically significant lung disease
 - d. An ECOG score greater than 1

Treatment of unresectable or metastatic HER2-low breast cancer:

Initial:

1. Patient has a diagnosis of unresectable or metastatic HER2-low breast cancer **AND**
2. Patient is 18 years of age or older **AND**
3. Prescribed by or in consultation with an oncologist **AND**
4. Patient has received prior chemotherapy in the metastatic setting **AND**
5. Patient developed disease recurrence during or within 6 months of completing adjuvant chemotherapy

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

Treatment of HER2 positive advanced gastric cancer

Initial:

1. Patient has a diagnosis of locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma; AND
2. Patient is 18 years of age or older; AND
3. Patient has received a prior trastuzumab-based regimen; AND
4. A documented ECOG score of 0-1; AND
5. Patient must not have any of the following:
 - a. Past cardiovascular events such as MI, CHF, unstable angina or serious cardiac arrhythmia
 - b. QTc prolongation
 - c. Clinically significant lung disease
 - d. An ECOG score greater than 1

Reauthorization

1. Prescriber attests clinical efficacy is achieved without unacceptable toxicity

Duration: Initial 6 months; Reauthorization 6 months

LAST REVISION: 1/1/2023

ENSPRYNG (SATRALIZUMAB-MWGE)

Authorization Criteria

1. A diagnosis of neuromyelitis optica spectrum disorder (NMOSD) **AND**
2. Prescriber attests the patient is anti-aquaporin-4 (AQP4) antibody positive **AND**
3. Prescriber attests that the patient is being treated as monotherapy or in combination with immunosuppressive therapy **AND**
4. Member must have failed treatment during the past 12 months prior to initiation with at least 2 immunosuppressive therapies (ie. Azathioprine, cyclosporine, mycophenolate, etc.), rituximab **OR** failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG). **AND**
5. Prescriber attests that satralizumab is not being used for acute treatment of NMOSD relapse **AND**
6. Prescriber attests the patient is negative for active Hepatitis B infection **AND**
7. Prescriber attests the patient is negative for active or latent tuberculosis **AND**
8. The patient must be 18 years of age or older **AND**
9. The requested medication must be prescribed by or in consultation with a neurologist

ENTYVIO (VEDOLIZUMAB)

Treatment of Crohn disease (CD)

- Member has a diagnosis of moderately to severely active Crohn 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

- Member is 18 years of age or older, AND
- Member has trial and failure of a compliant regimen of oral corticosteroids (moderate to severe CD) unless contraindicated or intravenous corticosteroids (severe and fulminant CD or failure to respond to oral corticosteroids), AND
- Member has trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months, AND
- Member has trial and failure of a compliant regimen of parenteral methotrexate for three consecutive months, AND
- Member has trial and failure of Humira

Treatment of Ulcerative Colitis (UC)

- Member has a diagnosis of moderately to severely active ulcerative colitis
- Member is 18 years of age or older, AND
- Member has trial and failure of a compliant regimen of oral corticosteroids unless contraindicated or intravenous corticosteroids (severe UC or failure to respond to oral corticosteroids), AND
- Member has trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months, AND
- Member has trial and failure of a compliant regimen of parenteral methotrexate for three consecutive months, AND
- Member has trial and failure of Humira

Approval Duration

- Initial – 12 months
- Renewal – 12 months

LAST REVISION: 7/1/21

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

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

EPIDIOLEX (CANNABIDIOL)

Criteria for Approval

- Diagnosis of Dravet Syndrome (DS), Lennox-Gastaut Syndrome (LGS), or tuberous sclerosis complex **AND**
- Patient is 1 years of age or older

Auth Duration: 12 months

LAST REVISION: 1/1/23

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)

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

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:

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):

Requests for continuing 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:

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.

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.*

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

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.

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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

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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

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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
- Chordoma used in combination with Erlotinib, OR
- Treatment of adult patients with metastatic colorectal cancer with BRAF V600E mutation in combination with Braftovi (encorafenib)

LAST REVISION: 5/1/22

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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

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ERLEADA (APALUTAMIDE)

Initial:

- Diagnosis of NON-metastatic castration-resistant prostate cancer (nmCRPC) OR
- Diagnosis of Metastatic castration-sensitive prostate cancer (mCSPC)
- AND ALL OF THE FOLLOWING
 - 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
- 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

EUCRISA (CRISABOROLE)

1. Must be at least 3 months old or older **AND**
2. Must have a diagnosis of mild to moderate atopic dermatitis **AND**
3. Prior documented trial and failure of 30 days for each trial (or contraindication of):
 - a. One (1) topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) **OR**
 - b. One (1) topical calcineurin inhibitors (tacrolimus or pimecrolimus)

Quantity Limit: 100gm per 30 days

Authorization Duration:

Initial approval: 12 months

Renewal approval: 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

LAST REVISION: 1/1/23

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:
 - 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.

References

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EVRYSDI (RISDIPLAM)

Initial Criteria

- Member is 2 months of age or older **AND**
- Member has a diagnosis of Spinal Muscular Atrophy (SMA) by supporting documentation

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

- SMA Type 1 confirmed by one of the following:
 - 1 to 2 copies of the SMN2 gene **OR**
 - 3 copies of the SMN2 gene in the absence of the c.859G>C single base substitution modification in exon 7 **OR**
- SMA Type 2 with symptomatic disease **OR**
- SMA Type 3 with symptomatic disease **AND**
- Supporting documentation supplied that member does NOT require invasive ventilation or tracheostomy **AND**
- Confirmation that risdiplam is NOT being used concurrently with nusinersen (Spinraza) or onasemnogene abeparvovec-xioi (Zolgensma) **AND**
- Member has NOT previously received Zolgensma **AND**
- Supporting documentation provided including baseline of at least 1 of the following:
 - Motor function **OR**
 - Respiratory function **OR**
 - Exacerbations necessitating hospitalizations and/or antibiotic therapy for respiratory infection in the preceding 365-day timeframe

Reauthorization Criteria

- Member continues to meet initial criteria **AND**
- Documentation supporting clinically significant improvement in SMA signs/symptoms compared to predicted natural history trajectory of disease **AND**
- Individual does not require use of invasive ventilation or tracheostomy due to advanced SMA disease **AND**
- Member continues to tolerate medication

LAST REVISION: 5/1/2022

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:

1. Evzio. In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
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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

EXKIVITY (MOBOCERTINIB)

Initial Approval:

- Confirm member has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC); AND
- Member is 18 years of age or older; AND
- Documentation of presence of epidermal growth factor receptor (EGFR) exon 20 insertion mutation as detected by an FDA-approved test (e.g. Oncomine Dx Target Test); AND
- Member has been previously treated with at least one platinum-based chemotherapy and experienced disease progression; AND
- Prescribed by or in consultation with an oncologist.

Renewal Approval:

- Documentation of positive response to therapy and member is tolerating therapy

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

EXJADE (DEFERASIROX)

Medication Prior Authorization Criteria Initial Therapy

Generic Exjade (deferasirox) must be tried and failed prior to Brand Exjade approval

Exjade® tablet for oral suspension is available in 125 mg, 250 mg, and 500 mg tablets.

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 >5mg/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*

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

baseline but no less than 3mg/g, and serum ferritin level no less than 300mcg/L within last month)

References

1. Deferasirox. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
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EXONDYS 51/VYONDYS 53/VILTEPSO/AMONDYS 45

Initial Criteria

- Member has been prescribed medication by or in consultation with a physician who specializes in treatment of Duchenne Muscular Dystrophy (DMD) **AND**
- Provider has submitted genetic testing results confirming the mutation of the DMD gene is amenable to one of the following:
 - Exon 51 skipping for Exondys 51
 - Exon 53 skipping for Vyondys 53 or Viltepsa 53
 - Exon 45 skipping for Amondys 45 **AND**
- Provider has submitted clinical documentation of a baseline evaluation, including a standardized assessment of motor function, by a neurologist with experience treating DMD along with goals of therapy **AND**
- Member is currently stabilized on one of the following for the past 6 months and will continue to take along with the requested medication:
 - Emflaza (deflazacort)
 - Prednisone
 - Prednisolone **AND**
- Member is NOT dependent on invasive ventilatory support or non-invasive ventilatory support other than during sleep **AND**
- Member must meet one of the following age requirements before initiation of therapy
 - Vyondys 53/Amondys 45 is initiated before the age of 16
 - Exondys 51 is initiated before the age of 14
 - Viltepsa is initiated before the age of 10 **AND**

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- For Vyondys 53/Viltepso or Amondys 45 approval, baseline renal function must be evaluated (documentation required of eGFR) **AND**
- Member's weight has been provided and dosage does not exceed:
 - 30mg/kg once weekly for Exondys/Vyondys/Amondys
 - 80mg/kg once weekly for Viltepso

Reauthorization Criteria

- Documentation provided which supports member has had a positive response to therapy which includes **ALL** the following:
 - Increase in dystrophin levels
 - Notation of member's current weight
 - Baseline renal function for Vyondys 53/Viltepso or Amondys 45

Approval Period 12 months.

LAST REVISION: 5/1/2022

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 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[®], Rebif[®]) 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.

Requests for continuing 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. Patient is concurrently receiving fingolimod. Use of interferon beta-1b SC with fingolimod has not been studied or established.

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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

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EYLEA (AFLIBERCEPT)

- Approved for the following indications:
 - Neovascular (Wet) age-related macular degeneration (AMD), **OR**
 - Macular edema following retinal vein occlusion, **AND**
 - Member must have tried and failed Avastin (bevacizumab) **OR** Lucentis (ranibizumab), **OR**
 - Diabetic macular edema, **OR**
 - Diabetic retinopathy in patients with diabetic macular edema
- **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
- **QL:** 2mg per eye per month.

EYSUVIS (LOTEPREDNOL)

INITIAL:

- Member has a diagnosis of dry eye disease such as xerophthalmia; **AND**
- Prescriber attests to utilizing Eysuvis for short-term treatment (up to 2 weeks of therapy); **AND**
- Member is 18 years of age and older; **AND**
- Member has tried/failed/intolerance to any non-prescription wetting agents (e.g., artificial tears) in the form of drops, ointments, or gels

Authorization Dates: 1 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

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:

ECOG PERFORMANCE STATUS

Grade	ECOG
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
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

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.
- 2.) Product Information: Farydak® (panobinostat) capsules, for oral use. Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, 2015.
- 3.) Eastern Cooperative Oncology Group (ECOG). ECOG performance status. [ECOG Web site].07/27/06. Available at: http://www.ecog.org/general/perf_stat.html. Accessed on March 14,2015.
- 4.) Rajkumar SV. Treatment of relapsed or refractory multiple myeloma. In: UpToDate®. Available at: <http://www.uptodate.com/contents/treatment-of-relapsed-or-refractory-multiplemyeloma>. Accessed on March 12, 2015.

FASENRA (BENRALIZUMAB)

Requests for continuing 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

- 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**
- 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

Requests for continuing 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.
- 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

1. Actiq prescribing information. Cephalon, Inc. February 2007.
2. Mystakidou D, Datsouda E, Parpa E, Vlahos L. Oral transmucosal fentanyl citrate: Overview of pharmacological and clinical characteristics. *Drug Delivery* 2006;13:269-276.
3. Virginia Premier
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FERRIPROX (DEFERIPRONE)

Documentation of the following:

1. A diagnosis of transfusional iron overload due to thalassemia syndrome; **AND**
2. Patient is 8 years of age or older; **AND**
3. An inadequate response, intolerance or a contraindication to TWO of the following:
 - a. Desferal (deferoxamine)
 - b. Exjade (deferasirox)
 - c. Jadenu;

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

4. Serum ferritin levels that are consistently > 2500 mcg/L (*demonstrated by at least two lab values in the previous 3 months*); **AND**
5. An absolute neutrophil count (ANC) >1.5 x 10⁹/L; **AND**
6. 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

Clinical Background Information and References

1. Product Information. Exjade® (deferasirox). Novartis Pharmaceuticals Corporation. East Hanover, New Jersey 07936. January 2013.
2. Schrier, S, Bacon, B. Chelation therapy for iron overload states. UptoDate® Accessed 2014 Feb; available from <http://uptodate.com>
3. Kwiatkowski JL. Management of transfusional iron overload – differential properties and efficacy of iron chelating agents. Journal of Blood Medicine 2011;2 135-149
4. Ferriprox (package insert). Rockville, MD: ApoPharma USA, Inc; October 2011
5. Deferiprone (Ferriprox); for iron overload. The Medical Letter 2012; 54:1384
6. Olivieri N et al. Long Term Safety and Effectiveness of Iron-Chelation Therapy with Deferiprone for Thalassemia Major. N Engl J Med 1998; 339:417-423.
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LAST REVISION: 11/1/21

FIRDAPSE (AMIFAMPRIDINE)

CRITERIA FOR USE

- The indicated diagnosis must be Lambert-Eaton myasthenic 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

Requests for continuing 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

- 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:

- 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

2. Badesch D B, Abman S H, et al. Medical therapy for pulmonary arterial hypertension: ACCP Evidence-Based Clinical Guidelines CHEST vol 126: supplement 2004 35S-62S.
3. Rich S, Calcium channel blockers and anticoagulants in the therapy of pulmonary hypertension. ACC Current Journal Review (1994), Nov/Dec:pp 19-22.
4. Gaien SP, Rubin LJ. Primary pulmonary hypertension. Lancet. 1998;352:719-725.
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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).

Requests for continuing 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 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

1. Eli Lilly and Company. Forteo® (teriparatide [rDNA origin] injection) prescribing information. Indianapolis, IN; November 2012.
2. Neer RM, Arnaud CD, Zanchetta JR et al. Effect of parathyroid hormone (1-34) on fractures and bone mineral density in postmenopausal women with osteoporosis. *N Engl J Med.* 2001; 344:1434-41.
3. Reeve J. Recombinant human parathyroid hormone: osteoporosis is proving amenable to treatment. *BMJ.* 2002
4. Orwoll ES, Scheele WH, Paul S et al. The effect of teriparatide [human 107ulticenter hormone (1-34)] therapy on bone density in men with osteoporosis. *J Bone Miner Res.* 2003; 18:9-17.

FOTIVDA (TOVOZANIB)

- Confirm member has a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC); **AND**
- Member is 18 years of age or older; **AND**
- Documentation provided that supports member has received at least two or more prior systemic therapies; **AND**
- Prescribed by or in consultation with an oncologist

Authorization Duration: Initial approval: 6 months, Renewal approval: 12 months

LAST REVISION: 7/1/21

FYLNETRA (PEGFILGRASTIM-PBBK)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Cancer patients receiving myelosuppressive chemotherapy.

1. Approve Fynetra if prescribed by, or in consultation with, an oncologist or hematologist.
2. Fynetra 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:

Requests for continuing 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. 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.

LAST REVISION: 10/1/22

References

1. Amgen Inc. Neulasta® (pegfilgrastim) injection prescribing information. Thousand Oaks, CA; November 2012. From Amgen website (<http://www.neulasta.com>).
2. Amgen. Neupogen (filgrastim) prescribing information. Thousand Oaks, CA; November 2012.
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5. Lieschke GJ, Burgess AW. Granulocyte colony-stimulating factor and granulocyte-macrophage colony-stimulating factor. (First of two parts.) *N Engl J Med*. 1992; 327:28-35.
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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

11. American Hospital Formulary Service Drug Information. Available at:
<http://www.medicinescomplete.com/mc/ahfs/current/>. Accessed Nov. 2012.

GAMUNEX/GAMUNEX C (IMMUNE GLOBULIN, HUMAN INTRAVENOUS)

- 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
- 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

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

- Renal Transplant rejection, 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 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

1. Berger M. Subcutaneous immunoglobulin replacement in primary immunodeficiency. *Clin Immunol* 2004;112:1-7.
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3. Chu Y-Way et al. "Idiopathic thrombocytopenia purpura." *Pediatrics Review* 2000; 21(3):94-105.
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6. Dalakas MC et al. "A controlled trial of high-dose intravenous immunoglobulins infusions as treatment for dermatomyositis." *N Engl J Med* 1993;329:1993-2000.
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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

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GATTEX (TEDUGLUTIDE)

- Diagnosis of short bowel syndrome **AND**
- Member is 1 year of age and older **AND**
- Prescribed in consultation with a gastroenterologist **AND**
- Short bowel management has been dependent on parental nutrition support on 3 or more days per week for at least 12 months prior to initiation of Gattex (supporting documentation attached demonstrating the requirement of parental nutrition) **AND**
- Documentation of colonoscopy or imaging to rule out polyps within the last 6 months **OR**
- Documentation of fecal occult blood testing prior to initiating treatment in pediatrics **AND**
- Member has not had a diagnosis of cancer within the past 5 years **AND**
- Patient does not have an active intestinal obstruction **AND**
- Maximum dosage should not exceed 0.05mg/kg once daily

Approval duration of 6 months

Renewal 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

- Documentation that the amount of parenteral nutrition support has been decreased at least 20% as a result of Gattex and there has not been any treatment related adverse events (medical records must be submitted for review which include volume of parental nutrition).

Approval for renewal of max of 6 months.

GAVRETO (PRALSETINIB)

- Treatment of Non-small cell lung cancer; AND
 - Member is greater than or equal to 18 years of age; AND
 - Member has metastatic disease; AND
 - Member has rearranged during transfection (RET) fusion-positive disease as detected by an approved test OR
- Treatment of advanced or metastatic RET-mutant medullary thyroid cancer (MTC); AND
 - Member is greater than or equal to 12 years of age; AND
 - Member requires systemic therapy OR
- Treatment of advanced or metastatic RET fusion-positive thyroid cancer; AND
 - Member is greater than or equal to 12 years of age; AND
 - Member requires systemic therapy; AND
 - Member is radioactive iodine-refractory (if radioactive iodine is appropriate)
- The medication is prescribed by or in consultation with an Oncologist
- There is confirmation that the member does NOT have uncontrolled hypertension; AND
- There is confirmation that the member has NOT had recent major surgery within the previous 14 days and will NOT have elective surgery in upcoming 5 days; AND
- There is confirmation that the member does not have neurologically unstable/symptomatic central nervous system (CNS) metastases; AND
- Gavreto will be used as a single agent; AND
- Gavreto will not be used concomitantly with other RET-type targeted therapies (e.g., selpercatinib, cabozantinib, vandetanib, etc.); AND
- Confirmation that the member will avoid concomitant therapy with any of the following:
 - Coadministration with strong CYP3A inhibitors (e.g., fluconazole, itraconazole, etc); if therapy is unavoidable, the member will be monitored for adverse reaction and/or dose modification; AND
 - Coadministration with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's wort, etc); if therapy is unavoidable, the member will be monitored for adverse reaction and/or dose modification; AND
 - Coadministration with combined P-gp and strong CYP3A inhibitors (e.g., azole-antifungals, cobicistat, HIV protease inhibitors, imatinib, boceprevir, etc); if therapy is unavoidable, the member will be monitored for adverse reaction and/or dose modification

Requests for continuing 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 Dates:

Initial: 6 months

Renewal: 6 months

RENEWAL

- The member continues to meet the above criteria; AND
- The member has experienced disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND
- The member is not experiencing any unacceptable toxicity from the drug (e.g., interstitial lung disease or pneumonitis, severe hypertension, severe hepatotoxicity, severe or life-threatening hemorrhage, impaired wound healing, etc.)

LAST REVISION: 11/1/21

GEMTESA (VIBEGRON)

- Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency:
 - Member is 18 years of age or older AND
 - Member has tried and failed at least 2 formulary urinary antispasmodics

Authorization Dates:

12 months

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
- 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

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

- 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 re- arrangements, 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

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GOCOVRI (AMANTADINE)

- Patient is experiencing dyskinesia or “off” episodes associated with a Diagnosis of Parkinson’s Disease **AND**
- Patient is 18 years of age or older **AND**
- Patient is currently on concomitant levodopa-based therapy **AND**
- 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) **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 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

LAST REVISION 7/1/21

GONADATROPIN RELEASING HORMONE AGONSITS

	Vantas	Supprelin LA	Zoladex	Lupron Depot Peds	Lupron Depot	Eligard	Trelstar
Breast Cancer *see specific criteria for exact diagnosis			X	X	X	X	
Dysfunctional/ Excessive Uterine Bleeding			X	X	X	X	
Edometrial Ablation/ Hysterectomy			X				
Endometriosis			X	X	X	X	X
Gender Dysphoria	X	X		X	X	X	X
Ovarian Cancer				X	X	X	
Premenstrual Syndrome				X	X	X	
Precocious Puberty		X	X	X	X	X	X
Prostate Cancer *see specific criteria for exact diagnosis	X		X	X	X	X	X
Testicular Cancer				X	X	X	

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

Uterine Leiomyoma (Fibroids)			X	X	X	X	X
Vascular Cancer				X	X	X	

The above table lists the formulary GnRH products and the diagnoses that can be approved if the below criteria is met. All criteria under each diagnosis must be met unless otherwise noted.

BREAST CANCER:

- Member has a diagnosis of Breast Cancer (Leupron and Eligard) or Hormone-receptor positive breast cancer in men and pre-menopausal women (Zoladex) or Advanced breast cancer in pre- and peri-menopausal women (Zoladex)

DYSFUNCTIONAL OR EXCESSIVE UTERINE BLEEDING:

- Member has a diagnosis of dysfunctional or excessive uterine bleeding; AND
- Member has tried and failed or is intolerant to oral contraceptive

ENDOMETRIAL ABLATION/ HYSTERECTOMY:

- Member has a diagnosis of endometrial ablation or hysterectomy; AND
- Zoladex is being used as a preoperative adjunct

ENDOMETRIOSIS:

Initial Therapy:

- Member has a diagnosis of endometriosis confirmed by ultrasound, laparoscopy, or other confirmatory diagnostic test; AND
- Prescribed by a gynecologist or obstetrician; AND
- Member has 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 a documented contraindication to hormonal therapy; AND
- For Trelstar: Member has tried and failed or is intolerant to leuprolide; AND
- The member’s medical records maintained by the requesting independent practitioner are provided confirming all of the above.

****If initial criteria is met, may approve Lupron 3.75 mg monthly (#6 injections) OR Lupron 11.25 mg every three (3) months (#2 injections) OR appropriate dosing for other products for a total of six (6) months 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

Continuation of Therapy:

- Member is still symptomatic with pain after the initial six (6) months of therapy; AND
- Member is taking concurrent norethindrone therapy (unless contraindicated such as in cerebral apoplexy, thrombophlebitis, or thromboembolic disorders); AND
- The member's medical records maintained by the requesting independent practitioner are provided confirming all of the above.

If the continuation of therapy criteria are met, may approve for a total of six (6) months of additional therapy (only 1 additional course of 6 months of therapy is allowed**)

GENDER DYSPHORIA

Please note that only the following regimens can be approved for this diagnosis. All other regimens are not able to be approved for gender dysphoria

- Vantas: 50 mg annual dose only
- Supprelin LA: 50 mg annual dose only
- Lupron Depot Peds: 11.25 mg 3-month formulation and 30 mg 3 month formulation only
- Lupron Depot: 22.25 mg 3-month formulation, 30 mg 4-month formulation, and 45 mg 6-month formulation only
- Eligard: 22.25 mg 3-month formulation, 30 mg 4-month formulation, and 45 mg 6-month formulation only
- Trelstar: 11.25 mg 3-month formulation and 22.25 mg 6-month formulation only

**The following products are Non-Formulary. If all below criteria has been met AND all above formulary products for gender dysphoria have been tried and failed or are contraindicated, the below products could be approved for this diagnosis. All other regimens of these products are not able to be approved for gender dysphoria*

- Fensolvi: 45 mg 6-month formulation only
- Triptodur: 22.25 mg 6-month formulation only
- Synarel: 1600-1800 mcg/day only

GnRH therapy will be approved for gender dysphoria in the following scenarios:

Puberty-suppressing and **gender-affirming** hormonal therapy for gender dysphoria is considered medically necessary when **ALL** the following criteria are met:

- The member has been assessed and diagnosed with gender dysphoria according to DSM-V criteria, by one of the following provider type;
 - A licensed mental health provider; **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

- If the member is over the age of 18, a gender dysphoria-informed hormone prescriber **AND**
- Medication is recommended and prescribed by, or in consultation with, an endocrinologist or other medical provider experienced in gender dysphoria hormone therapy; **AND**
- Coexisting behavioral health and medical comorbidities or social problems that may interfere with diagnostic procedures or treatment are being appropriately treated and are not causing symptoms of gender dysphoria; **AND**
- Member has experienced puberty development to at least Tanner stage 2 (stage 2 through 4) or has lab values for Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH), and the endogenous sex hormones consistent with at least Tanner stage 2 **AND**
- The member has capacity to make informed treatment decisions and has assented to treatment after discussion of the potential benefits and risks. The process should include parental or legal guardian consent for unemancipated members under the age of 18 **OR**

The regimen is a **trans-feminine regimen** (male to female); **AND**

- Failure to achieve physiologic hormone levels or an intolerance with use of oral estrogens and spironolactone **OR**

The regimen is a **trans-masculine regimen** (female to male) **AND**

- Member is experiencing persistent menstrual bleeding with testosterone supplementation **AND**
- Attestation of prescriber that addition of a GnRH agonist is warranted in addition to testosterone supplementation to treat persistent menstrual bleeding

OVARIAN CANCER:

- Member has a diagnosis of ovarian cancer.

PREMENSTRUAL SYNDROME:

- Member has a diagnosis of premenstrual syndrome.

PRECOCIOUS PUBERTY:

Initial Therapy:

- Member has a clinical diagnosis of central precocious puberty 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

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

- Assessment of bone age versus chronological age; AND
- Member is ≥ 2 years old; AND
- For Eligard (leuprolide acetate), Supprelin LA (histrelin), Trelstar (triptorelin pamoate), and Zoladex (goserelin acetate): member has a previous trial and failure with Lupron Depot or generic leuprolide (failure described as the inability to suppress physical signs of puberty)

Continuation of Therapy:

- Height and weight have regressed to a more normal linear pattern
- Secondary Sex characteristics have not progressed

*Duration of therapy should last until onset of puberty (girls ~age 11, boys ~age 12)

PROSTATE CANCER:

Vantas:

- Member has a diagnosis of advanced prostate cancer; AND
- Member is 18 years of age or older; AND
- Member is male.
- For Continuation of Therapy: Testosterone continues below castration level.

Lupron Depot, Leuprolide (generic), Eligard, Trelstar, or Zoladex:

- Member has a diagnosis of prostate cancer or Stage B2-C Prostatic Cancer (Trelstar); AND
- Member has tried and failed or is intolerant to orchietomy or estrogen

TESTICULAR CANCER:

- Member has a diagnosis of testicular cancer.

UTERINE LEIOMYOMA (FIBROIDS):

- Member has a diagnosis of uterine leiomyoma (uterine fibroids).
- For Trelstar: member has tried and failed or is intolerant to leuprolide.
- For Zoladex: this is being used preoperatively as an adjunct to surgical treatment)

VASCULAR CANCER:

- Member has a diagnosis of vascular cancer.

LAST REVISION: 2/1/22

Requests for continuing 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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24. 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

GRASTEK

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

- the member is 5 years of age or older for **Grastek**
- AND-**
- the medication is prescribed by an allergist, immunologist, or ENT (ear, nose, throat) specialist, or the prescriber is from BLAND COUNTY MEDICAL CLINIC
- AND-**
- **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
- AND-**
- 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.
- AND-**
- the member is NOT currently receiving subcutaneous allergen immunotherapy.
- When approved, members may obtain 30 sublingual **Grastek** tablets per 30 days

References:

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GROWTH HORMONE

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Indication >	Growth Hormone Deficiency		Growth failure due to Chronic Renal Insufficiency	Growth failure in children born small for gestational age	Prader-Willi Syndrome in children	Turner's Syndrome	Cachexia AIDS-related	Short Bowel Syndrome
	Children	Adults						
Accretropin	X					X		
Genotropin	X	X		X	X			
Humatrope	X	X				X		

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

Norditropin	X	X		X		X		
Nutropin	X	X	X			X		
Nutropin AQ	X	X	X			X		
Saizen	X	X						
Sogroya		X						
Serostim							X	
Skytrofa	X							
Omnitrope	X	X						
Tev-Tropin	X							
Zorbtive								X

Genotropin and Norditropin FlexPro are the preferred drugs. Member must have tried/failed Genotropin and Norditropin FlexPro 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

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

Requests for continuing 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. 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)

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

11. Pediatric Chronic Kidney Disease/Chronic Renal insufficiency

Requests for continuing 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. 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

12. 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
 - Arginine
 - iii. Peak GH level was shown to be below normal (***medical record documentation required***)

13. Short Bowel Syndrome

- a. Member will receive specialized nutritional support

Requests for continuing 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. 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).
6. Burn injury (severe) in children.
7. Cardiac transplantation.
8. Central precocious puberty.
9. Chronic fatigue syndrome.
10. Congenital adrenal hyperplasia.
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.
13. Crohn's disease.
14. Cystic fibrosis.
15. Dilated cardiomyopathy and heart failure.
16. Down's syndrome.
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-125 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).
21. Infertility.
22. Kidney transplant patients (children) with a functional renal allograft.
23. Liver transplantation.
24. Multiple system atrophy (MSA).
25. Myelomeningocele.
26. Obesity.

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

27. Osteogenesis imperfecta.
28. Osteoporosis, postmenopausal women, idiopathic in men, or glucocorticoid-induced.
29. Thalassemia.
30. X-linked hypophosphatemic rickets (familial hypophosphatemia, hypophosphatemic rickets).

CONTRADICTIONS

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 (OmnitropinI, SaizenI, Tev-TropinI, ZorbtivelI)
- 5) hypersensitivity to metacresol (GenotropinI 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 (NutropinI, Nutropin AQI, SaizenI)
- 4) diabetic retinopathy, active proliferative or severe non-proliferative (NutropinI, Nutropin AQI, SaizenI, SerostimI)
- 5) hypersensitivity to somatropin, mammalian-derived or any excipients
- 6) hypersensitivity to benzyl alcohol (SaizenI, SerostimI, ZorbtivelI)
- 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 (NutropinI, Nutropin AQI, SaizenI)

c) Lonapegsomatropin

1. Acute critical illness
2. Hypersensitivity to somatropin or any of the excipients in Skytrofa
3. Children with closed epiphyses
4. Active malignancy
5. Active proliferative or severe non-proliferative diabetic retinopathy

Requests for continuing 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. Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment due to risk of sudden death

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LAST REVISION: 1/1/22

HEPATITIS C AGENTS NON-PREFERRED (HARVONI, VOSEVI, SOVALDI, EPLUSA, VIEKIRA, PEGASYS, OLYSIO, TECHNIVIE, ZEPATIER)

- Medication must be prescribed by or in consultation with a gastroenterologist, hepatologist, transplant specialist, or infectious disease specialist **AND**
- Member must have a diagnosis of Acute or 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 **AND**
- 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 **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 must have trial/failure or intolerance to both preferred agents Mavyret and sofosbuvir/velpatasvir unless clinically inappropriate **AND**
- 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

LAST REVISION: 11/3/2022

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.
 - 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)

Hetlioz capsules only

- Member has diagnosis of non-24-hour sleep wake disorder (non-24 or N24) in completely blind members; AND
- Age 18 years of age or older; AND
- Member must have tried OTC melatonin and failed to achieve an adequate response; 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 or in consultation with a specialist in Sleep Disorders
- NONE the following:
 - Severe hepatic impairment (Child-Pugh Class C); **OR**
- Member has diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS); AND
- Age is 16 years of age or older; AND
- NONE the following:
 - Severe hepatic impairment (Child-Pugh Class C);

Hetlioz LQ oral suspension only

- Member has diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS); AND
- Age is 3 to 15 years of age; AND
- 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
- Relapsing-Remitting Multiple Sclerosis, 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

- 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
- Renal Transplant rejection, 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 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

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HORIZANT (GABAPENTIN EXTENDED RELEASE)

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

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

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.

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

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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

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IBSRELA (TENAPANOR)

- Diagnosis of irritable bowel syndrome with constipation (IBS-C) in adults
- Patient must be at least 18 years old
- A clinical trial period of lifestyle changes and dietary modifications prior to starting medication therapy
- 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)
- Treatment failure with at least ONE of the following:
 - Linzess
 - Amitiza (females)
 - Trulance

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:

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

- 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
- Adult onset Still's disease
- 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. OR
- Acute Gouty Arthritis **AND**
- Member has a documented history of repeated acute gouty arthritis flares **AND**
- Member has tried and failed or had a contraindication to 2 of the following
 - NSAID
 - Colchicine
 - Corticosteroid**AND**
 - Member has tried and failed or had an intolerance/contraindication to Humira or Enbrel **AND**
 - Member has tried and failed or had an intolerance/contraindication to use of Kineret **AND**
 - Quantity requested for gout attack does not exceed 1 dose (150mg) per 60 days
- **Note:** Must NOT be the following CAPS disorders:
 - Neonatal-Onset Multisystem Inflammatory Disease (NOMID),OR
 - Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA)

LAST REVISION: 7/1/21

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ILUMYA (TILDRAKIZUMAB-ASMN)

Treatment of Plaque Psoriasis (PSO):

- Member has a diagnosis of moderate-to-severe plaque psoriasis for at least 6 months with at least 1 of the following:
 - Involvement of at least 10% of body surface area (BSA); OR
 - Psoriasis Area and Severity Index (PASI) score of 10 or greater; OR

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- Incapacitation due to plaque location (e.g., head and neck, palms, soles or genitalia); AND
- Member has not responded adequately (or is not a candidate) to a 3 month minimum trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues); AND
- Member has not responded adequately (or is not a candidate) to a 3 month minimum trial of at least 1 systemic agent (e.g. Immunosuppressives, retinoic acid derivatives, and/or methotrexate); AND
- Have not responded adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (e.g. Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol)
- Member has tried and failed Humira and Enbrel

Approval Duration

- Initial – 12 months
- Renewal – 12 months

LAST REVISION: 7/1/21

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.

OR

- Clinically diagnosed with Chronic graft versus host disease (cGVHD); **AND**
- The member has received at least one prior systemic therapy

Criteria for continuation of therapy:

- Patient responding to treatment without disease progression
- Patient tolerating treatment
- **Caution:**
 - Hemorrhage

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

- 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:

1. Imbruvica prescribing information. Horsham, PA: Janssen Biotech, Inc.; 2014 February.
2. National Cancer Institute. Non-Hodgkin's Lymphoma (PDQ®). URL: www.cancer.gov/cancertopics/pdq/treatment/adult-non-hodgkins/HealthProfessional. Accessed 2013 November 27.
3. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphoma. 2013 November. URL: www.nccn.org/professionals/physician_gls/pdf/nhl.pdf. Accessed 2013 November 27.
4. 1. Oken MM, Creech RH, Tormey DC et-al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am. J. Clin. Oncol. 1983;5 (6): 649-55.

LAST REVISION 1/1/2023

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

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

- Open epiphyses
- Age ≥ 2 and ≤ 20 years of age

Reauthorization.continuing therapy:

- Increase in height velocity > 2.5cm total growth in 1 yr, AND
- 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 \leq the 25th percentile (defined as 68 inches in males and 63 inches in females).

References

1. Increlex. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
2. Mecasermin. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.

INQOVI (DECITABINE/CEDAZURIDINE)

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

- Individual has a diagnosis of myelodysplastic syndrome (MDS) or chronic myelomonocytic leukemia (CMML); **AND**
- Individual has intermediate to high-risk disease; **AND**
- Age is 18 years or older; **AND**
 - Prescribed by an oncologist; **AND**
 - The member has 1 of the following French-American-British (FAB) sub-types with an International Prognostic Scoring System (IPSS) group risk classification of Intermediate-1, Intermediate-2, or High:
 - Refractory anemia; **OR**
 - Refractory anemia with ringed sideroblasts; **OR**
 - Refractory anemia with excess blasts; **OR**
 - Chronic Myelomonocytic Leukemia (CMML); **AND**
 - Confirmation that the member does NOT have a diagnosis of acute myelogenous leukemia (AML); **AND**
 - Confirmation that therapy will not be substituted for IV decitabine within the same cycle; **AND**
 - Confirmation that decitabine/cedazuridine will be used as a single agent therapy; **AND**

RENEWAL

- The member continues to meet the above criteria; **AND**
- Member has adequate documentation of disease stability and/or improvement as indicated by the following:
 - Decrease in bone marrow blasts percentage; **OR**
 - Increase in platelets; **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

- Increase in hemoglobin; OR
- Decrease in transfusions (if transfusion dependent); OR
- Increase in white blood cell (WBC) and absolute neutrophil counts (ANC) over pretreatment values; OR
- Reduction in abnormal cytogenetic metaphases; AND
- The member is not experiencing any unacceptable toxicity from the drug (e.g., severe myelosuppression, serious infectious complications)

Authorization Dates:

- Initial: 6 months
- Renewal: 6 months

LAST REVISION: 11/1/21

INREBIC (FEDRATINIB)

Initial:

- Patient must have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF)
AND
- Patient must be 18 years old
- Medication should be limited for those patients who are ineligible for allogeneic hematopoietic cell transplantation (HCT)
- Platelet count must be greater than or equal to $50 \times 10^9/L$
- Prescriber agrees to monitor thiamine (Vitamin B1) levels and monitor for encephalopathy

Reauth:

- Patient has shown symptomatic improvement
- Platelet count must be greater than or equal to $50 \times 10^9/L$
- Prescriber agrees to monitor thiamine (Vitamin B1) levels and monitor for encephalopathy

ISTURISA (OSILODROSTAT)

CRITERIA FOR USE

INITIAL (3 months authorization)

- 1) Prescriber attests to a documented diagnosis of Cushing's disease
AND
- 2) Prescribed by or in consultation with an endocrinologist
AND
- 3) Age is 18 years 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

- 4) Prescriber attests to a documented failed pituitary surgery or contraindication to pituitary surgery
AND
 - 5) Baseline electrocardiogram (ECG) obtained and prescriber agrees to monitor for QTc prolongation
AND
 - 6) If indicated, hypokalemia and hypomagnesemia will be corrected prior to initiating therapy
AND
 - 7) Prescriber agrees to monitor cortisol levels
AND
 - 8) Prescriber agrees to monitor for hepatic impairment
- REAUTHORIZATION (12 months reauthorization)**
- 1) Prescriber attests to a documented diagnosis of Cushing's disease
AND
 - 2) Prescriber agrees to monitor for ALL of the following:
 - a. QTc prolongation
 - b. Cortisol levels
 - c. Hepatic impairment

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.

Requests for continuing 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. 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.
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

JUXTAPID (LOMITAPIDE MESYLATE)

- Confirmed diagnosis, supported by medical records, or homozygous familial hypercholesterolemia
- Member is at least 18 years of age
- Prescriber is certified with the applicable REMS program
- Member has had treatment failure, maximum dosage with, or contraindication to all of the following:
 - a. Statin
 - b. Zetia (ezetimibe)
 - c. Fibric acid derivatives
 - d. Omega-2 agents
 - e. Bile Acid sequestrants
- Reauthorization Criteria:
 - a. Member is currently tolerating Juxtapid therapy
 - b. Maintenance dose does not exceed 60 mg
 - c. Member's current LDL-C is at least 20% lower than the levels immediately prior to the initiation of treatment with Juxtapid
 - d. Prescriber attestation that liver function is being monitored

Coverage duration: Initial 6 months, Reauthorization 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

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.
- For Granules the member is 4 months of age to less than 6 years of age.

References

Virginia Premier

KERENDIA (FINERENONE)

Initial Approval:

- Confirm member has a diagnosis of type 2 diabetes mellitus; AND
- Member has stage 2, 3, or 4 chronic kidney disease (CKD); AND
- Member is 18 years of age or older; AND
- Member has eGFR > 25ml/min/1.73m²; AND
- Member has serum potassium < 4.8 mEq/L at initiation; AND
- Member is taking an ACE inhibitor or ARB concurrently (e.g. Lisinopril, losartan, etc); AND
- Member has an adequate trial and failure Farxiga

Renewal Approval:

- Documentation of positive response to therapy, such as reduce risk of kidney function decline, and tolerating therapy.

Authorization Duration:

Initial approval: 12 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

KESIMPTA (OFATUMUMAB)

- The member is 18 years of age or older; **AND**
- The member has been diagnosed with a relapsing form of multiple sclerosis (e.g., relapsing remitting disease [RRMA], OR active secondary progressive disease [SPMS], OR clinically isolated syndrome [CIS]) as documented WITH ICD 10 CODE; **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

- Must have tried either a preferred injectable product OR preferred Tecfidera.
- **Approval duration** is for 12 months for initial and 12 months for reauthorization.

References

1. Virginia Premier Health Plan

LAST REVISION: 7/1/21

KEVZARA (SARILUMAB)

Initial Review Criteria:

- Member has a diagnosis of moderately to severely active rheumatoid arthritis (RA); AND
- Member is 18 years of age or older; AND
- Prescribed by or in consultation with a rheumatologist; AND
- Member has tried and failed Humira and Enbrel
- Member has a history of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., Rheumatrex /Trexall (methotrexate), Arava (leflunomide), Azulfidine (sulfasalazine)]; AND
- For continuation of prior Kevzara therapy, member is not receiving Kevzara in combination with any of the following:
 - Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
 - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
 - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Renew Criteria:

- Documentation of positive clinical response to Kevzara therapy

Approval Duration

- Initial – 12 months
- Renewal – 12 months

LAST REVISION: 7/1/21

KIMYRSA (ORITAVANCIN)

- Confirm member has a diagnosis of acute bacterial skin and skin structure infection caused by susceptible isolates of the following Gram-positive microorganisms; **AND**
- Member is 18 years of age or older; **AND**
- Confirm susceptible isolates include one of the following: Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus anginosus group (includes S. anginosus, S. intermedius, and S.

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

constellatus), and Enterococcus faecalis (vancomycin-susceptible isolates only), **AND**

- Member has no concomitant use with Orbactive

Authorization Duration: One-time approval

Last revision: 7/1/21

KINERET (ANAKINRA)

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 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. Riloncept 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.

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

Deficiency of Interleukin-1 Receptor Antagonist

Approve for 12 months

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 JIA.

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 biologic improvement) to therapy with anakinra. Intravenous methylprednisolone was discontinued in 7 of 7 patients who had been on this therapy for months. Oral prednisone was stopped in one patient and tapered in 6 of 7.

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),

Requests for continuing 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 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.

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

Muckle-Wells Syndrome (MWS).

Approve for 12 months if the patient has tried two other drugs (e.g., riloncept [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. Riloncept 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, riloncept, 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. Riloncept 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.³⁸⁻⁴⁰ NSAIDs, antihistamines, colchicine, immunosuppressive drugs, and corticosteroids are not consistently effective in treating this syndrome.

Acute gout.

Approve 5 doses for a 30 days supply for 12 months 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.

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

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 erythematosus (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, corticosteroids, MTX, cyclophosphamide, and azathioprine. SLE was controlled with stable doses of corticosteroids and/or antirheumatic or

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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 (HbA_{1c}) 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 glycemia 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, HbA_{1c}, 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.

Quantity Limit Alert:

- One syringe per day, quantities above 30/30 require a quantity limit review.

LAST REVISION: 1/1/22

References

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2. JA Singh et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res* 2012; 64: 625-639. <http://www.rheumatology.org/practice/clinical/guidelines/Singh%20et%20al-ACR%20RA%20GL-May%202012%20AC&R.PDF>
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4. Cohen S, Hurd E, Cush J, Schiff M et al. Treatment of rheumatoid arthritis with anakinra, a recombinant human interleukin-1 receptor antagonist, in combination with methotrexate: results of a twenty-four-week, multicenter, randomized, double-blind, placebo-controlled trial. *Arthritis Rheum* 2002;46:614-24.5. Yang BB, Baughman S, Sullivan JT. Pharmacokinetics of anakinra in subjects with different levels of renal function. *Clin Pharmacol Ther*. 2003;74:85-94.

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

KLISYRI (TIRBANIBULIN)

- Confirm member has a diagnosis of actinic keratosis; **AND**
- Documentation provided that supports member has trial and failure of fluorouracil **and** imiquimod.

Authorization Duration: 12 months

LAST UPDATED: 10/1/21

KORLYM (MIFEPRISTONE)

Initial Criteria:

- Member is 18 years of age and older **AND**
- Prescribed by an endocrinologist or in consultation with **AND**
- Member has a diagnosis of Endogenous Cushing's Syndrome and **ONE** of the following:
 - Type 2 Diabetes Mellitus **OR**
 - Glucose intolerance **AND**
- Member has either failed surgery or is not a candidate for surgery **AND**
- Provider has attached documentation of clinical failure (unable to normalize cortisol levels) of **ONE** of the following steroidogenesis inhibitors:
 - Ketoconazole
 - Metopirone
 - Mitotane **OR**
- Member has treatment/failure pituitary directed therapy of cabergoline or pasireotide **AND**
- Documentation supplied which supports clinical failure to control glucose levels with metformin and **TWO** the following agents:
 - Glucagon-Like Peptide-1 (GLP-1) receptor agonist (ie. Trulicity, Ozempic, etc)
 - Insulin (Humalog, Lantus, Levemir, etc.)
 - Dipeptidyl Peptidase (DPP-4) inhibitor (Januvia, Onglyza, etc) **AND**
- Member has documented normal potassium levels and is not currently taking CYP3A metabolized agents, is not receiving systemic corticosteroids for lifesaving purposes, and no history of unexplained vaginal bleeding or endometrial hyperplasia with atypica or endometrial carcinoma **AND**
- For reproductive females, pregnancy has been excluded before initiation of treatment and plans for prevention are implemented and documented during treatment and for 1 month after discontinuation (hormonal contraceptives are contraindicated)

Reauthorization 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

- Member continues to meet initial criteria **AND**
- Documentation submitted supports improvement in disease shown by improved glycemic control (current lab work must be submitted) **AND**
- Member is not experiencing any intolerable side effects or drug toxicity

Initial approval: 3 months

Continuation approval: 12 months

Quantity Limitation: 120 tablets per 30 days

LAST REVISION: 5/1/2022

KOSELUGO (SELUMETINIB)

Approval Duration: 1 year for Initial and Reauthorizations

Initial:

- Prescriber attests that patient has inoperable neurofibromatosis type 1 that is symptomatic with inoperable plexiform neurofibromas (PN) (defined as PN(s) that may not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN); AND
- Prescriber attests that patient has significant morbidity related to PN as defined by the prescriber; AND
- Initial treatment will be started in a patient that is 21 years of age or younger; AND
- Provider attests to monitor for cardiomyopathy, ocular, gastrointestinal, skin toxicity as well as rhabdomyolysis (creatinine phosphokinase levels); AND
- Prescriber will use caution in co-prescribing Koselugo with vitamin-K antagonists or anti-platelet antagonists; AND
- Prescribed in conjunction with a provider that specializes in treating patients with NF1; AND
- Patient is 2 years of age or older

Reauthorization:

- For inoperable neurofibromatosis type 1
- Patient has had at least a 20% or greater reduction in target NF1 PN volume confirmed after at least 3 months of treatment; OR
- If renewal is beyond the time frame for the first renewal request, prescriber attests to a continued reduction in target NF1 PN volume or stabilization of target NF1 PNs; AND
- Prescriber attests to significant improvements in morbidity and/or patients quality of life while taking Koselugo; 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

- Prescriber continues to monitor for possible side effects such as cardiomyopathy, ocular, gastrointestinal, skin toxicity as well as rhabdomyolysis (i.e. creatine phosphokinase levels)

KYRSTEXXA (PEGLOTICASE)

Initial Criteria:

- Member is 18 years of age and older **AND**
- Medication is prescribed by a rheumatologist or nephrologist **AND**
- Member is hyperuricemic with serum urate level of ≥ 6 mg/dl at baseline **AND**
- Member does not have glucose-6-phosphate (G6PD) deficiency **AND**
- Member has symptomatic hyperuricemia with the presence of at least **ONE** of the following:
 - Chronic gouty arthropathy
 - 3 or more flares within the previous 18 months
 - ≥ 1 tophus **AND**
- Member must have a documented 3-month trial and failure with both of the following:
 - Allopurinol
 - Febuxostat

Reauthorization Criteria:

- Documentation submitted member has improvement or stabilization in condition **AND**
- Documentation submitted of two recent consecutive serum uric acid levels (levels should be less than 6 mg/dl showing treatment efficacy)

Initial approval: 6 months

Reauthorization approval: 6 months

Quantity Limit: Max of two 1ml vials (8mg per vial) per 28 days

LAST REVISION 1/1/2023

KUVAN (SAPROPTERIN DIHYDROCHLORIDE)

- Hyperphenylalaninemia due to 151ulticenter151y151terin- (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.

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

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

1. Doggrell SA. Is sapropterin treatment suitable for all subjects with phenylketonuria? Expert Opinion Pharmacotherapy. 2008; 9(1):145-7.
2. Giovannini M, Verduci E, Salvatici E et al. Phenylketonuria: dietary and therapeutic challenges. J Inherit Metab Dis. 2007; 30:145-52.
3. Kuvan. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
4. Sapropterin. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.

LAMPIT (NIFUTIMOX)

- Confirm member has a diagnosis of Chagas disease confirmed by serologic testing by one of the following:
 - For members <8 months of age: direct observation of *Trypanosoma cruzi* by concentration test; OR
 - For members 8 months to <18 years of age: positive conventional ELISA result for both recombinant ELISA and total purified antigen ELISA; **AND**
- The member is less than 18 years of age and weighs greater than or equal to 2.5 kg; **AND**
- The member has been counseled not to drink alcohol while on treatment; **AND**
- For female members, the member has a negative pregnancy test; **AND**
- For female members, confirmation that the member was counseled to use effective contraception during treatment; **AND**
- For male members with female partners of reproductive potential, confirmation that the member was counseled to use condoms; **AND**
- Prescriber attestation that a member with neurological and/or psychiatric conditions will be closely monitored; **AND**
- Prescriber attestation that the member's body weight will be monitored every 14 dfays to assess the need for dose adjustment

Authorization Duration:

- 60 days

LAST REVISION: 11/1/21

LEQVIO (INCLISIRAN)

Initial therapy:

1. Member has one of the following diagnoses:
 - a. High risk of ASCVD with documented history of 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

- i. Myocardial infarction
 - ii. Acute coronary syndromes
 - iii. Coronary artery disease
 - iv. Stable or unstable angina
 - v. Coronary or other arterial revascularization
 - vi. Stroke
 - vii. Transient ischemic attack
 - viii. Peripheral arterial disease
- b. HeFH as confirmed by:
- i. World Health Organizations (WHO)/Dutch Lipid Network Criteria with score of greater than 8 points; or
 - ii. Diagnosis per Simon Broome criteria
2. Member is at least 18 years of age; **AND**
 3. Prescribed by or in conjunction with a statin at the maximally tolerated dose for at least 4 months in patients who have failed to achieve their LDL-C goal; **AND**
 4. Member has inability to tolerate at least 2 high-intensity statins due to adverse events (statin-associated muscle symptoms) or contraindication; **AND**
 5. Member has been adherent to ezetimibe used concomitantly with a statin at a maximally tolerated dose for at least 4 months unless contraindicated; **AND**
 6. Member has tried and failed Repatha and Praluent.

Renewal therapy:

1. Member continues to receive concomitant maximally tolerated statin therapy (unless there is a contraindication or member is statin-intolerant); **AND**
2. Confirmation of LDL-C reduction.

Quantity Limit: 1 syringe (1.5 mL) per 6 months

LAST REVISION: 5/1/22

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

1. Bayer HealthCare. Leukine® (sargramostim) prescribing information. Seattle, WA; November 2012.

Requests for continuing 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. Grant SM, Heel RC. Recombinant granulocyte-macrophage colony-stimulating factor (rGM-CSF): a review of its pharmacological properties and prospective role in the management of myelosuppression. *Drugs*. 1992; 43:516-60.
3. Nemunaitis J, Singer JW, Buckner CD et al. Use of recombinant human granulocyte-macrophage colony-stimulating factor in autologous marrow transplantation for lymphoid malignancies. *Blood*. 1988; 72:834-6.
4. Nemunaitis J, Rabinowe SN, Singer JW et al. Recombinant granulocyte-macrophage colony-stimulating factor after autologous bone marrow transplantation for lymphoid cancer. *N Engl J Med*. 1991; 324:1773-8.
5. Goldstone AH, Khwaja A. The role of haemopoietic growth factors in bone marrow transplantation. *Leukemia Research*. 1990; 14:721-9.
6. Devereaux S, Linch DC, Gribben JG et al. GM-CSF accelerates neutrophil recovery after autologous bone marrow transplantation for Hodgkin's disease. *Bone Marrow Transplant*. 1989; 4:49-54.
7. Brandt SJ, Peters WP, Atwater SK et al. Effect of recombinant human granulocyte-macrophage colony-stimulating factor on hematopoietic reconstitution after high-dose chemotherapy and autologous bone marrow transplantation. *N Engl J Med*. 1988; 318:869-76.
8. Advani R, Chao NJ, Horning SJ et al. Granulocyte-macrophage colony-stimulating factor (GM-CSF) as an adjunct to autologous hemopoietic stem cell transplantation for lymphoma. *Ann Intern Med*. 1992; 116:183-9.
9. Nemunaitis J, Singer JW, Buckner CD et al. Use of recombinant human granulocyte-macrophage colony-stimulating factor in graft failure after bone marrow transplantation. *Blood*. 1990; 76:245-53.
10. Vose JM, Bierman PJ, Kessinger A et al. The use of recombinant human granulocyte-macrophage colony-stimulating factor for the treatment of delayed engraftment following high dose therapy and autologous hematopoietic stem cell transplantation for lymphoid malignancies. *Bone Marrow Transplant*. 1991; 7:139-43.
11. De Witte T, Gratwohl A, Van Der Lely N et al. Recombinant human granulocyte-macrophage colony-stimulating factor accelerates neutrophil and monocyte recovery after allogeneic T-cell-depleted bone marrow transplantation. *Blood*. 1992; 79:1359-65.
12. Nemunaitis J, Anasetti C, Storb R et al. Phase II trial of recombinant human granulocyte-macrophage colony-stimulating factor in patients undergoing allogeneic bone marrow transplantation from unrelated donors. *Blood*. 1992; 79:2572-7.
13. Powles R, Smith C, Milan S et al. Human recombinant GM-CSF in allogeneic bone-marrow transplantation for leukaemia: double-blind, placebo-controlled trial. *Lancet*. 1990; 336:1417-20.
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15. Herrmann F, Schulz G, Wieser M et al. Effect of granulocyte-macrophage colony-stimulating factor on neutropenia and related morbidity induced by myelotoxic chemotherapy. *Am J Med*. 1990; 88:619-24.
16. Furman WL, Fairclough DL, Huhn RD et al. Therapeutic effects and pharmacokinetics of recombinant human granulocyte-macrophage colony-stimulating factor in childhood cancer patients receiving myelosuppressive chemotherapy. *J Clin Oncol*. 1991; 9:1022-8.
17. Delannoy A. GM-CSF therapy for drug-induced agranulocytosis. *J Intern Med*. 1992; 231:269-71.
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19. Scadden DT, Bering HA, Levine JD et al. Granulocyte-macrophage colony-stimulating factor mitigates the neutropenia of combined interferon alfa and zidovudine treatment of acquired immune deficiency syndrome-associated Kaposi's sarcoma. *J Clin Oncol*. 1991; 9:802-8.
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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

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LINZESS (LINACLOTIDE)

- Diagnosis of Idiopathic Chronic Constipation or Constipation-Predominant Irritable Bowel Syndrome (IBS), 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) AND
- Patient is at least 18 years old

Authorization: 6 months

LIVMARLI (MARALIXIBAT)

Initial Approval:

- Confirm member has a diagnosis of Alagille syndrome (ALGS); AND
- Member is 1 year of age or older; AND;
- Member presents symptoms of moderate to very severe pruritus; AND
- Member has cholestasis, as indicated by at least one of the following:
 - Total serum bile acid >3 x upper limit of normal (ULM) for age;
 - Conjugated bilirubin > 1mg/dL;
 - Fat soluble vitamin deficiency that is otherwise unexplainable;
 - Gamma Glutamyl Transferase (GGT) > 3x ULN for age;
 - Intractable pruritus explainable only by liver disease
- Member does not have chronic diarrhea requiring ongoing intravenous fluid or nutritional intervention; 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 does not have history of surgical interruption of enterohepatic circulation (eg. Partial external biliary diversion [PEBD] surgery); AND
- Member has no history of liver transplant; AND
- No clinical evidence of decompensated cirrhosis; AND
- Member has adequate trial and failure of THREE of the following medications used to treat pruritus:
 - Ursodiol
 - Cholestyramine
 - Rifampin
 - Naltrexone
 - Sertraline
- Prescribed by or in consultation with a specialist experienced in ALGS treatment such as hematologist or gastroenterologist.

Renewal Approval:

- Documentation that member is tolerating therapy and there has been an improvement in pruritus

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

LIVTENCITY (MARIBAVIR)

Initial therapy:

1. Member must have a diagnosis of post-transplant cytomegalovirus (CMV) infection; **AND**
2. Member is 12 years of age or older and weighs at least 35 kg; **AND**
3. Prescriber attest to active CMV via a polymerase chain reaction (PCR) test; **AND**
4. Prescriber attests to refractory CMV, which has failed ganciclovir, valganciclovir, cidofovir, or foscarnet; **AND**
5. Prescribed by or in conjunction with a transplant specialist or infectious disease specialist

Approval Duration:

Initial: 2 months

Renewal: not allowable

LAST REVISION: 5/1/22

LODOSYN (CARBIDOPA)

- Diagnosis of Parkinson's disease or Parkinsonism; 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

- Being used as an adjunct to therapy with Carbidopa/Levodopa; AND
- Documented allergy to Carbidopa (generic of Lodosyn)

References

1. Lodosyn (carbidopa) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America; February 2014.

LOREEV XR (LORAZEPAM)

Initial Approval:

- Confirm member has a diagnosis of anxiety disorders; AND
- Member is 18 years of age or older; AND
- Member has been receiving stable, evenly divided three times daily dosing with lorazepam tablets; AND
- Prescriber provides clinical documentation of medical necessity to extended-release capsule and medical justification on why lorazepam tablet cannot be given.

Renewal Approval:

- Documentation of response to therapy and tolerating therapy

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

LOTROX (ALOSETRON)

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

- Clinically diagnosed severe diarrhea-predominant irritable bowel syndrome (IBS)
- Adult female
- 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

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

of constipation, have resulted in hospitalization and, rarely, blood transfusion, surgery, and death.

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.

Last updated: 6/1/2021

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

Requests for continuing 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 must have tried and failed Avastin (bevacizumab)
- 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
- QL: 0.05 mL (of a 10mg/ml or 6mg/ml solution) administered by one (1) intravitreal injection every 28 days.

References:

1. Lucentis [Prescribing Information] South San Francisco, CA: Genentech, Inc.; February 2015.
2. Ranibizumab versus Bevacizumab to Treat Neovascular Age-related Macular Degeneration: One-Year Findings from the IVAN Randomized Trial. The IVAN Study Investigators, Chakravarthy U, Harding SP, Rogers CA, Downes SM, Lotery AJ, Wordsworth S, Reeves BC. *Ophthalmology*. 2012;7:1399-1411. Epub 2012 May 11.
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LUMAKRAS (SOTORASIB)

Initial Approval:

- Confirm member has a diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC); **AND**
- Member is 18 years of age or older; **AND**
- KRAS G12C-mutation is confirmed by an FDA-approved test (e.g. theascreen KRAS RGQ PCR Kit; Guardant360® CDx); **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 have received at least one prior systemic therapy; **AND**
- Prescribed by or in consultation with an oncologist.

Renewal Approval:

- Documentation of positive response to therapy and tolerating therapy.

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 11/1/21

LUPKYNIS (VOCLOSPORIN)

Initial Approval:

- Confirm member has a diagnosis of systemic lupus erythematosus (SLE) with active lupus nephritis (LN); **AND**
- Kidney biopsy (documentation required) confirmed member has LN classes III, IV, V, alone in combination; **AND**
- Member has eGFR $\geq 45\text{mL}/\text{min}/1.73\text{m}^2$; **AND**
- Member has no history of kidney transplant; **AND**
- Documentation provided which supports member has received standard-of-care therapy for the last 90 days with corticosteroids along with either mycophenolate or cyclophosphamide; **AND**
- Member must have trial and failure of cyclosporine taken over the last 90 days **AND**
- Trial and failure of Rituximab within the last 12 months **AND**
- Prescribed by or in consultation with a specialist such as rheumatologist or nephrologist

Renewal Approval:

- Documentation provided supporting member is tolerating and is adherent to therapy; **AND**
- Documentation provided supporting there was an improvement in UPCR (urine protein creatinine ratio) and eGFR, or no confirmed decrease from baseline in eGFR of $\geq 20\%$

Authorization Duration: 12 months

Informational: Quantity Limit 180/30

LAST REVISION: 7/1/21

MACUGEN (PEGAPTANIB)

1. Approved for the following indications:

- a. Neovascular (Wet) age-related macular degeneration (AMD), 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

b. Diabetic macular edema AND

2. Member must have tried and failed Avastin (bevacizumab) **OR** Lucentis (ranibizumab)

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

- **QL:** 0.3 mg (1 syringe) per eye every 6 weeks

MAVENCLAD (CLADRIBINE ORAL TABLET)

- Individual has a diagnosis of relapsing multiple sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; **AND**
- The member had a baseline MRI before initiating the first treatment course (within 3 months prior to start of therapy); **AND**
- Age is 18 years or older; **AND**
- Requested drug is being used as a single-agent therapy; **AND**
- Failure of or intolerance to TWO of the following preferred MS therapies: Copaxone, Glatiramer, Avonex, Betaseron, or Rebif; **AND**
- The member has been tested for antibodies to varicella zoster virus (VZV) or received immunization for VZV four weeks prior to beginning therapy; **AND**
- The member has been screened for the presence of tuberculosis according to local guidelines; **AND**
- The member has been evaluated and screened for the presence of hepatitis B and hepatitis C (HBV/HCV) prior to initiating treatment; **AND**
- The prescriber attests the member has a lymphocyte count greater than or equal to 800 cells/mL prior to the start of therapy; **AND**
- The prescriber attests that women of child bearing age are not pregnant **AND** that members of reproductive potential must use effective contraception during treatment with therapy and for at least six months after the last dose; **AND**
- The prescriber attests that the member does **NOT** have the human immunodeficiency virus (HIV) infection.

MAYZENT (SIPONIMOD)

CRITERIA FOR USE

(Criteria listed is all inclusive unless otherwise noted)

- Individual has a diagnosis of relapsing multiple sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; **AND**
- The member had a baseline MRI before initiating the first treatment course (within 3 months prior to start of therapy); **AND**
- Age is 18 years 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

- Requested drug is being used as a single-agent therapy; **AND**
- Failure of or intolerance to TWO of the following preferred MS therapies: Copaxone, Avonex, Betaseron, **AND**
- The member has been tested for antibodies to varicella zoster virus (VZV) or received immunization for VZV four weeks prior to beginning therapy; **AND**
- The member has been screened for the presence of tuberculosis according to local guidelines; **AND**
- The member has been evaluated and screened for the presence of hepatitis B and hepatitis C (HBV/HCV) prior to initiating treatment; **AND**
- The member has been tested for CYP2C9 variant status to determine genotyping (required for dosing); **AND**
- The prescriber attests the member has obtained a baseline electrocardiogram (ECG); **AND**
- The prescriber attests the member has had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- The prescriber attests the member does NOT have any of the following: Recent Myocardial Infarction, Unstable Angina, Stroke, Transient Ischemic Attack, Decompensated Heart Failure with Hospitalization, Class III/IV Heart Failure within the Previous 6 Months, Prolonged QTc Interval at Baseline (greater than 500 msec) or History of Mobitz Type II second or third-degree atrioventricular block or sick sinus syndrome (unless treated with a functioning pacemaker); **AND**
- The prescriber attests the member does NOT have the CYP2C9 3 3 Genotype; **AND**
- Mayzent will NOT be used in combination with any of the following: a. Moderate or strong CYP3A4 inducers (e.g., modafinil, efavirenz, etc.) in members with a CYP2C9 1 3 and CYP2C9 2 3 genotypes; OR b. Drug regimens that contain CYP2C9/CY3A4 dual inhibitors (e.g., fluconazole); OR c. Moderate CYP2C9 inhibitor plus a moderate-to-strong CYP3A4 inhibitor; OR d. Other antineoplastic, immunosuppressive or immunomodulating drugs.

MEKINIST (TRAMETINIB; MEK-INHIBITOR)

- Patient must be \geq 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**
 - 0: 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)

Requests for continuing 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**
- Does 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? (If Yes, Please Sign and Submit, no further information required) **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

- 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**

Requests for continuing 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 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

MONJUVI (TAFASITAMAB-CXIX)

CRITERIA FOR USE:

1. A diagnosis of relapsed or refractory diffuse large B-cell lymphoma; **AND**
 2. Patient is ≥ 18 years of age; **AND**
 3. Patient has been treated with at least one prior chemotherapy regimen; **AND**
 4. According to the prescriber, the patient is not eligible for autologous stem cell transplant; **AND**
 5. Patient meets one of the following:
 - a. Monjuvi will be used in combination with Revlimid (lenalidomide capsules); **OR**
 - b. Patient has already received 12 cycles of Monjuvi;
- AND**
6. The agent is prescribed by or in consultation with an oncologist.

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

1. Adams ME. An analysis of clinical studies of the use of crosslinked hyaluronan, hylan, in the treatment of osteoarthritis. J Rheumatol. 1993;39 (Suppl):16-18.
2. Adams ME, Atkinson MH, Lussier AJ, et al. The role of viscosupplementation with hylan G-F 20 (Synvisc) in the treatment of osteoarthritis of the knee: A Canadian multicenter trial comparing hylan G-F 20 alone, hylan G-F 20 with non-steroidal anti-inflammatory drugs (NSAIDs) and NSAIDs alone. Osteoarthritis Cartilage. 1995;3(4):213-225.
3. Balazs EA, Denlinger JL. Viscosupplementation: A new concept in the treatment of osteoarthritis J Rheumatol Suppl. 1993;39:3-9.

Requests for continuing 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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5. Dougados M, Nguyen M, Listrat V, et al. High molecular weight sodium hyaluronate (hyalectin) in osteoarthritis of the knee: A 1 year placebo-controlled trial. *Osteoarthritis Cartilage.* 1993;1(2):97-103.
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9. Hyalgan. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
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12. Lussier A, Cividino AA, McFarlane CA, et al. Viscosupplementation with hylan for the treatment of osteoarthritis: Findings from clinical practice in Canada. *J Rheumatol.* 1996;23(9):1579-1585.
13. Tamir E, Robinson D, Koren R, et al. Intra-articular hyaluronan injections for the treatment osteoarthritis of the knee: a randomized, double blind, placebo controlled study. *Clin Exp Rheumatol* 2001 May-Jun; 19(3):265-70.

MOTTEGRITY (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 ≥ 2 Preferred traditional laxative therapy (e.g., polyethylene glycol, lactulose)

AND

4. An inadequate response/intolerance to ≥ 1 of the preferred products indicated for CIC
 - o A. Linzess OR
 - o B. Amitiza OR
 - o C. Trulance

Not Approved if:

- Does not meet above criteria
- Any contraindication to treatment

Approval Duration: 6 months

MOVEMENT DISORDERS (AUSTEDO, INGREZZA, TETRABENAZINE, XENAZINE)

Requests for continuing 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):

- Member is 18 years of age or older, **AND**
- Member has a diagnosis of Huntington's Disease **OR** Tardive Dyskinesia, **AND**
- Medication is prescribed by, or in consultation with, a Neurologist or Psychiatrist, **AND**

DURATION:

Initial – 12 months, Renewal 12 months

QUANTITY LIMITS:

Austedo: 120 tablets/ 30 days

Ingrezza: 30 capsules/ 30 days

Xenazine: 120 tablets/ 30 days

LAST REVISION: 1/1/22

MYALEPT (METRELEPTIN)

Initial Authorization

- Patient has a diagnosis of congenital generalized lipodystrophy (ie. Berardinelli-Seip syndrome), acquired generalized lipodystrophy (ie. Lawrence Syndrome) or partial lipodystrophy, **AND**
- Therapy is being prescribed by, or in consultation with, an Endocrinologist or Geneticist **AND**
- Documentation of fasting laboratory leptin assay results provided
 - < 4.0 ng/ml for females
 - < 3.0 ng.ml for males **AND**
- Prescriber attests that the patient does not have Anti-retroviral therapy induced lipodystrophy or drug induced localized lipodystrophy **AND**
- Therapy is being used as an adjunct to diet **AND**
- Patient has at least **ONE** of the following complications of lipodystrophy:
 - Diabetes mellitus
 - Hypertriglyceridemia
 - Increased fasting insulin levels **AND**
- Patient has hypertriglyceridemia and has failed a 30-day trial of:
 - Low fat diet and/or dietary restrictions **AND**
 - Fenofibrate or fenofibrate derivative **OR**
 - Niacin or omega-3 fatty acid **OR**
 - Statin 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

Reauthorization

- Initial criteria continue to be met **AND**
- Documentation provided supporting patient has experienced an improvement from baseline in metabolic control (ie. Improved glycemic control, decrease in triglycerides, decrease in hepatic enzymes)

Initial authorization: 4 months

Renewal: 12 months

LAST REVISION: 5/1/2022

References:

1. Myalept [package insert]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; September 2015.
2. Brown RJ, Araujo-Vilar D, Cheung PT, et al. The diagnosis and management of lipodystrophy syndromes: A multi-society practice guideline. J Clin Endocrinol Metab. 2016;101(12):4500-4511.
3. Handelsman Y, Oral AE, Bloomgarden ZT, et al. The clinical approach to the detection of lipodystrophy – an AACE consensus statement. Endocr Pract. 2013;19:107-116.
4. Chan JL, Lutz K, Cochran E, et al. Clinical effects of long-term metreleptin treatment in patients with lipodystrophy. Endocr Pract. 2011;17:922-932.
5. Garg A. Lipodystrophies: genetic and acquired body fat disorders. J Clin Endocrinol Metab. 2011;96:3313- 3325.
6. Rodriguez AJ, Mastronardi CA, Paz-Filho GJ. New advances in the treatment of generalized lipodystrophy: role of metreleptin. Ther Clin Risk Manag. 2015; 11:1391-1400

MYCAPSSA (OCTREOTIDE)

- Confirm member has a diagnosis of acromegaly
- The member is 18 years of age or older; AND
- Mycapssa is being prescribed by or in consultation with an endocrinologist; AND
- The member responded to and tolerated treatment with a somatostatin analogue (e.g., octreotide or lanreotide) for the last 6 months with a stable dose for the last 3 months; AND
- Prescriber attests that the member will be monitored for safety parameters (e.g., cholelithiasis and its complications, hypoglycemia or hyperglycemia, thyroid function, cardiac function, vitamin B12 levels, etc.); AND
- Prescriber attests that potential drug interactions will be monitored for and dose adjustments of coadministered drug (e.g., cyclosporine, insulin or antidiabetic agents, digoxin, Lisinopril, combined oral contraceptives, bromocriptine, beta blockers, calcium channel blockers, drugs metabolized by CYP 450 with a narrow therapeutic index [e.g., quinidine]) OR octreotide (e.g., proton pump inhibitors, H2-receptor antagonists, or antacids) will be made as necessary; AND
- Prescriber attests that Mycapssa will be withdrawn periodically to evaluate disease activity; AND
- Confirmation that Mycapssa therapy will be discontinued if IGF-1 levels remain above the upper normal limit after treatment at the maximum recommended dosage (80 mg daily) OR if the member cannot tolerate treatment; AND
- The member is unable to administer the injectable formulation (e.g., age-related

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

decline in dexterity, visual impairment) OR has a documented requirement for oral therapy.

RENEWAL

- The member continues to meet the above criteria; AND
- The member demonstrates disease response with treatment as defined by stabilization of disease or relevant clinical laboratory parameters (e.g., IGF-1 level normalization, stabilization, or improvement in signs/symptoms); AND
- Confirmation that the member has NOT experienced any treatment-restricting adverse effects (e.g., cholelithiasis and its complications, hypoglycemia or hyperglycemia, thyroid function, cardiac function, vitamin B12 levels, intolerable gastrointestinal symptoms)

Authorization Duration:

- Initial: 1 year
- Renewal: 1 year

LAST REVISION: 11/1/21

MYFEMBREE (RELUGOLIX;ESTRADIOL;NORETHINDRONE)

Initial Approval:

- Confirm member has a diagnosis of heavy menstrual bleeding due to uterine fibroids (uterine leiomyomas); **AND**
- Member is 18 years of age or older; **AND**
- Member is premenopausal; **AND**
- Documentation of failure, intolerance, or contraindication to one or more prior treatments to reduce menstrual bleeding (oral contraceptives, levonorgestrel-releasing intrauterine systems, oral progesterone, etc.); **AND**
- Member has not previously received more than 24 months of therapy **AND**
- Prescribed by or in consultation with an obstetrician/gynecologist

OR

- Being used for management of moderate to severe pain associated with endometriosis in premenopausal members; **AND**
- Prescriber attests member has a diagnosis of endometriosis; **AND**
- Prescriber attests the member has current symptoms of moderate to severe pain (not mild); **AND**
- Prescriber attests that member has tried and failed (for at least a 3 month trial) or has a contraindication to a hormonal contraceptive (such as: progestin, combined oral contraceptives, medroxyprogesterone acetate, levonorgestrel-releasing intrauterine system); **AND**
- Prescriber attests to appropriate measure/assessment of bone health (i.e. DXA, FRAX score); **AND**
- Member has not previously received more than 24 months of therapy; **AND**
- Prescribed by or in consultation with an obstetrician/gynecologist

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

Renewal Approval:

- Documentation of positive response to therapy **AND**
- Member has not previously received more than 24 months of therapy

Authorization Duration:

Initial approval: 12 months

Renewal approval: 12 months (total of 24 months)

LAST REVISION: 1/1/2023

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):
 - tried/failed/intolerance to oral therapy:
 - Glycopyrrolate, OR
- Overactive Bladder:
- Tried/failed/intolerance to oral therapy:
 - Oxybutynin/oxybutynin er, and trospium, AND
 - Propantheline with bladder training,

References

1. Basciani M, Di Rienzo F, Fontana A, Copetti M, Pellegrini F, Intiso D. Botulinum toxin type B for sialorrhea in children with cerebral palsy: a randomized trial comparing three doses. *Dev Med Child Neurol.* 2011 Jun;53(6):559-64.
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7. Boghen Dr. Disorders of facial motor function. *Curr Opin Ophthalmol.* 1996 Dec;7(6): 48-52.
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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

NAGLAZYME (GALSULFASE)

Initial Criteria

- Member is 5 years of age and older **AND**
- Member has a diagnosis of Mucopolysaccharidosis VI (MPS VI) confirmed by the following (documentation must be submitted):
 - Pathogenic mutations in ARSB gene by molecular genetic testing **OR**
 - Arylsulfatase B (ASB) enzyme activity of <10% of the lower limit of normal in cultured fibroblasts or isolated leukocytes **AND**
 - Member has normal enzyme activity of a different sulfatase (excluding members with Multiple Sulfatase Deficiency “MSD”) **AND**
 - Member has an elevated urinary glycosaminoglycan (uGAG) level defined as being above the upper limit of normal by the reference lab **AND**
- Documentation provided of the following:
 - Baseline pulmonary function tests **AND**
 - Baseline uGAG **AND**
 - Baseline of 12-minute walk test or 3-minute stair climbing test **AND**
- Daily dosage is 1mg/kg once weekly
 - Member’s weight submitted per documentation

Reauthorization Criteria

- Member continues to meet all initial criteria **AND**
- Member shows no toxicity from therapy **AND**
- Member has shown clinically significant response to therapy since initial review by supporting documentation of:
 - Reduction in uGAG level by greater than 50% from baseline or maintenance level at greater than 50% of baseline **AND**
 - Improvement in pulmonary function tests **AND**
 - Improvement in 12-minute walk test and/or 3-minute stair climbing test

LAST REVISION: 5/1/2022

NEULASTA (PEGFILGRASTIM)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Cancer patients receiving myelosuppressive chemotherapy.

4. Approve Neulasta if prescribed by, or in consultation with, an oncologist or hematologist.
5. Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive

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

anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

6. **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 Ia
Strength of Evidence: Adult, Category B

Radiation Injury

Approve pegfilgrastim under the following circumstances:

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

- 3. **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.

Requests for continuing 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. **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.

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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**

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

- **Febrile neutropenia, In patients with acute myeloid leukemia receiving chemotherapy; Prophylaxis**
- **Harvesting of peripheral blood stem cells**

Neutropenic disorder, chronic (Severe), Symptomatic

REFERENCES

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2. Hollingshead LM, Goa KL. Recombinant granulocyte colony-stimulating factor (rG-CSF): a review of its pharmacological properties and prospective role in neutropenic conditions. *Drugs*. 1991; 42:300-30.
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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

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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 eprubicin chemotherapy regimen, OR
- Metastatic (advanced) thyroid cancer, AND
 - The patient has tried and failed or intolerant to vandetanib and carbazantinib, 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).

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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

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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 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

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

NEXLETOL (BEMPEDOIC ACID) & NEXLIZET (BEMPEDOIC ACID + EZETIMIBE)

Initial: 3 months; Reauthorization: 6 months

- Diagnosis of one of the following:
 - HeFH (heterozygous familial hypercholesterolemia)

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

- Confirmed by definite diagnosis of HeFH as defined by the Dutch Lipid Clinic Network criteria (total score greater than 8 – Lab report required with LDL-C at time of diagnosis and other pertinent diagnostic supporting evidence) or
 - Members has definite diagnosis of HeFH as defined by Simon Broome diagnostic criteria OR
- ASCVD (clinical atherosclerotic cardiovascular disease) or history of a cardiovascular event without homozygous/heterozygous familial hypercholesterolemia
 - Confirmed by member history of ANY of the following:
 - Acute coronary syndromes
 - Myocardial infarction
 - Stable or unstable angina
 - Stroke of presumed atherosclerotic origin
 - Transient ischemic attack (TIA)
 - Coronary or other arterial revascularization procedure (e.g. PTCA, CABG)
 - Peripheral arterial disease of presumed atherosclerotic origin
 - Findings from CT angiogram or catheterization consistent with clinical ASCVD

AND

- The member has not been able to achieve target LDL-C levels using other lipid lowering interventions; AND
- The members pre-treatment LDL-C level (prior to therapy) level is provided as well as current LDL-C level if applicable
- The member has had prior treatment history with the highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe for at least three continuous months with failure to reach target LDL-C AND is in one of the three groups identified by NLA: extremely high risk ASCVD members with LDL-C greater than or equal to 70 mg/dL, very high risk ASCVD members with LDL-C greater than or equal to 100 mg/dL, and high risk members with LDL-C greater than or equal to 130 mg/dL AND
- IF the member is unable to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, then documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the member experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
 - Muscle symptoms resolved after discontinuation of statin; 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

- Muscle symptoms occurred when re-challenged at a lower dose of the same statin; AND
- Muscle symptoms occurred after switching to an alternative statin; AND
- Documentation ruling out non-statin causes of muscle symptoms (e.g. hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatic, steroid myopathy, vitamin D deficiency, or primary muscle disease); OR
- The member has been diagnosed with statin-induced rhabdomyolysis

CONTINUING THERAPY

- The member has achieved at least a 15-20% reduction in LDL-C since beginning of treatment with Nexletol/Nexlizet which is confirmed by laboratory results/clinical chart notes
- The member continues to receive benefit from treatment as measured by either of the following (chart notes/laboratory results required):
 - Continued decrease in LDL-C levels or Maintenance of optimum LDL-C level

NEXVIAZYME (AVALGLUCOSIDASE ALFA-NGPT)

Initial Approval:

- Confirm member has a diagnosis of late-onset Pompe disease (LOPD), as evidenced by **BOTH** of the following:
 - Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle ; AND
 - Genetic testing showing a mutation in the GAA gene; AND
- Member is 1 year of age or older; AND
- Member has measurable signs of Pompe disease, such as impairment in pulmonary function or motor weakness; AND
- Documentation of baseline percent-predicted forced vital capacity (FVC) and 6-minute walk test (6MWT); AND
- Member does NOT have any of the following:
 - Concomitant use of alglucosidase alfa (Lumizyme)
 - Previous failure of alglucosidase alpha(Lumizyme)
 - Member is not able to ambulate 40 meters without stopping and without an assistive device
 - Member has Pompe-specific cardiac hypertrophy
 - Member requires invasive ventilation
 - Member has a percent-predicted FVC of <30% or ≥85%; AND
- Prescribed by or in consultation with a specialist experienced in Pompe disease treatment such as genetic and metabolic specialists, neurologists, cardiologists, and pediatricians.

Renewal 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 response to therapy, as evidenced by an improvement or stabilization in percent-predicted FVC and/or 6MWT.

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

NON FORMULARY EXCEPTIONS

- Has the member had a therapeutic failure to at least **TWO** Preferred agents within the same class as appropriate for diagnosis unless otherwise noted in the clinical criteria, if appropriate **OR**
- If less than two formulary alternatives are available for treatment, than there must be a trial and failure of **ONE** formulary alternative **OR**
- Is the member not able to tolerate the preferred agents within the same class because:
 - Allergy to Preferred drug (documentation must be submitted) **OR**
 - History of intolerance to preferred drug (documentation must be submitted) **OR**
 - Member’s condition is clinically stable and switching to a Preferred drug might cause deterioration of the member’s condition
- Certain non-formulary medications are subject to individualized criteria

LAST REVISION: 6/1/22

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**

Requests for continuing 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. 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®

NOURIANZ (ISTRADefylline)

Initial: 6 months

- Diagnosis of Parkinson’s disease (PD) in patients experiencing “off” episodes
- Documentation that “Off” episodes are lasting at least 2 hours in duration
- Must be utilized as an adjunctive treatment with levodopa/carbidopa
- Prescriber is a neurologist or prescribing in consultation with a neurologist
- Patient must be 18 years old
- Documentation of current or previous treatment with at least two of the following agents used as adjunctive treatment to levodopa/carbidopa:
 - Dopamine agonist (e.g. ropinirole, pramipexole)
 - COMT inhibitor (e.g. entacapone, tolcapone)
 - MAO-B inhibitor (e.g. rasagiline, selegiline)

Reauthorization: 12 months

- Documented positive response to Nourianz therapy

NOXAFIL (POSACONAZOLE)

Initial:

For Tablets or suspension:

- Patient greater than 13 years old who is recipient of hematopoietic stem cell transplant (HSCT) with Graft-vs-Host Disease (GVHD) and who is at risk of developing invasive *Aspergillus fumigatus* and/or *Candida* infections. 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

- Patient greater than 13 years old with hematological malignancies causing prolonged neutropenia from chemotherapy and who is at risk of developing *Aspergillus fumigatus* and/or *Candida* infections; **OR**

For Suspension:

- Clinically documented Oropharyngeal Candidiasis infection, **AND**
- Fungal culture and other relevant laboratory studies (including histopathology) obtained to isolate and identify causative organisms; **OR**
- Clinically documented Oropharyngeal Candidiasis refractory to standard course of fluconazole and/or itraconazole

All Patients:

- The patient is not receiving concomitant treatment with sirolimus, CYP 3A4 substrates that prolong QT interval (pimozide, quinidine), HMG-CoA Reductase inhibitors primarily metabolized through CYP 3A4, or ergot alkaloids

Reauthorization:

- Patient is tolerating and responding to therapy and there continues to be a need for the medication

Approval duration: 12 weeks initial and reauthorization

NPLATE (ROMIPLOSTIM)

Treatment of Immune Thrombocytopenia (ITP)

- 18 years 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-Rh₀[D]), or splenectomy.

Reauthorization/continuing treatment:

- Platelet count of at least 50,000/mm³ (after 4 weeks at a maximum dose of 10mcg/kg per week), **OR**
- Increase in platelet count over baseline to a level sufficient to avoid clinically important bleeding.

Treatment of hematopoietic syndrome of acute radiation syndrome (HS-ARS)

- Patient has hematopoietic syndrome of acute radiation syndrome; **AND**
- Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP;

LAST REVISION 7/1/21

References

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NUBEQA (DAROLUTAMIDE)

- Diagnosis of non-metastatic castration-resistant prostate cancer **AND**
- Must use concurrently with a gonadotropin-releasing hormone (GnRH) analog unless the patient has had a bilateral orchiectomy **AND**
- Must not be used with P-gp and strong or moderate CYP3A inducers (i.e. rifampin) **AND**
- Must be prescribed by an Oncologist or Urologist **OR**
- Diagnosis of metastatic hormone sensitive prostate cancer **AND**
- Member is 18 years of age or older **AND**
- Must use concurrently with docetaxel **AND**
- Must not be used with P-Glycoprotein and strong or moderate CYP3A inducers (ie. rifampin) **AND**
- Must be prescribed by an Oncologist or Urologist

LAST REVISION 1/1/2023

NUCALA (MEPOLIZUMAB)

For the treatment of severe eosinophilic asthma/EGPA:

- Being used as add-on maintenance in patients who have severe asthma, with eosinophilic phenotype; **AND**
- Patient must be ≥ 6 years of age; **AND**
- Medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; **AND**
- 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**
- Patient has received at least 3 consecutive months of combination therapy with **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

- Inhaled corticosteroid (e.g. Asmanex, Aerospan, Pulmicort Flexhaler, Qvar)
 - Inhaled long-acting beta agonist, OR Leukotriene receptor antagonist (montelukast)
2. 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 OR
 3. Patient has a documented diagnosis of eosinophilic granulomatosis with polyangitis based on the presence of at least four of the following diagnostic criteria: Asthma, Eosinophilia, Mono or polyneuropathy, Migratory or transient pulmonary infiltrates on chest x-rays, or Paranasal sinus abnormalities, or Biopsy containing a blood vessel with extravascular eosinophils.
 - Patient must be 18 years old
 - Patient is stable on corticosteroids or corticosteroids are not clinically appropriate therapy for the patient and have severe disease (such as vasculitis with cerebral, cardiac, renal, or GI involvement) or disease flares with tapering of corticosteroid therapy.
 - Patient has failure, intolerance or contraindication to one of the following immunosuppressants: azathioprine, cyclophosphamide, or methotrexate.
 - Prescribed by a Pulmonologist, Rheumatologist, Allergist/Immunologist

For the treatment of chronic rhinosinusitis with nasal polyps

5. Diagnosis of chronic rhinosinusitis with nasal polyps, AND
6. Member is at least 18 years of age or older, AND
7. Medication will be used as add-on therapy; AND
8. Presence of nasal polyps; AND
9. Member has experienced signs and symptoms (e.g. nasal congestion/blockage/obstruction, loss of smell, rhinorrhea) for over 12 weeks; AND
10. 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)
11. Nucala is not being used concurrently with Dupixent, Cinqair, Fasenna, or Xolair; AND
12. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist.

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

For RENEWAL THERAPY,

1. For Eosinophilc Asthma: 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).
2. For EGPA: Documentation of positive clinical response to therapy (e.g., increase in remission time)
3. For chronic rhinosinusitis with nasal polyps: Member is responding positively to therapy (examples may include but are not limited to: reduced nasal polyp size, reduced need for systemic corticosteroids, improved sense of smell, improved quality of life); Nucala is not being used concurrently with Dupixent, Cinqair, Fasenra, or Xolair.

NOT COVERED FOR:

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

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

References

1. Nucala injection for subcutaneous [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; October 2021.

LAST REVISION: 1/1/22

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)

Requests for continuing 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 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

Not approved if:

- Does not meet the above stated criteria.
- Being used for convenience purposes only.

References

- Virginia Premier

OLUMIANT (BARICITINIB)

Treatment of Rheumatoid Arthritis (RA):

- Member has a diagnosis of moderately to severely active RA; AND
- Member is 18 years of age or older; AND
- Member has tried and failed Humira and Enbrel; 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

- Use in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants, such as azathioprine and cyclosporine, is not recommended.

Treatment of COVID-19 hospitalized patients:

- Member is 18 years of age or older; AND
- Member is hospitalized with COVID-19 requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation.

Approval Duration

- Initial – 12 months
- Renewal – 12 months

LAST REVISION: 10/1/21

ONGENTYS (OPICAPONE)

Approval Duration: 1 year for Initial and Reauthorizations

Initial Therapy:

- Patient is diagnosed with Parkinson’s disease; AND
- Patient will take Ongentys in combination with levodopa/carbidopa; AND
- Patient experiences “off-episodes” (hypomobility) associated with their Parkinson’s diagnosis; AND
- Patient is not currently on MAOI therapy; AND
- Patient does not have a history or diagnosis of catecholamine secreting neoplasms, pheochromocytoma or paraganglioma
- Ongentys is being prescribed by, or in consultation with a neurologist or specialist in the treatment of Parkinson’s disease

Reauthorization:

- Patient is diagnosed with Parkinson’s disease; AND
- Patient experiences “off-episodes” (hypomobility) associated with their Parkinson’s diagnosis; AND
- Patient has experienced a positive clinical response to therapy; AND
- Ongentys continues to be prescribed by, or in consultation with a neurologist or specialist in the treatment of Parkinson’s disease

ONUREG (AZACITIDINE)

- The member is 18 years of age or older; AND
- Onureg is being prescribed by an oncologist; AND
- The member has achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRi) within 4 months following intensive induction therapy for acute myeloid leukemia (AML); AND
- Confirmation the member is unable to complete intensive curative therapy for

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

- AML; AND
- Confirmation that the medication will be used as continuation maintenance treatment for AML; AND
 - Confirmation that the therapy will NOT be substituted for intravenous or subcutaneous azacitidine; AND
 - Confirmation that the member does NOT have a diagnosis of Myelodysplastic Syndrome (MDS); AND
 - Confirmation that the member does NOT have central nervous system (CNS) leukemia; AND
 - Confirmation that the member does NOT have severe hepatic impairment (i.e., total bilirubin > 3 times the upper limit of normal); AND
 - Member's creatinine clearance (calculated by Cockcroft-Gault formula) will be monitored and if the member has severe renal impairment (ClCr 15-29 mL/min), confirmation that the member will be monitored more frequently for adverse reactions and the dosage of Onureg will be modified for adverse reactions; AND
 - Confirmation that the member has NOT had a prior bone marrow or stem cell transplant (HSCT); AND
 - Confirmation that the member does NOT have molecular evidence of any of the following genetic translocations: inv(16), t(8;21), t(16;16), t(15/17), or t(9;22).

RENEWAL

- The member continues to meet the above criteria; AND
- The member demonstrates disease response with treatment as defined by stabilization of disease or improvement as evidenced by a CR (e.g., morphologic, cytogenetic, or molecular CR); complete hematologic response or a partial response by CBS; bone marrow cytogenetic analysis; quantitative polymerase chain reaction (QPCR); or fluorescence in situ hybridization (FISH); AND
- Confirmation that the member has NOT experienced any treatment-restricting adverse effects (e.g. severe myelosuppression).

Authorization Duration:

- Initial: 6 months
- Renewal: 6 months

LAST REVISION: 11/1/21

OPIOIDS

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 90 morphine milligram equivalents (MME) per day. Quantity limits apply to each drug**
- 4) For Non-Preferred Products (Reject MR)**

Requests for continuing 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. **Member must have a trial a failure of two different preferred products (list below) – drug names, length of trial and reason for discontinuation must be documented for alternatives.**

i. **Long-Acting Opioids (C III-VI)**

1. **Butrans Patch**

ii. **Long Acting Opioids (CII)**

1. **Fentanyl 12,25,50,75 and 100mcg patches**

2. **Morphine Sulfate ER tab**

3. **OxyContin**

4. **Oxymorphone ER**

iii. **Short-Acting Opioids**

1. **Codeine/APAP**

2. **Codeine**

3. **Hydrocodone/APAP**

4. **Hydrocodone/IBU**

5. **Hydromorphone**

6. **Morphine IR**

7. **Oxycodone IR**

8. **Oxycodone/APAP**

Tramadol Criteria for both Preferred (75) and Non-Preferred (MR)(Non-Preferred must pass tollgate of 2 t/f above)

5)

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 90, 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

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 90, 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
- **Authorization period**
 - 6 months based on diagnosis
 - Cancer pain
 - Sickle cell disease
 - Palliative care
 - End-of-life care
 - Hospice patient
 - 3 months based on diagnosis
 - HIV/AIDS
 - Chronic back pain
 - Arthritis
 - Fibromyalgia
 - Diabetic Neuropathy
 - Postherpetic Neuralgia
 - Other pain
- **Sample Physician/Patient Agreement:**
<https://www.drugabuse.gov/sites/default/files/files/SamplePatientAgreementForms.pdf>
- **Tapering Guidelines for Opioids and Benzodiazepines:**
<http://www.oregonpainguidance.org/app/content/uploads/2016/05/Opioid-and-Benzodiazepine-Tapering-flow-sheets.pdf>

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

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

References:

1. Actelion Pharmaceuticals US, Inc. Opsumit package insert. South San Francisco, CA. October 2013.

OPZELURA (RUXOLITINIB)

Initial Approval:

- Confirm member has a diagnosis of mild-to-moderate atopic dermatitis; **AND**
- Member is 12 years of age or older; **AND**
- Member has had adequate trial and failure of at least one moderate- to very high potency topical corticosteroids for at least 8 consecutive weeks **AND**
- One topical calcineurin inhibitors (e.g. pimecrolimus, tacrolimus) for 8 consecutive weeks, or when those therapies are not advisable.
- Member is not immunocompromised; **AND**
- Medication is not in concomitant use with other topical or systemic agents for atopic dermatitis **AND**
- Member has a trial failure of Dupixent **AND**
- Member has a trial and failure of Eucrisa

Renewal Approval:

- Documentation of response to therapy (clinical improvement in signs and symptoms of AD)

Quantity Limit:

240gm (4 x 60gm) per 30 days

Authorization Duration:

Approval 12 months

LAST REVISION: 1/1/2023

ORACEA (DOXYCYCLINE) DELAYED-RELEASE

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

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**,

-AND-

- 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.

-AND-

- 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.

-AND-

- the member has tried and failed subcutaneous allergen immunotherapy (allergy shots) and is NOT currently receiving subcutaneous allergen immunotherapy; **AND**
- The member had a treatment failure with (or contraindication) to antihistamines (e.g. diphenhydramine, loratadine, etc) and Montelukast/Singulair; **AND**

The prescriber attests the member has access to an auto-injectable epinephrine product at home and has been trained to use this product and been instructed to seek immediate medical care upon its use

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:

1. Grastek® prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. April 2014.
2. Oralair® prescribing information. Greer Laboratories, Inc. Lenoir, NC. April 2014.
3. Ragwitek® prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. April 2014.
4. Cox, L, Nelson, H, Lockey, R, et al. Allergen immunotherapy: A practice parameter third update. American Academy of Allergy, Asthma & Immunology. December 2010.
5. Wallace, DV, Dykewicz, MS, et al. The diagnosis and management of rhinitis: An updated practice parameter. American Academy of Allergy, Asthma & Immunology. August 2008.

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

ORGOVYX (RELUGOLIX)

INITIAL:

- Member has a diagnosis of advanced prostate cancer; AND
- Member is 18 years of age and older; AND
- The prescriber attests the quantity does not exceed: Loading dose 3 tabs (360mg)/1 time, then 1 tab per day (30 tab/30days); AND
- Member has serum testosterone levels at initial diagnosis > 150ng/dL; AND
- Member has serum PSA level at diagnosis > 2.0ng/mL; AND
- Prescribed by or in consultation with an oncologist or urologist

RENEWAL:

- Prescriber attests member is continuing therapy; AND
- Prescriber attests the member is responding positively to therapy

Authorization Dates:

Initial: 6 months

Renewal: 12 months

ORILISSA (ELAGOLIX)

CRITERIA FOR USE

- Patient is 18 years of age and older **AND**
- 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**
- Patient must not have severe hepatic impairment classification of Child-Pugh C **AND**
- For patient with co-existing conditions such as dyspareunia or moderate hepatic impairment, treatment duration cannot exceed 6 months

Reauthorization Criteria

- Chart documentation provided to support positive clinical improvement **AND**
- Serum ALT levels are being monitored for elevations

Auth Duration:

Initial approval - 6 months

Reauthorization approval - 6 months

- Orilissa 150mg max of 24 months of therapy
- Orilissa 200mg max of 6 months of therapy

LAST REVISION: 11/1/21

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

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
- 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 Psoriatic Arthritis:

- 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)
- 18 years of age or older

Criteria for Acute Graft Versus Host Disease (aGVHD) Prophylaxis:

- Member is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1-allele-mismatched unrelated donor
- Member is using this in combination with a calcineurin inhibitor and methotrexate
- 2 years of age or older

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.

Requests for continuing 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 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.

LAST REVISION: 5/1/22

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

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

- Orenitram is being used in combination with other vasodilators

Approval Duration:

- Initial: 3 months
- Renewal: 1 year

References

1. Product Information: ORENITRAMI oral extended release tablets, treprostinil oral extended release tablets. United Therapeutics Corp. (per FDA), Research Triangle Park, NC, 2014.
2. Jenkins A, Wang-Smith L, Marbury T, et al: Pharmacokinetics of treprostinil diolamine in subjects with end-stage renal disease on or off dialysis. J Cardiovasc Pharmacol 2013; 61(4):272-276.

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 $\geq 40\%$
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**AND**
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

Requests for continuing 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

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

1. Orkambi [Prescribing Information]. Boston, Massachusetts. Vertex Pharmaceuticals, Inc. July 2015.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: chronic medications for maintenance of lung function. *Am J Respir Crit Care Med.* 2013;187(7):680-689.
3. Katkin JP. Cystic fibrosis: genetics and pathogenesis. Up to Date, accessed July 2015; available from <http://www.uptodate.com>
4. Simon RH. Cystic fibrosis: overview of the treatment of lung disease. Up to Date, accessed July 2015; available from <http://www.uptodate.com>
5. FDA Pulmonary and Allergy Drugs Advisory Committee. Orkambi (lumacaftor/ivacaftor): treatment for cystic fibrosis. Vertex Pharmaceuticals, Inc. May 12, 2015; available from <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/UCM447293.pdf>

ORLADEYO (BEROTRALSTAT)

- The medication is prescribed by or in consultation with an specialist in allergy, immunology, hematology, pulmonology, or medical genetics
- Member is greater than or equal to 12 years of age; AND
- Member has HAE type I or type II and is using Orladeyo for angioedema prophylaxis; AND
- The prescriber attest that the diagnosis was confirmed by a C4 level below the lower limit of normal as defined by laboratory test and any of the following
 - C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory
 - performing the test; OR
 - C1-INH functional level below the lower limit of normal as defined by the laboratory performing the
 - test; OR
 - Presence of a known HAE-causing C1-INH mutation; AND
- The member has history of attacks with airway compromise/hospitalization; AND
- The prescriber attests that treatment with “on demand” therapy (i.e. Balbitor, Firazyr, Ruconest, Berinert) did not provide satisfactory control (i.e. treatment for acute attacks was unsuccessful; AND
- The prescriber attests to trial/failure, intolerance, or contraindication to attenuated (17 alpha-alkylated) androgens (i.e. danazol) for HAE prophylaxis; AND
- The prescriber attests to trial/failure, intolerance, or contraindication to Cinryze for angioedema prophylaxis

Authorization Dates:

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

ORTHOVISC (HYALURONIC ACID DERIVATIVES, INTRA-ARTICULAR)

Euflexxa is the preferred drug. 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

1. Adams ME. An analysis of clinical studies of the use of crosslinked hyaluronan, hylan, in the treatment of osteoarthritis. J Rheumatol. 1993;39 (Suppl):16-18.
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OTEZLA (APREMILAST)

Treatment of Psoriatic Arthritis:

Requests for continuing 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 active psoriatic arthritis; AND
- Member is 18 years of age or older; AND
- Member has tried and failed Humira and Enbrel.

Treatment of Plaque Psoriasis:

- Member has a diagnosis of mild or moderate to severe plaque psoriasis; AND
- Member is 18 years of age or older; AND
- Member must have previous failure on a topical psoriasis agent and be a candidate for phototherapy or systemic therapy; AND
- Member has tried and failed Humira and Enbrel.

Treatment of Behçet's Disease:

- Member has a diagnosis of oral ulcers associated with Behçet's Disease; AND
- Member is 18 years of age or older

Approval Duration

- Initial – 12 months
- Renewal – 12 months

Quantity Limit Alert:

- 2 tablets per day, quantities above 60/30 require a quantity limit review.

LAST REVISION: 5/1/22

OTREXUP, RASUVO (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
- 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

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

- 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:

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

- 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

PADCEV (ENFORTUMAB VEDOTIN)

Initial

1. Patient has a diagnosis of locally advanced or metastatic urothelial cancer AND
2. Patient is 18 years of age or older AND
3. Prescribed by or in consultation with an oncologist AND
4. Trial and inadequate response or intolerance to both of the following in the neoadjuvant/adjuvant, locally advanced or metastatic setting:
 - a. A programmed death receptor-1 (PD-1 or programmed death-ligand 1 (PD-L1) inhibitor (i.e. Keytruda, Tecentriq, Opdivo, Imfinzi, Bavencio)
 - b. A platinum-containing chemotherapy (i.e. DDMVAC, gemcitabine with either cisplatin or carboplatin)

Reauthorization

1. Prescriber attests clinical efficacy is achieved without unacceptable toxicity

Duration: Initial 6 months; Reauthorization 12 months

PALFORZIA (PEANUT (ARACHIS HYPOGAEA) ALLERGEN POWDER-dnfp)

INITIAL (6 months):

- Diagnosis of clinical history of allergy to peanuts or peanut-containing foods AND
- Patient is between 4-17 years of age at initiation of treatment 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 or in consultation with a specialist (Allergist or Immunologist) AND
- Prescriber attests the patient's history has been reviewed and that the prescriber has verified the patient is a candidate for Palforzia treatment following the REMS requirement AND
- Prescriber attests that Palforzia will be initiated at a REMS-certified healthcare facility and initial dose escalation phase as well as the first dose of each of the 11 up-dosing phases will be given at this REMS-certified healthcare facility

REAUTHORIZATION (12 months):

- The patient continues to meet initial approval criteria AND
- Patient must continue to tolerate the prescribed daily doses of Palforzia AND
- Patient has not experienced recurrent asthma exacerbations AND
- Patient has not experienced any treatment-restricting adverse effects (i.e. repeated systemic allergic reaction and/or severe anaphylaxis) AND
- If patient is greater than or equal to 18 years of age the patient can continue maintenance treatment if approved

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
- Postmenopausal osteoporosis, AND
 - Tried/failed/intolerance to alendronate

References

1. American College of Rheumatology. Recommendations for the prevention and treatment of glucocorticoid-induced osteoporosis. *Arthritis and Rheumatism*. 2001;44(7):1496-1503.
2. National Osteoporosis Foundation. The Clinician's Guide to Prevention and Treatment of Osteoporosis. Available from <http://www.nof.org/professionals/clinical-guidelines>.
3. Pamidronate. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
4. Pamidronate. In: G.K. McEvoy et al. (Eds.), *American Hospital Formulary Service Drug Information*. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>

Requests for continuing 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. The North American Menopause Society. Management of postmenopausal osteoporosis: 2010 position statement of the North American Menopause Society. Menopause: The Journal of the North American Menopause Society Vol. 17, No.1, pp 22-54.

PCSK9: REPATHA and PRALUENT

Initial: 3 months; Reauthorization: 6 months

- Diagnosis of one of the following:
 - HoFH (homozygous familial hypercholesterolemia),
 - Genetic testing confirming the presence of 2 mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus (documentation of genetic testing result required) OR
 - The diagnosis was confirmed with ANY of the following (documentation of laboratory report with LDL-C level at time of diagnosis and other documentation supporting the presence of xanthoma or family history of HoFH required – chart notes or medical records)
 - Untreated LDL-C > 500 mg/dL AND cutaneous or tendon xanthoma before age 10 years
 - Untreated LDL-C > 500 mg/dL AND untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
 - Treated LDL-C ≥ 300 mg/dL AND cutaneous or tendon xanthoma before age 10 years
 - Treated LDL-C ≥ 300 mg/dL AND untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
 - Member is ≥ 13 years of age if diagnosed HoFH
 - HeFH (heterozygous familial hypercholesterolemia) – REPATHA AND PRALUENT
 - Confirmed by definite diagnosis of HeFH as defined by the Dutch Lipid Clinic Network criteria (total score greater than 8 – Lab report required with LDL-C at time of diagnosis and other pertinent diagnostic supporting evidence) or
 - Member has definite diagnosis of HeFH as defined by Simon Broome diagnostic criteria OR
 - ASCVD (clinical atherosclerotic cardiovascular disease) or history of a cardiovascular event without homozygous/heterozygous familial hypercholesterolemia – REPATHA OR PRALUENT
 - Confirmed by member history of 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

- Acute coronary syndromes
- Myocardial infarction
- Stable or unstable angina
- Stroke of presumed atherosclerotic origin
- Transient ischemic attack (TIA)
- Coronary or other arterial revascularization procedure (e.g. PTCA, CABG)
- Peripheral arterial disease of presumed atherosclerotic origin
- Findings from CT angiogram or catheterization consistent with clinical ASCVD

AND

- The member has not been able to achieve target LDL-C levels using other lipid lowering interventions; AND
- The members pre-treatment LDL-C level (prior to PCSK9 inhibitor therapy) level is provided as well as current LDL-C level if applicable
- The member has had prior treatment history with the highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe for at least three continuous months with failure to reach target LDL-C AND is in one of the three groups identified by NLA: extremely high risk ASCVD members with LDL-C greater than or equal to 70 mg/dL, very high risk ASCVD members with LDL-C greater than or equal to 100 mg/dL, and high risk members with LDL-C greater than or equal to 130 mg/dL AND
- IF the member is unable to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, then documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the member experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
 - Muscle symptoms resolved after discontinuation of statin; AND
 - Muscle symptoms occurred when re-challenged at a lower dose of the same statin; AND
 - Muscle symptoms occurred after switching to an alternative statin; AND
 - Documentation ruling out non-statin causes of muscle symptoms (e.g. hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatic, steroid myopathy, vitamin D deficiency, or primary muscle disease; OR
 - The member has been diagnosed with statin-induced rhabdomyolysis

CONTINUING 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

- The member has achieved at least a 30% reduction in LDL-C since the beginning of treatment with Praluent/Repatha which is confirmed by laboratory results/clinical chart notes **AND**
- The member continues to receive benefit from Praluent/Repatha treatment as measured by either of the following (chart notes/laboratory results required):
 - Continued decrease in LDL-C levels or

Maintenance of optimum LDL-C level

PDE-5 INHIBITORS (SILDENAFIL/TADALAFIL)

- Diagnosis of pulmonary artery hypertension, **AND**
- Prescribed by pulmonary specialist or cardiologist, **AND**
- Member is greater than 18 years of age **AND**
- Must have rationale for not taking the sildenafil tablets to receive an approval for injectable Revatio.

LAST REVISION: 1/1/2023

PEMAZYRE (PEMIGATINIB)

Approval Duration: 1 year for Initial and Reauthorizations

Initial Therapy

- Diagnosis of locally advanced or metastatic cholangiocarcinoma; **AND**
- All of the following:
 - Patient has trialed one previous therapy for treatment; **AND**
 - Confirmed Fibroblast growth factor receptor 2 (FGFR2) fusion/or other rearrangement by an FDA-approved test; **AND**
 - For Females (with reproductive potential)
 - Must be counseled to use effective contraception during treatment (including 1 week after treatment completion); **OR**
 - For Males of female partners (with reproductive potential)
 - Must be counseled to use effective contraception during treatment (including 1 week after treatment completion); **AND**
 - Attestation that the prescriber will monitor for hyperphosphatemia while taking steps to keep phosphate level under control (by initiating a lower phosphate diet or initiating phosphate-lowering medications), as clinically appropriate; **AND**
 - Patient is 18 years of age or older

OR

- Diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGRF1 rearrangement; **AND**
- All 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

- Patient has trialed one previous therapy for treatment; **AND**
- For Females (with reproductive potential)
 - Must be counseled to use effective contraception during treatment (including 1 week after treatment completion); **OR**
- For Males of female partners (with reproductive potential)
 - Must be counseled to use effective contraception during treatment (including 1 week after treatment completion); **AND**
- Attestation that the prescriber will monitor for hyperphosphatemia while taking steps to keep phosphate level under control (by initiating a lower phosphate diet or initiating phosphate-lowering medications), as clinically appropriate; **AND**
- Patient is 18 years of age or older

Reauthorization:

- Patient has locally advanced or metastatic cholangiocarcinoma or relapsed or refractory myeloid/lymphoid neoplasms; **AND**
- No disease progression or unacceptable toxicity; **AND**
- Attestation that the prescriber will monitor for hyperphosphatemia while taking steps to keep phosphate level under control (by initiating a lower phosphate diet or initiating phosphate-lowering medications), as clinically appropriate; **AND** Effective contraception is being followed (as outlined above) for both males and females through 1 week post therapy

LAST REVISION 1/1/2023

PIZENSY (LACTITOL MONOHYDRATE)

CRITERIA FOR USE

1. Diagnosis of Chronic Idiopathic Constipation
AND
2. Age is 18 years or older;
AND
3. An adequate response to lifestyle changes, including dietary modifications and increases in fiber
AND
4. An inadequate response of at least ONE (1) preferred product 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).**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

5. An inadequate response/intolerance to ≥ 1 of the preferred products indicated for CIC
 - o A. Linzess OR
 - o B. Amitiza

Approval Duration: 6 months

PONVORY (PONESIMOD)

- Confirm member has a diagnosis of relapsing multiple sclerosis (RMS), including isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; **AND**
- Member is 18 years of age or older; **AND**
- Documentation provided that supports member has received at least two or more prior systemic therapies; **AND**
- Member will not use Ponvory concomitantly with other disease-modifying medications for the treatment of MS; **AND**
- Prescribed by or in consultation with a neurologist

Authorization Duration:
12 months

LAST REVISION: 7/1/21

PRETOMANID (PRETOMANID)

- Documented diagnosis of highly drug-resistant tuberculosis (TB)- XDR-TB or MDR-TB
- Must be utilized in combination with bedaquiline and linezolid
- Prescriber is an infectious disease specialist or pulmonologist
- Treatment of TB is based on in vitro susceptibility results
- Should not be used with any of the following:
 - o Drug-sensitive TB
 - o Latent infection due to Mycobacterium tuberculosis
 - o Extra-pulmonary infection due to Mycobacterium tuberculosis
 - o MDR-TB that is not treatment-intolerant or nonresponsive to standard therapy

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**

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

- 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
 - 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 OR
- Documentation of gastrostomy or other feeding tube OR
- 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. 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

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

PROCYSBI (CYSTEAMINE BITARTRATE)

Initial Criteria

- Patient is 1 year of age and older **AND**
- Patient has a diagnosis of nephropathic cystinosis confirmed by a nephrologist, urologist, or other specialist of cystinosis **AND**
- Documentation provided to support diagnosis confirmed by presence of increased cysteine or genetic testing **AND**
- White blood cell (WBC) cysteine level is > 1 nmol ½ cystine/mg protein **AND**
- Serum creatine level is < 3.0mg/dL per documented lab values **AND**
- Member must be unable or intolerant to cysteamine immediate release tablets 4 times daily or has a contraindication to the immediate release formulation such as Cystagon **AND**
- Documentation provided stating member's current height and weight submitted **AND**
- Member able take Procysbi on an empty stomach (30 minutes before eating or 2.5 hours after eating)

Reauthorization Criteria

- Initial criteria continue to be met **AND**
- Documentation that patient is tolerating and responding to medication evident by WBC cysteine level <1 nmol ½ cysteine/mg protein **AND**
- Member has not experienced any significant medication related adverse reactions **AND**
- Member's serum creatinine is < 3.0 mg/dL and has not increased from baseline

Approval: 12 months

LAST REVISION: 5/1/2022

References

1. Virginia Premier

PRODIGY VOICE KIT METER AND TEST STRIPS

- Clinically diagnosed with Diabetes Mellitus **AND**
- Must have clinical need for a speaking meter and corresponding test strips (i.e. patient is blind) **AND**
- Quantity limit of 100 strips in 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

PROLIA (DENOSUMAB)

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 Patient is currently taking calcium 1000mg plus 400 IU of vitamin D daily.
OR
 2. Contraindication to ORAL bisphosphonate use.

OR

- Men receiving androgen deprivation therapy for nonmetastatic prostate cancer:
 1. ECOG \leq 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.

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

- 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
 - A prior osteoporotic fracture
 - Femoral neck BMD
 - Low body mass index
 - Oral glucocorticoids > 5 mg/d of prednisone for > 3mo (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 1ml of 60mg/ml solution.

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

References

- Virginia Premier

PROMACTA (ELTROMBOPAG)

- Member is ≥ 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-Rh₀[D]), or splenectomy, OR
- Thrombocytopenia secondary to cirrhosis of the liver due to hepatitis C.
- Maximum daily dosage of 100mg/day

Reauthorization/continuing 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

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

References

1. Bussel JB, Cheng G, Saleh MN, et al. Eltrombopag for the treatment of chronic idiopathic thrombocytopenic purpura. *N Engl J Med.* 2007;357(22):2237-2247.
2. Eltrombopag. In: G.K. McEvoy et al. (Eds.), *American Hospital Formulary Service Drug Information*. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>
3. Promacta. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
4. Sugar NF, Graham EA, Common Gynecologic Problems in Prepubertal Girls. *Pediatrics in Review* June 2006;27(6): 214-223.
5. Van Eyk N, Allen L, Giesbrecht E, et. al. Pediatric Vulvovaginal Disorders: A Diagnostic Approach and Review of the Literature. *J Obstet Gynaecol Can* 2009;31(9):850–862.

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

1. Biederman J, et al. A comparison of once-daily and divided doses of modafinil in children with attention-deficit/hyperactivity disorder: a randomized, double-blind, and placebo-controlled study. *J Clin Psychiatry.* 2006;67:727-35.
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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

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PYRUKYND (MITAPIVAT)

INITIAL:

- Diagnosis of PKD with at least two mutant alleles in the PKLR gene, of which at least one is a missense mutation; **AND**
- Member is 18 years of age or older; **AND**
- Member is not homozygous for the R479H mutation or had two non-missense variants, without the presence of another missense variate, in the PKLR gene; **AND**
- Member has required RBC transfusion for hemolytic anemia due to PKD withing the previous year; **AND**
- Hemoglobin level is currently less than or equal to 10 mg/dL; **AND**
- Member will use 0.8 mg folic acid daily; **AND**
- Prescribed by or in consultation with a specialty; **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 will not use hematopoietic-stimulating agents or strong Cyp3A inhibitors or induces concomitantly; **AND**
- Member does not have moderate or severe hepatic dysfunction

RENEWAL:

- Increase in Hb greater than or equal to 1.5 mg/dL over baseline **and/or**
- Reduction in transfusion burden

Authorization:

Initial: 3 months

Renewal: 6 months

Quantity Limits apply:

- 60 tablets per 30 days

LAST REVISION: 8/1/2022

References

1. Virginia Premier

QBREXZA (GLYCOPYRRONIUM TOSYLATE)

NF-PA criteria; Coverage duration: 12 months

- Diagnosis of primary axillary hyperhidrosis; **AND**
- Patient has had diagnosis of primary axillary hyperhidrosis for greater than 6 months; **AND**
- Prescribed by, or in consultation with a dermatologist (skin doctor); **AND**
- Patient has a hyperhidrosis disease severity scale grade 3 or 4; **AND**
- Patient has had an intolerance, or inadequate response to Aluminum Chloride (i.e. Drysol)

QINLOCK (RIPRETINIB)

Approval Duration: 1 year

1. Patient is diagnosed with advanced Gastrointestinal stromal tumor (GIST); **AND**
2. Patient has previously trialed imatinib (Gleevec); **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

3. Patient has previously trialed 2 additional kinase inhibitors (not counting imatinib);
AND
4. Patient is 18 years of age or older

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 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 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, AND
- Must have tried either over the counter Prevacid24OTC 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

RADICAVA ORS (EDARAVONE)

Requests for continuing 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:

- Member has a diagnosis of ALS supported by submission of medical records; **AND**
- Prescribed by or in conjunction with a neurologist with expertise in the diagnosis of ALS; **AND**
- The member's most recent ALS Functional Rating Scale-Revised (ALSFRRS-R) score is greater than or equal to 2; **AND**
- The member has a % forced vital capacity (%FVC) greater than or equal to 80%

RENEWAL:

- Member is currently receiving Radicava therapy; **AND**
- Member is not dependent on invasive ventilation or tracheostomy.

Initial approval: 6 cycles (6 months)

Renewal: 6 cycles (6 months)

LAST REVISION: 10/01/22

RAGWITEK

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

- the member is 5 years of age or older
- AND-**
- the medication is prescribed by an allergist, immunologist, or ENT (ear, nose, throat) specialist, or the prescriber is from BLAND COUNTY MEDICAL CLINIC
- AND-**
- **Ragwitek** therapy is initiated 12 weeks prior to the expected onset of the short ragweed pollen season
- AND-**
- 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)
- AND-**
- the member is NOT currently receiving subcutaneous allergen immunotherapy.

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

LAST REVISION: 11/1/21

References

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4. Ragwitek® prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. April 2014.

Requests for continuing 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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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 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 ≤ 2 mg/dL
2. Albumin Stable and within normal limits
3. Prothrombin Time < 3 seconds prolonged
4. WBC ≥ 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

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.

Requests for continuing 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. 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

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2. Ghany MG, Nelson DR, et al. An Update on Treatment of Genotype 1 Chronic Hepatitis C Virus Infection. AASLD Practice Guidelines. Available at <http://www.aasld.org/practiceguidelines/Documents/2011UpdateGenotype1HCVbyAASLD24641.pdf>.
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RECARBRIO (IMIPENEM, CILASTATIN AND RELEBACTAM)

- Diagnosis of Complicated urinary tract infection, including pyelonephritis OR
 - Diagnosis of Complicated intra-abdominal infection
- AND
- Patient greater than 18 years of age
 - Patient has limited or no alternative treatment options available
 - Prescriber attests medication is not being used empirically
 - Prescribed by an infectious disease specialist

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:

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

- 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 zoledronic acid, OR
 - Hypercalcemia of malignancy
 - Bone metastasis - Solid tumor configuration
 - Multiple myeloma
 - Osteopenia, Secondary to androgen-deprivation therapy in prostate cancer patients; Prophylaxis

References

1. American College of Rheumatology. Recommendations for the prevention and treatment of glucocorticoid-induced osteoporosis. Arthritis and Rheumatism. 2001;44(7):1496-1503.
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RECORLEV (LEVOKETOCONAZOLE)

INITIAL:

- Diagnosis of Cushings syndrome; **AND**
- Member is 18 years of age or older; **AND**
- Prescribed by or in conjunction with an endocrinologist; **AND**
- Prescriber attests to surgery not being an option for the member or surgery has not been curative for the member; **AND**
- Prescriber attests to obtaining AST and ALT levels prior to treatment and continued monitoring of liver function while on Recorlev and AST and ALT are not greater than 3 times the upper limit of normal; **AND**
- Member has baseline urine free cortisol (UFC); **AND**
- Member has tried and failed, or has a contraindication to ketoconazole.

RENEWAL:

- Member has a reduction from baseline in urine free cortisol; **AND**
- Provider is continuing to monitor liver function

Authorization:

Initial: 6 months

Renewal: 12 months

QUANTITY LIMITS: 240 tablets/30 days

LAST REVISION: 8/1/2022

References

1. Virginia Premier

RECTIV (NITROGLYCERIN)

APPROVAL DURATION: 21 days

APPROVAL CRITERIA

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

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records. **AND**
- Must be clinically diagnosed with chronic anal fissures and have moderate to severe pain associated with it. **AND**
- 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.
- 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.

REDITREX (METHOTREXATE)

- Diagnosis of severe, active rheumatoid arthritis (RA); symptomatic control of severe, recalcitrant disabling psoriasis; or polyarticular juvenile idiopathic arthritis (pJIA); **AND**
- For polyarticular juvenile idiopathic arthritis (pJIA):
 - Prescribed by or in consultation with a rheumatologist; **AND**
 - Member is 2 years of age or older; **AND**
 - Failure of generic methotrexate injection, unless contraindicated or clinically significant adverse effects are experienced

References

1. Virginia Premier Health Plan

LAST REVISION: 7/1/22

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**

Requests for continuing 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 confirms to provide wound follow-up care, including debridement if needed.

References

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RELEUKO (FILGRASTIM-AYOW)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Cancer patients receiving myelosuppressive chemotherapy.

4. Approve Releuko if prescribed by, or in consultation with, an oncologist or hematologist.
5. Releuko 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.
6. **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**
- **Neutropenic disorder, chronic (Severe), Symptomatic**

LAST REVISION: 8/1/2022

REFERENCES

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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

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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

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

- History of inadequate response or intolerance to both polyethylene glycol AND lactulose.
- Quantity limits 2 vials/day and 8 kits/28 days and 90 tablets/30 days

LAST UPDATED: 6/1/2021

References

1. Virginia Premier

RELYVRIO (SODIUM PHENYLBUTYRATE/TAURUSODIOL)

INITIAL:

- Member has a diagnosis of ALS supported by submission of medical records; **AND**
- Prescribed by or in conjunction with a neurologist with expertise in the diagnosis of ALS; **AND**
- The member's most recent ALS Functional Rating Scale-Revised (ALSFRS-R) score is greater than or equal to 2 **AND**
- Member has a % forced vital capacity (%FVC) > 60%

LAST REVISION: 1/1/23

REMODULIN (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.

Requests for continuing 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 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:

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RETEVMO (SELPERCATINIB)

Approval Duration: 1 year

- **Metastatic Non-Small Cell Lung Cancer (NSCLC)**
 - Patient is diagnosed with metastatic Non-Small Cell Lung Cancer (NSCLC); AND
 - Patient has confirmed RET fusion-positive tumors as supported by FDA-approved testing; AND
 - Patient is 18 years of age or older; OR
- **Medullary Thyroid Cancer**
 - Patient is diagnosed with advanced or metastatic Medullary Thyroid Cancer; AND
 - Patient has confirmed RET fusion-positive disease as supported by FDA-approved testing; AND
 - Prescriber attests that systemic therapy is needed for treatment
 - Patient is 12 years of age or older
- **Thyroid Cancer**
 - Patient is diagnosed with advanced or metastatic Thyroid Cancer; AND
 - Patient has confirmed RET fusion-positive disease as supported by FDA-approved testing; AND
 - Prescriber attests that the disease state is radioactive iodine-refractory (if applicable); 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

- Prescriber attests that systemic therapy is needed for treatment; AND
- Patient is 12 years of age or older

REVCovi (ELAPEGADEMASE)

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; Renewal – 6 months

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 cytogenetic 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:

Requests for continuing 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 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.
- Follicular Or Marginal Zone Lymphoma
 - Prescribed by an oncologist or a hematologist
 - Clinically diagnosed with Marginal Zone or Follicular Lymphoma
 - Absolute neutrophil count (ANC) of at least 500/ml
 - Platelet count of at least 50,000/ml
 - Serum creatinine < 2.5 mg/dl.
 - Used in conjunction with Rituxan (rituximab) (PA required)
- **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.
 - Cytogenetic response. (50% or greater reduction in abnormal metaphases)

Approval Duration:

Initial - 3 months

Renewal - 3 months

References

- 1.) DRUGDEX®, accessed 03/2/2016.
- 2.) Product Information: Revlimid® (lenalidomide) capsules, for oral use. Celgene Corporation Summit, New Jersey, 2013.

REXULTI (BREXPIRAZOLE)

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

- 1) Diagnosed with Schizophrenia and at least 13 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)

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

- 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.

LAST REVISION: 5/1/22

References

- 1) Virginia Premier.

REZUROCK (BELUMOSUDIL)

Initial Approval:

- Confirm member has a diagnosis of chronic graft-versus-host disease (cGVHD); AND
- Member is 12 years of age and older AND
- Member has an adequate trial and failure of at least two previous lines of systemic therapy (e.g. corticosteroids, mycophenolate, etc) ; AND
- If member is using concomitant proton pump inhibitors (e.g. omeprazole), member is transitioned off of the PPI to H2 blocker (e.g. famotidine) or if member has tried and failure at least one H2 blocker dosage increased to 200mg twice daily AND
- Prescribed by or in consultation with a specialist such as oncologist or hematologist.

Renewal Approval:

- Documentation of positive response to therapy and tolerating therapy.
- No progression of chronic GVHD

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

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

- 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

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 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 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

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.

Requests for continuing 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. Patients with a history of significant or unstable cardiac disease.
6. Creatinine clearance < 50ml/min.
7. Coverage is not recommended

References

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2. Ghany MG, Nelson DR, et al. An Update on Treatment of Genotype 1 Chronic Hepatitis C Virus Infection. AASLD Practice Guidelines. Available at <http://www.aasld.org/practiceguidelines/Documents/2011UpdateGenotype1HCVbyAASLD24641.pdf>.
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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

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38. Gonzalez-Peralta RP, Kelly DA, Haber B et al. Interferon alfa-2b in combination with ribavirin for the treatment of chronic hepatitis C in children: efficacy, safety, and pharmacokinetics. *Hepatology*.

RINVOQ (UPADACITINIB)

Initial: 12 months

- Diagnosis of moderate to severely active rheumatoid arthritis (RA), active psoriatic arthritis, ankylosing spondylitis, or moderately to severely active ulcerative colitis in patients 18 years of age or older; OR
- Diagnosis of refractory, moderate to severe atopic dermatitis in patients 12 years of age or older whose disease is not adequately controlled with other systemic drug products; AND
- Prescribed by or in consultation with a rheumatologist
- **AND ALL** of the following:
 - Patient has had an inadequate response following ≥ 3 months of treatment, is intolerant of, or has a contraindication to methotrexate; if methotrexate is not tolerated or is contraindicated, treatment with at least one other conventional DMARD (i.e. azathioprine, hydroxychloroquine, leflunomide, sulfasalazine) was ineffective.
 - Patient has had an inadequate response following treatment, is intolerant of, or has a contraindication of Enbrel and Humira
 - Result for latent TB infection is negative OR result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
- **AND NONE** of the following:
 - Active bacterial, invasive fungal, viral, and other opportunistic infections
 - Severe hepatic impairment (Child Pugh C)
 - A lymphocyte count less than 500 cells/mm³
 - An absolute neutrophil count less than 1000 cells/mm³
 - History of thrombotic events including deep vein thrombosis (DVT) or pulmonary embolism (PE)

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

- Used in combination with any other biologic DMARD or targeted synthetic DMARD
- Used in combination with potent immunosuppressants azathioprine or cyclosporine
- Given concurrently with live vaccines

Reauthorization: 12 months

- Condition has improved or stabilized
- Absence of active bacterial, invasive fungal, viral, and other opportunistic infections
- NOT to be used in combination with any other biologic DMARD or targeted synthetic DMARD
- NOT used in combination with potent immunosuppressants azathioprine or cyclosporine
- NOT given concurrently with live vaccines
- No development of thrombotic events (including DVTs or PEs)

LAST REVISION: 7/1/22

RITUXAN (RITUXIMAB)

- Non-Hodgkin's Lymphoma, OR
- Autoimmune hemolytic anemia, OR
- B-cell lymphoma, or advanced stage CD20-positive diffuse large B-cell lymphoma (DLBCL), or mature B-cell acute lymphoma (BAL), OR
- Burkitt lymphoma (BL) or Burkitt-like lymphoma (BLL), 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 regimens, 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
- Granulomatosis with polyangiitis (Wegener granulomatosis) and microscopic polyangiitis in adults and pediatric patients 2 years and older OR
- Follicular or Marginal Zone Lymphoma, AND
- Is being used with Revlimid (lenalidomide), OR Moderate to severe active rheumatoid arthritis with at least four of the following symptoms:
 - Morning stiffness.

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

- 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
 - 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.

LAST REVISION: 5/1/22

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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

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ROLVEDON (EFLAPEGRASTIM-XNST)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Cancer patients receiving myelosuppressive chemotherapy.

1. Approve Rolvedon if prescribed by, or in consultation with, an oncologist or hematologist.
2. Rolvedon 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.

LAST REVISION: 1/1/23

ROZLYTREK (ENTRECTINIB)

- Diagnosis of ROS1-positive metastatic non-small cell lung cancer (NSCLC) AND
- Patient is greater than or equal to 18 years old **OR**
- Diagnosis of a Solid Tumor with a Neurotrophic Receptor Tyrosine Kinase (NTRK) Gene Fusion AND
- Patient is greater than or equal to 12 years old AND
- Histologically or cytologically confirmed diagnosis of locally advanced or metastatic solid tumors that have a NTRK1, NTRK2, NTRK3, ROS1 or ALK molecular alteration
- No known acquired resistance mutations
- Progressed following initial treatment (or have no alternative treatments)
- If locally advanced disease surgical resection of tumor would likely result in severe morbidity for patient
- No history of prolonged QTc interval or a history of torsades de pointes
- No known hepatic impairment

RYLAZE (ASPARAGINASE ERWINIA CHRYSANTHEMI (RECOMBINANT)-RYWN)

Requests for continuing 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 Approval:

- Confirm member has a diagnosis of acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) ; AND
- Member is 1 months of age or older: AND
- Member has developed hypersensitivity to E. coli-derived asparaginase; AND
- Prescribed by or in consultation with an oncologist

Renewal Approval:

- Documentation of positive response to therapy

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 11/1/21

RYPLAZIM (PLASMINOGEN, HUMAN-TVMH)

Initial Approval:

- Confirm member has a diagnosis of Plasminogen Deficiency (PLGD) Type I (or hypoplasminogenemia) ; AND
- Member is 11 months of age or older: AND
- Documentation provided for ALL of the following
 - Plasminogen activity level \leq 45%; AND
 - History of lesions (external and/or internal) and symptoms consistent with a diagnosis of congenital PLGD, examples include but not limited to gum lesions; eye lesions; ear lesions, respiratory tract lesions, occlusive hydrocephalus; AND
- Member has documented vaccination history to HAV and HBV, or member has received their first vaccine dose and is scheduled to receive the second vaccine dose; AND
- Prescribed by or in consultation with a specialist experienced in the treatment of PLGD, such as hematologist, pulmonologist, etc.

Renewal Approval:

- Documentation of positive response to therapy (i.e. no new or recurring lesions)
- Trough plasminogen activity levels maintained during follow-up visits.
DISCONTINUE Ryplazim therapy if the trough plasminogen level is <10% above the baseline trough after 12 week.

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 11/1/21

RYZOLT (TRAMADOL HYDROCHLORIDE) EXTENDED-RELEASE

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

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

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

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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

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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.
- Or
- 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

SAPHNELO (ANIFROLUMAB-FNIA)

Initial Approval:

- Confirm member has a diagnosis of moderate to severe systemic lupus erythematosus (SLE); AND
- Member is 18 years of age or older; AND
- Laboratory testing has documented the presence of autoantibodies (ie, ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB) 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 is receiving standard-of-care therapy with at least one of the following: prednisone (or equivalent), hydroxychloroquine, azathioprine, mycophenolate mofetil, methotrexate; **AND**
- Member is not taking Saphnelo with Benlysta concurrently; **AND**
- Member does not have severe active central nervous system (CNS) lupus; **AND**
- Member does not have active lupus nephritis; **AND**
- Prescribed by or in consultation with a specialist such as rheumatologist.

Renewal Approval:

- Documentation demonstrates member is responding positively to therapy based on reduction in signs and symptoms of SLE, which may include number of flares, disease activity in specific organs, etc.

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

SARCLISA (ISATUXIMAB-IRFC)

CRITERIA FOR USE

- 1) Prescriber attests to a documented diagnosis multiple myeloma; **AND**
- 2) Age is 18 years or older; **AND**
- 3) Prescribed by or in consultation with an oncologist; **AND**
- 4) Patient meets one of the following:
 - a.** Patient must have failed at least **TWO** prior therapies including Revlimid and a proteasome inhibitor (such as Velcade, Kyprolis or Ninlaro) **AND**
 - b.** Prescriber attests Sarclisa is being utilized with Pomalyst and dexamethasone; **OR**
 - a.** Patient must have failed at least 1 to 3 prior therapies; **AND**
 - b.** Prescriber attests Sarclisa is being utilized with Kyprolis and dexamethasone

AND

- 5) Must have ECOG performance status of 0 to 1

LAST REVISION 7/1/21

SAVAYSA (EDOXYBAN)

- 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**

Requests for continuing 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 that Creatinine Clearance is *NOT* ≥ 95 mL/min calculated by Cockcroft-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.

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SCEMBLIX (ASCIMINIB)

1. Member has a diagnosis of Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP) and one of the following:
 - Ph+ CML-CP that has been treated with at least two other TKIs; **OR**
 - Ph+ CML-CP with the *T315I* mutation; **AND**
2. Member is over 18 years of age

LAST REVISION: 5/1/22

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

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).

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)

Requests for continuing 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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SICKLE CELL DISEASE AGENTS

(NON-PREFERRED AGENTS: ADAKVEO, SIKLOS)

(PREFERRED AGENTS: DROXIA, ENDARI, AND OXYBRYTA DO NOT REQUIRE PRIOR AUTHORIZATION)

Initial Criteria:

- Medication is being prescribed by or in consultation with an oncologist, hematologist, or sickle cell specialist **AND**
- Member has a diagnosis of Sickle Cell Disease presenting as one of the following (HbSS, HbSC, HbS β^0 -thalassemia, or HbS β^+ -thalassemia) **AND**
- Medication dose is proper for patient's age or other conditions affecting the dose, according to the FDA approved package insert **AND**
- **Adakveo** – member has had an insufficient response to a minimum of 3-month trial of hydroxyurea (unless contraindicated or intolerant) **AND**
- **Adakveo** – member has experienced TWO or more vaso-occlusive crises (VOCs) in the previous year despite adherence to hydroxyurea therapy **AND**
- **Siklos** – member is between the age of 2-17 years of age

Renewal Criteria:

- Member continues to meet original criteria **AND**
- Member has shown improvement in disease **AND**
- **Adakveo** – member's response compared to pre-treatment baseline evidenced by a decrease in frequency of VOCs necessitating treatment, reduction in the number or duration of hospitalizations, and/or reduction in severity of VOC

Initial Approval: 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

Renewal Approval: 12 months

Revised 1/1/2023

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

SILIQ (BRODALUMAB)

Initial Review Criteria:

- Member has a diagnosis of moderate to severe active plaque psoriasis; AND
- Member is 18 years of age or older; AND
- Member has greater than or equal to 5% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis; AND
- Member has a history of failure, contraindication, or intolerance to both of the following conventional therapies:
 - Topical therapy with one of the following:
 - Corticosteroids (e.g., betamethasone, clobetasol, desonide)
 - Vitamin D analogs (e.g., calcitriol, calcipotriene)
 - Tazarotene

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

- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
 - Anthralin
 - Coal tar; AND
 - Systemic therapy of at least 3 onths duration with methotrexate; AND
- Member has tried and failed Humira and Enbrel
- Member is not receiving Siliq in combination with any of the following:
 - Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
 - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
 - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
- For continuation, member meets all of the following:
 - Member is currently on Siliq therapy; AND
 - Diagnosis of chronic moderate to severe plaque psoriasis; AND
 - Member is not receiving Siliq in combination with any of the following:
 - Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
 - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
 - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Renew Criteria:

- Documentation of positive clinical response to Siliq therapy; AND
- Member is not receiving Siliq in combination with any of the following:
 - Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
 - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
 - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Psoriatic Arthritis:

- Member has a diagnosis of Psoriatic Arthritis; AND
- Member is 18 years of age or older; AND
- Member has tried and failed Enbrel and Humira

Approval Duration

- Initial – 12 months
- Renewal – 12 months

LAST REVISION: 7/1/21

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.

4. Polyarticular juvenile idiopathic arthritis

Golimumab is FDA-approved for the treatment of active polyarticular juvenile idiopathic arthritis in patients ≥ 2 years of age.

5. Ulcerative Colitis

- o Member has a diagnosis of moderately to severely active ulcerative colitis; AND
- o Member is 18 years of age or older; AND
- o Member has trial and failure of a compliant regimen of oral or rectal aminosalicylates (i.e., sulfasalazine or mesalamine) for two consecutive months, AND
- o Member has trial and failure of a compliant regimen of oral corticosteroids (for moderate to severe CD) unless contraindicated, or intravenous corticosteroids (for severe and fulminant CD or failure to respond to oral corticosteroids), AND
- o Member has trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months

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 TNF α 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

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

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 TNF α 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.

LAST REVISION: 7/1/21

References

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8. Kavanaugh A, McInnes I, Mease P et al. Golimumab, a new human tumor necrosis factor alpha antibody, administered every four weeks as a subcutaneous injection in psoriatic arthritis: Twenty-four-week efficacy and safety results of a randomized, placebo-controlled study. *Arthritis Rheum*. 2009; 60:976-86.
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10. Anderson JJ, Baron G, van der Heijde D et al. Ankylosing spondylitis assessment group preliminary definition of short-term improvement in ankylosing spondylitis. *Arthritis Rheum*. 2001; 44:1876-86.
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SKYRIZI (RISANKIZUMAB-RZAA)

Treatment of Plaque Psoriasis:

Requests for continuing 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 moderate to severe plaque psoriasis for ≥ 6 months with ≥ 1 of the following;
 - Affected body surface area (BSA) of $\geq 10\%$; OR
 - Psoriasis Area and Severity Index (PASI) score ≥ 10 ; OR
 - Incapacitation due to plaque location (e.g., head and neck, palms, soles or genitalia); AND
- Member is 18 years of age or older; AND
- Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues); AND
- Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of ≥ 1 systemic agent (e.g. Immunosuppressives, retinoic acid derivatives, and/or methotrexate); AND
- Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (e.g., psoralens with UVA light (PUVA) or UVB with coal tar or dithranol); AND
- Member is not receiving risankizumab-rzaa in combination with another biologic agent for psoriasis or non-biologic immunomodulator (e.g., apremilast, tofacitinib, baricitinib); AND
- Member has tried and failed Humira and Enbrel.

LAST REVISION: 7/1/21

SOTYKTU (DEUCRAVACITNIB)

Initial Criteria

- Diagnosis of moderate to severe chronic plaque psoriasis for > 6 months; **AND**
- Member is 18 years of age or older; **AND**
- Prescribed by or in consultation with a dermatologist or rheumatologist; **AND**
- Member has plaque psoriasis that impacts greater than 10% of the body surface area; **AND**
- Member has a Psoriasis Area and Severity Index (PASI) score ≥ 12 **AND**
- Member has a static Physician's Global Assessment (sPGA) ≥ 3 **AND**
- Member has tried and failed, or has a contraindication to high- to ultra-high-potency topical corticosteroids (such as betamethasone dipropionate, clobetasol, or halobetasol) used concurrently with either a generic topical calcipotriene product or a generic tazarotene product; **AND**
- Sotyktu will not be used in combination with other oral targeted immunomodulators, biologic targeted immunomodulators, or conventional oral agents (such as methotrexate)

Reauthorization:

- Prescriber documentation provided which supports clinical improvement in signs and symptoms of plaque psoriasis.

Requests for continuing 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 Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/23

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)

PA CRITERIA FROM THE PLAN: **PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH):**

- A documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as evidenced by having detectable glucose phosphate isomerase (GPI)-deficient hemopoetic clones (Type III PNH red blood cells [RBC]) via flow cytometry **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

- Prescriber attests that a meningococcal vaccine was given at least two (2) weeks prior to the administration of the first dose of eculizumab **AND**
- The patient must be 18 years of age or older **AND**
- The requested medication must be prescribed by or in consultation with a hematologist, oncologist, immunologist or genetic specialist **AND**
- Patient has one of the following:
 - 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**
 - History of thromboembolism, pulmonary hypertension, renal insufficiency, or other end organ complications from PNH
- For renewal: Prescriber attests that patient continues to meet initial criteria **AND** Prescriber attests that patient has had disease improvement or stabilization since using the medication.

PA CRITERIA FROM THE PLAN: ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS):

- A diagnosis of atypical hemolytic uremic syndrome (aHUS) based on clinical presentation of microangiopathic hemolytic anemia, thrombocytopenia, and acute kidney injury, and presentation of complement dysregulation **AND**
- Prescriber attests that a meningococcal vaccine was given at least two (2) weeks prior to the administration of the first dose of eculizumab **AND**
- The patient must be 2 months or older **AND**
- The requested medication must be prescribed by or in consultation with a hematologist, oncologist, immunologist or genetic specialist
- For renewal: Prescriber attests that patient continues to meet initial criteria **AND**
- Prescriber attests that patient has had disease improvement or stabilization since using the medication.

PA CRITERIA FROM THE PLAN: GENERALIZED MYASTHENIA GRAVIS (gMG):

- Prescriber attests to a diagnosis of generalized myasthenia gravis (gMG) **AND**
- Prescriber attests that patient has a MG-activities of daily living (MG-ADL) total score of greater than 6 **AND**
- Prescriber attests that patient has had positive serologic test for anti-ACR antibodies **AND**
- One of the following:
 - 1) Prescriber attests that patient has failed treatment over 1 year or more with 2 or more immunosuppressive therapies either in combination or as monotherapy **OR**
 - 2) Prescriber attests that patient has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIg) **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

- Prescriber attests that a meningococcal vaccine was given at least two (2) weeks prior to the administration of the first dose of eculizumab **AND**
- The patient must be 18 years of age or older **AND**
- The requested medication must be prescribed by or in consultation with a hematologist, oncologist, immunologist or genetic specialist
- For renewal: Prescriber attests that patient continues to meet initial criteria **AND**
- Prescriber attests that patient has had disease improvement or stabilization since using the medication.

PA CRITERIA FROM THE PLAN: **NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD)**

- A diagnosis neuromyelitis optica spectrum disorder (NMOSD) **AND**
- Prescriber attests the patient is anti-aquaporin-4 (AQP4) antibody positive **AND**
- Prescriber attests that a meningococcal vaccine was given at least two (2) weeks prior to the administration of the first dose of eculizumab **AND**
- Prescriber attests the patient has failed treatment with a corticosteroid and another immunosuppressive agent OR failed treatment with a corticosteroid and intravenous immunoglobulin (IVIG) **AND**
- The patient must be 18 years of age or older **AND**
- The requested medication must be prescribed by or in consultation with a neurologist

References

1. Eculizumab. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
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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.

Requests for continuing 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:

- 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

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
- 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)

Requests for continuing 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

- 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

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

Requests for continuing 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 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)

References

1. Virginia Premier

SPRIX (KETOROLAC TROMETHAMINE) INTRANASAL

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

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

STELARA (USTEKINUMAB)

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

FDA-Approved Indications

1. Plaque psoriasis in patients (6 years or older).

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 $\geq 5\%$.
Exceptions can be made to the requirement for $\geq 5\%$ 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.

1. Individual is 6 years of age or older with active PsA; **AND**
2. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as non-biologic DMARDs); **AND**
3. Individual has had an inadequate response to TWO preferred biologic therapies in the previous 180 days. (Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab))

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

4. Moderate to Severely Active, Ulcerative Colitis

- Must be 18 years of age or older AND
- Must have tried and failed or been intolerant to, therapy with at least two (2) of the following:
 - i. Corticosteroids (i.e. prednisone, prednisolone, methylprednisolone)
 - ii. 5-Aminosalicylates (i.e. sulfasalazine, mesalamine)
 - iii. 6-Mercaptopurine (6-MP) and/or azathioprine
 - iv. Immunosuppressants (i.e. cyclosporine, tacrolimus) AND
- Must have tried and failed, or been intolerant to, therapy with Humira

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).

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

EXCLUSIONS

Coverage of ustekinumab is *NOT* recommended in the following circumstances:

1. **Ustekinumab should not be given in combination with a TNF α 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.

2. **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

1. Chandler SKD, Griffiths CEM, Helliwell P. Guideline for anti-TNF- α therapy in psoriatic arthritis. *Rheumatology* 2005; 44:390-97
2. Leonardi CL, Kimball AB, Papp KA et al. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 76-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 1). *Lancet*. 2008; 371:1665-74.
3. Papp KA, Langley RG, Lebwohl M et al. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 52-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 2). *Lancet*. 2008; 371:1675-84.
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5. Lebwohl M, Yeilding N, Szapary P et al. Impact of weight on the efficacy and safety of ustekinumab in patients with moderate to severe psoriasis: rationale for dosing recommendations. *J Am Acad Dermatol*. 2010; 63:571-9.

LAST REVISION 1/1/2023

STIMUFEND (PEGFILGRASTIM-FPQK)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Cancer patients receiving myelosuppressive chemotherapy.

1. Prescribed by, or in consultation with, an oncologist or hematologist **AND**
2. Stimufend is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving

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

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.

LAST REVISION: 1/1/23

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

STRENSIQ (ASFORASE ALFA)

Initial Criteria

- Member has been diagnosed with perinatal/infantile and/or juvenile onset hypophosphatasia (HPP) **AND**
- Prescribed by or in consultation with a geneticist, metabolic specialist, or endocrinologist **AND**
- Documentation of laboratory values of **ALL** the following:
 - Baseline serum alkaline phosphatase (ALP) activity below the age and gender adjusted normal range
 - Presence of a tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing recognized to be detrimental with this condition
 - Baseline laboratory documentation confirming elevated level of tissue nonspecific alkaline phosphatase (TNSALP) substrate (e.g. serum pyridoxal 5'- phosphate (PLP), urinary inorganic pyrophosphate (PPi), serum or urine phosphoethanolamine (PEA) without B6 or other MVI supplementation.
 - Baseline ophthalmic and renal ultrasound **AND**
- Documentation of a least **ONE** of the following characteristics prior to age 18 indicative of HPP:
 - Vitamin B6 dependent seizures
 - Respiratory insufficiency
 - Hypotonia
 - Loss of deciduous teeth before the age of four
 - Gait disturbances
 - Osteopenia, osteoporosis, or low bone mineral content for age attributable to HPP
 - Radiographic evidence of knock knees, rachitic chest, bowling of legs, osteochondral spurs, or infantile rickets. **AND**
- Documentation provided of member's current height and weight:
 - Members weighing < 40kg will not be approved for an 80mg/0.8ml vial
 - Maximum approved dosage for perinatal/infantile onset HPP is 9mg/kg/week
 - Maximum approved dosage for juvenile onset HPP is 6mg/kg/week

Reauthorization Criteria

- Documentation that member has had clinically significant improvement in bone manifestations or respiratory status with **ONE** of the following: radiographic evidence of skeletal improvement, pulmonary function tests improvement from

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baseline, and/or improvement in functional ability as evidenced by increased height, strength, growth, and motor function **AND**

- Documentation provided which supports therapy adherence **AND**
- Documentation of annual retinal exam and renal ultrasound for calcium deposition **AND**
- Documentation of current height and weight

Initial Approval: 6 months

Reauthorization: 12 months

Quantity Limits: 24 single use vials per 28 days

Dosing:

SubQ 2mg/kg 3 times per week or 1mg/kg 6 times weekly

LAST REVISION: 5/1/2022

SUNOSI (Solriamfetol)

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

- Clinically diagnosed narcolepsy confirmed via sleep study, AND
- 18 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
- 18 years of age or older

Approval Duration: 12 months

References

1. Virginia Premier Health Plan

LAST REVISION: 8/1/21

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

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- 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

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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.

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SYMDEKO (TEZACAFTOR/IVACAFTO)

Initial:

Requests for continuing 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 Cystic Fibrosis (CF); AND
- **ONE** of the following:
 - Documentation confirming patient is homozygous for the F508del mutation in the CFTR gene
 - **OR** -
 - Documentation confirming the patient has at least **one** of the following mutations in the CFTR gene that is responsive to Symdeko:

A1067T	D1270N	F1052V	R1070W	S945L	3272-26A→G
A455E	D579G	F1074L	R117C	S977F	3849+10kbC→T
D110E	E193K	K1060T	R347H		711+3A→G
D110H	E56K	L206W	R352Q		2789+5G→A
D1152H	E831X	P67L	R74W		

- 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)

Criteria

- Type 1 or Type 2 Diabetes, **AND**
- Symlin used as an adjunctive therapy with insulin, **AND**
- Patient has a history of insulin use for at least 90 days as supported by claims history or chart notes; **AND**
- Failure to achieve adequate glycemic control defined as Hgb A1C less than 6.5% (chart notes providing Hgb A1C required)

References

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SYNAGIS (PALIVIZUMAB)

Inter-seasonal approval ONLY if local virology data supplied from the NREVSS: RSV Surveillance website OR recent surveillance data from a local/regional hospital (dated within 14 days of patient's intended dose) indicates an incidence of RSV greater than or equal to 10% (percent positive total antigen detection tests greater than or equal to 10%) for that locality AND the patient meets the criteria for their chronological and/or gestational age.

Initial Criteria

- Prevention of RSV for children < **24 months** at high risk of RSV disease. RSV prophylaxis with Synagis (palivizumab) may be considered medically necessary in the following infants and children up 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)**
 - Preterm infants younger than 24 months at the start of RSV season who develop chronic lung disease (CLD) or bronchopulmonary dysplasia (BPD) defined as:

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- 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

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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 extra-corporeal 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.
 - 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.
- **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
- **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 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%).

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

- ***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.

Dosage and Administration

Synagis will be authorized according to the FDA recommended dose.

Infants and children < 24 months of age at 15mg/kg IM once monthly.

- Dosing Allowance: Synagis available in 50mg and 100mg vials. To decrease waste while still maintaining efficacy the approved dosage permitted will be within +/- 5% of the calculated dose. See dosing chart below for allowances.

Weight	Calculated Dosage (15mg/kg)	Dose allowed	Dispense
0-3.5 kg	≤ 53mg	50mg	one 50mg vial
3.6-7 kg	54 - 105 mg	100mg	one 100mg vial
7.1-10.3 kg	106.5 - 154.5mg	150mg	one 50mg vial and one 100mg vial
10.4-13.6 kg	156 - 205mg	200mg	two 100mg vials
13.7-16.93 kg	205.5 - 254mg	250mg	one 50mg vial and two 100mg vials
17-20.3 kg	255 - 305mg	300mg	three 100mg vials

Updated 1/1/2023

References

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2. American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guideline Committee. Policy Statement: updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*.2014;134(2):415-420
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6. The Virginia Department of Medical Assistance. Virginia Medicaid Synagis Service Authorization. Available from https://www.virginiamedicaidpharmacyservices.com/documents/VAMps_FaxSA_Synagis-20110913.pdf
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

SYNDROS (DRONABINOL)

NF-PA criteria; Coverage duration: 6 MONTHS FOR Chemotherapy-induced nausea and vomiting 3 MONTHS FOR Anorexia in Patients with AIDS

Chemotherapy-induced nausea and vomiting:

- Diagnosis of chemotherapy-induced nausea and vomiting; **AND**
- Individual is 18 years of age or older **AND**
- Patient is receiving cancer chemotherapy; **AND**
- Trial and failure or intolerance to formulary generic dronabinol capsules, or patient is unable to swallow capsules; **AND**
- Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]); **AND**
- Trial and failure, contraindication, or intolerance to one of the following: Ativan (lorazepam), Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Phenergan (promethazine), Reglan (metoclopramide), or Zyprexa (olanzapine)

OR

Anorexia in Patients with AIDS:

- Diagnosis of anorexia with weight loss in patients with acquired immunodeficiency syndrome (AIDS); **AND**
- Individual is 18 years of age or older **AND**
- Patient is on antiretroviral therapy; **AND**
- One of the following:
 - 1) Patient is 65 years of age or greater, **OR**
 - 2) Patient is less than 65 years of age, **AND**
 - Trial and failure, contraindication, or intolerance to Megace (megestrol); **AND**
 - Trial and failure or intolerance to formulary generic dronabinol capsules, or patient is unable to swallow capsules.

Quantity Limit of 4 bottles (120 mL) per 30 days

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**

Requests for continuing 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, intolerance, or contraindication to Euflexxa

References

1. Adams ME. An analysis of clinical studies of the use of crosslinked hyaluronan, hylan, in the treatment of osteoarthritis. *J Rheumatol*. 1993;39 (Suppl):16-18.
2. Adams ME, Atkinson MH, Lussier AJ, et al. The role of viscosupplementation with hylan G-F 20 (Synvisc) in the treatment of osteoarthritis of the knee: A Canadian multicenter trial comparing hylan G-F 20 alone, hylan G-F 20 with non-steroidal anti-inflammatory drugs (NSAIDs) and NSAIDs alone. *Osteoarthritis Cartilage*. 1995;3(4):213-225.
3. Balazs EA, Denlinger JL. Viscosupplementation: A new concept in the treatment of osteoarthritis *J Rheumatol Suppl*. 1993;39:3-9.
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5. Dougados M, Nguyen M, Listrat V, et al. High molecular weight sodium hyaluronate (hyalectin) in osteoarthritis of the knee: A 1 year placebo-controlled trial. *Osteoarthritis Cartilage*. 1993;1(2):97-103.
6. Formiguera SSE. Intra-articular hyaluronic acid in the treatment of osteoarthritis of the knee: A short-term study. *Eur J Rheumatol Inflamm*. 1995;15:33-38.
7. Graf J, Neusel E, Schneider E, et al. Intra-articular treatment with hyaluronic acid in osteoarthritis of the knee joint: A controlled clinical trial versus mucopolysaccharide polysulfuric acid ester. *Clin Exp Rheumatol*. 1993;11(4):367-372.
8. Huskisson EC, Donnelly S. Hyaluronic acid in the treatment of osteoarthritis of the knee. *Rheumatology*. 1999;38(7):602-607.
9. Kirwan JR, Rankin E. Intra-articular therapy in osteoarthritis. *Baillieres Clin Rheumatol*. 1997;11(4):769-794.
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11. Lussier A, Cividino AA, McFarlane CA, et al. Viscosupplementation with hylan for the treatment of osteoarthritis: Findings from clinical practice in Canada. *J Rheumatol*. 1996;23(9):1579-1585.
12. Synvisc. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
13. Tamir E, Robinson D, Koren R, et al. Intra-articular hyaluronan injections for the treatment osteoarthritis of the knee: a randomized, double blind, placebo controlled study. *Clin Exp Rheumatol* 2001 May-Jun; 19(3):265-70.

TABRECTA (CAPMATINIB)

Approval Duration: 1 year

1. Patient is diagnosed with Non-Small Cell Lung Cancer (NSCLC); AND
2. Patient has advanced, metastatic or recurrent disease; AND
3. Patient has confirmed mutation that leads to mesenchymal-epithelial transition exon 14 skipping, as supported by FDA-approved tests; AND
4. Patient is 18 years of age or older

TACLONEX (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

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

- 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 \geq 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 bed or chair

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

- 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 AND
- Must be 6 years of age or older AND
- Must be clinically diagnosed with moderate to severe plaque psoriasis AND
- Must be a candidate for phototherapy or systemic therapy AND
- Must have tried and failed or intolerant to at least one corticosteroid AND
- Must have tried and failed or intolerant to methotrexate (unless age inappropriate) AND
- Must have tried and failed or intolerant to Enbrel and Humira (unless age inappropriate) AND
- Must have a negative tuberculosis test or received treatment if tested positive

OR

- Diagnosis of active Psoriatic Arthritis AND
- Member is 18 years of age or older AND
- Must have tried and failed or intolerant to at least one corticosteroid AND
- Must have tried and failed or intolerant to methotrexate AND
- Must have tried and failed or intolerant to Enbrel and Humira AND
- Must have a negative tuberculosis test or received treatment if tested positive

OR

- Diagnosis of Ankylosing Spondylitis (AS) AND
- Member is 18 years of age or older; AND
- Must have tried and failed or be intolerant to conventional therapy (such as NSAIDs or non-biologic DMARDs); AND
- Must have tried and failed or intolerant to Enbrel and Humira AND

Must have a negative tuberculosis test or received treatment if tested positive

OR

- **Diagnosis of Non-Radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; AND**
- 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

- Must have tried and failed or be intolerant to conventional therapy (such as NSAIDs or non-biologic DMARDs); AND
- Must have tried and failed or intolerant to Humira; AND

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.
- 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

1. Bone Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
2. Erlotinib. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
3. Gatzemeier U, Pluzanska A, Szczesna A, et al. Results of a phase III trial of erlotinib (OSI-774) combined with cisplatin and gemcitabine (GC) chemotherapy in advanced non-small cell lung cancer (NSCLC). *Proc Am Soc Clin Oncol*. 2004; 23:617.
4. Oken M, Creech RH, et al. Toxicity and response criteria of the eastern cooperative oncology group. *Am J Clin Oncol*. 1982;5:649-655.
5. Pancreatic Adenocarcinoma. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
6. Perez-Soler R, Chachoua A, Hammond LA, et al. Determinants of tumor response and survival with erlotinib in patients with non-small cell lung cancer. *J Clin Oncol* 2004;22:3238-3247.
7. Non-Small Cell Lung Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
8. Tarceva. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

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)

References

1. Bexarotene. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
2. Duvic M, Martin AG, Kim Y, et al. Phase 2 and 3 clinical trial of oral bexarotene for the treatment of refractory or persistent early-stage cutaneous T-cell lymphoma. *Arch Dermatol*. 2001;137:581-93.
3. National Cancer Institute. Mycosis fungoides and the Sézary syndrome treatment. Available at: <http://www.cancer.gov/cancertopics/pdq/treatment/mycosisfungoides/HealthProfessional>
4. Non-Hodgkin's Lymphomas. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.

Requests for continuing 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. .Targretin. In:DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
6. Whittaker SJ, Marsden JR, Spittle M, Russell Jones R. Joint British Association of Dermatologists and U.K. Cutaneous Lymphoma Group guidelines for the management of primary cutaneous T-cell lymphomas. Br J Dermatol. 2003 Dec;149:1095-107

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)
- Electrolytes (baseline and periodic)

Requests for continuing 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 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
 - i. 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

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

- 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
 - 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

1. Chronic Myelogenous Leukemia. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
2. Nilotinib. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
3. Soft Tissue Sarcoma. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
4. Tasigna. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

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

Requests for continuing 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 at increased risk for bleeding as indicated by platelet count (within the previous 28 days) of less than $30 \times 10^9 /L$ ($30,000/mm^3$); AND
- Tavalisse is not being used to attempt to normalize platelet count.

IV. Renewal Criteria - Coverage can be renewed based upon the following criteria:

- Chronic immune (idiopathic) thrombocytopenia (ITP)
 - Patient continues to meet the criteria identified in section III; AND
 - 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

1. Tavalisse [package insert]. San Francisco, CA; Rigel Pharmaceuticals; April 2018. Accessed April 2018.
2. Neunert C, Lim W, Crowther M, et al. The American Society of Hematology 2011 evidencebased practice guideline for immune thrombocytopenia. *Blood*. 2011 Apr 21; 117(16):4190- 207. doi: 10.1182/blood-2010-08-302984. Epub 2011 Feb 16. Review.
3. Lambert MP, Gernsheimer TB. Clinical updates in adult immune thrombocytopenia. *Blood*. 2017. 129:2829-2835. doi:10.1182/blood-2017-03-754119

TAVNEOS (AVACOPAN)

Initial therapy:

1. Member must have a clinical diagnosis of severe active antineutrophil cytoplasmic autoantibody-associated vasculitis (granulomatosis with polyangiitis (GPS) or microscopic polyangiitis (MPA)); **AND**
2. Member is at least 18 years of age; **AND**
3. Prescribed by or in conjunction with a rheumatologist or nephrologist
4. The diagnosis is confirmed by prescriber attestation of BOTH of the following:
 - Positive test for either anti-PR3 or anti-MPO; **AND**
 - Patient's EGFR greater than or equal to $15 \text{ mL}/\text{min}/1.73\text{m}^2$; **AND**
5. Member does not currently require dialysis or have a kidney transplant; **AND**
6. Member has not received plasma exchange in the past 12 weeks; **AND**
7. Member is currently receiving standard therapy with cyclophosphamide or rituximab

Renewal therapy:

1. Prescriber attests that member has had clinically significant improvements or stabilization of disease with the addition of this medication; **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. Confirmation that the member continues to be on standard therapy cyclophosphamide or rituximab.

Approval Duration: 12 months initial and renewal

LAST REVISION: 5/1/22

TAZORAC (TAZAROTENE)

- Acne vulgaris, AND
 - Tried/failed/intolerance to topical tretinoin, OR
- Plaque psoriasis, AND
 - Applied to < 20% of Body Surface Area, AND
 - Tried/failed/intolerance 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

1. Callen JP et al. AAD consensus statement on psoriasis therapies. J Am Acad Dermatol 2003; 49:897-9.
2. Mason AR, Mason J, Cork M et al. Topical treatments for chronic plaque psoriasis. Cochrane Database System Review 2009; 15:CD005028.
3. Tazarotene. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat! Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
4. Tazorac. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.
5. The American Urological Association. The management of benign prostatic hyperplasia. 2003. Available from http://www.guideline.gov/summary/pdf.aspx?doc_id=3740&stat=1&string=
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

TAZVERIK (TAZEMETOSTAT)

CRITERIA FOR USE

- 1) Prescriber attests to a documented diagnosis of histologically confirmed metastatic or locally advanced epithelioid sarcoma, with INI1 loss detected using local tests
AND
- 2) Age is 16 years or older
AND
- 3) Prescribed by or in consultation with an oncologist
AND
- 4) Patient is not eligible for complete resection

Requests for continuing 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

5) Must have ECOG performance status of 0 to 2

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

Ionis Pharmaceuticals. Efficacy and Safety of Inotersen in Familial Amyloid Polyneuropathy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000

TEKTURNA (ALISKIREN)

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

- 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

TEPMETKO (TEPOTINIB)

- Confirm member has a diagnosis of metastatic non-small cell lung cancer (NSCLC); **AND**
- Member is 18 years of age or older; **AND**
- Documentation provided to support plasma or tumor specimens confirming presence of MET exon 14 skipping alterations; **AND**
- Prescribed by or in consultation with an oncologist

Authorization Duration: Initial approval: 6 months, Renewal approval: 12 months

LAST REVISION 7/1/21

TERSI (SELENIUM SULFIDE) FOAM

- PA criteria for FDA age indications.

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

- Clinically diagnosed seborrheic 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.

References

1. Virginia Premier

TESZPIRE (TEZEPELUMAB-EKKO)

APPROVAL DURATION: Initial 6 months, Renewal 12 months.

APPROVAL CRITERIA

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

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

INITIAL

4. Patient is 12 years of age or older, AND
5. Diagnosis of moderate to severe asthma, AND
6. Prescribed by, or in consultation with an allergist or pulmonologist, AND
7. 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;
5. Will not be used in combination with Dupixent, Xolair, Nucala, Cinqair or Fasenna

RENEWAL

3. Patient has experienced an improvement in symptoms (reduction in exacerbation, reduction in oral glucocorticoids, or improvement in FEV1)
4. Patient continues to tolerate 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

-OR- INITIAL

13. Diagnosis of chronic rhinosinusitis with nasal polyps, AND
14. Medication will be used as add on therapy, AND
15. Member is at least 18 years of age or older, AND
16. 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

3. Initial therapy criteria continues to be met AND
4. 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 therapy

-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)

LAST REVISION: 5/1/22

Requests for continuing 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:
 - o Alternative therapies have failed or are considered inappropriate.
 - o Understands and can reliably carry out instructions
 - o 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.
 - o Has received both oral and written warnings of the hazards of taking thalidomide during pregnancy and exposing a fetus to the drug.
 - o 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.
 - o Has a negative pregnancy test within 24 hours prior to beginning therapy.
 - o 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:
 - o Alternative therapies have failed or are considered inappropriate.
 - o Understands and can reliably carry out instructions
 - o 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.
 - o Has received both oral and written warnings of the hazards of taking thalidomide and exposing a fetus to the drug.
 - o 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.

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

- o 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:

Erytherma 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
2. Alexanian R & Weber D: Thalidomide for resistant and relapsing myeloma. Semin Hematol 2000; 37(1; suppl 3):22-25
3. Singhal S, Mehta J, Desikan R, et al: Antitumor activity of thalidomide in refractory multiple myeloma. N Engl J Med 1999; 341(21):1565-1571.

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

*** 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 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 ANTIFUNGAL AGENTS (CICLOPIROX, JUBLIA, LUZU, KERYDIN)

- The member is 18 years of age or older; AND
- The member has been diagnosed with a onychomycosis, tinea pedis (athlete's foot), or tinea cruris/tinea corporis (ringworm); AND
- For Penlac, CNL-8, or Julia: must have failure of an adequate trial of **ONE** oral alternative or allergy or contraindication to oral terbinafine, fluconazole, or itraconazole:
 - Terbinafine (6 weeks for fingernail infections; 1 week for toenail infections)
 - Fluconazole (6 months)
 - Itraconazole (60 days for fingernail infections; 90 days for toenail infections)
- For Luzu: must have failure of an adequate trial of **TWO** preferred topical antifungal medications or allergy or contraindication to oral terbinafine, fluconazole, or itraconazole.
- **Approval duration** is for 12 months for initial and 12 months for reauthorization.

References

1. Virginia Premier Health Plan

LAST REVISION: 7/1/21

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

TOPIRAGEN, TOPAMAX, TOPIRAMATE ER

- The patient has a diagnosis of:
 - Adjunct treatment for Lennox-Gastaut syndrome, 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

- 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.
- 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

1. Topiramate. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
2. Topiragen. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

TREMFYA (GUSELKUMAB)

Treatment of Plaque Psoriasis:

- Member has a diagnosis of moderate to severe plaque psoriasis for ≥ 6 months with ≥ 1 of the following;
 - Affected body surface area (BSA) of $\geq 10\%$; OR
 - Psoriasis Area and Severity Index (PASI) score ≥ 10 ; OR
 - Incapacitation due to plaque location (e.g., head and neck, palms, soles or genitalia); AND
- Member is 18 years of age or older; AND
- Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of topical agents (e.g., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues); AND
- Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of ≥ 1 systemic agent (e.g. Immunosuppressives, retinoic acid derivatives, and/or methotrexate); AND
- Member did not respond adequately (or is not a candidate) to a 3 month minimum trial of phototherapy (e.g., psoralens with UVA light (PUVA) or UVB with coal tar or dithranol); AND
- Member is not receiving Tremfya in combination with another biologic agent for psoriasis or non-biologic immunomodulator (e.g., apremilast, tofacitinib, baricitinib); AND
- Member has tried and failed Humira and Enbrel.

Approval Duration

- Initial – 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

- Renewal – 12 months

LAST REVISION: 7/1/21

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

1. Virginia Premier

TRIKAFTA (ELEXACAF TOR, TEZACAF TOR, IVACAF TOR)

Initial:

- Diagnosis of Cystic Fibrosis (CF); 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

- Documentation confirming patient has at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
- 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
- Attestation that liver function tests have been assessed prior to initiating therapy

Renewal

- Patient continues to meet criteria for initial therapy, AND
- Documentation of **one** of the following while on Trikafta therapy:
 - Improved lung function
 - Stable lung function

Authorization

- Initial – 6 months
- Renewal – 12 months

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.

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

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)

References

1. Virginia Premier

TRODELVY (SACITUZUMAB GOVITECAN)

Approval Duration: 1 year for Initial and Reauthorizations

For treatment of triple-negative breast cancer

Initial Therapy:

- Patient is diagnosed with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC); **AND**
- Patient has trialed two appropriate therapies for treatment prior to use of Trodelvy, at least one of them for metastatic disease; **AND**
- Patient has their blood counts monitored for neutropenia; **AND**
- Patient will be monitored for diarrhea; **AND**
- For Females (with reproductive potential)
 - Must be counseled to use effective contraception during treatment (including 6 months after treatment completion); **OR**
- For Males of female partners (with reproductive potential)
 - Must be counseled to use effective contraception during treatment (including 3 months after treatment completion); **AND**
- Patient is 18 years of age or older

Reauthorization

- Patient is diagnosed with metastatic triple-negative breast cancer (mTNBC); **AND**
- Prescriber will continue to monitor for neutropenia and diarrhea; **AND**
- No disease progression or unacceptable toxicity; **AND**
- Effective contraception is being followed (as outlined above) for both males (duration of therapy +3 months post-treatment) and females (duration of therapy + 6 months post-treatment)

For treatment of urothelial cancer

Initial therapy:

- Patient is diagnosed with locally advanced or metastatic urothelial cancer (mUC); **AND**
- Patient 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

- Patient has previously received a platinum-containing chemotherapy and either programmed death receptor -1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor; **AND**
- Patient has their blood counts monitored for neutropenia; **AND**
- Patient will be monitored for diarrhea; **AND**
- For Females (with reproductive potential)
 - Must be counseled to use effective contraception during treatment (including 6 months after treatment completion); **OR**
- For Males of female partners (with reproductive potential)
 - Must be counseled to use effective contraception during treatment (including 3 months after treatment completion)

Reauthorization

- Patient is diagnosed with locally advanced or metastatic urothelial cancer (mUC); **AND**
- Prescriber will continue to monitor for neutropenia and diarrhea; **AND**
- No disease progression or unacceptable toxicity; **AND**
- Effective contraception is being followed (as outlined above) for both males (duration of therapy +3 months post-treatment) and females (duration of therapy + 6 months post-treatment)

LAST REVISION: 11/1/21

TRUSELTIQ (INFIGRATINIB)

Initial Approval:

- Confirm member has a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement; **AND**
- Member is 18 years of age or older; **AND**
- FGFR2 fusion or other rearrangement is confirmed by an FDA-approved test (e.g. FoundationOne CDx); **AND**
- Member have received at least one prior systemic therapy; **AND**
- Prescribed by or in consultation with an oncologist.

Renewal Approval:

- Documentation of positive response to therapy and tolerating therapy.

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 11/1/21

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

TUKYSA (TUCATINIB)

Approval Duration: 1 year for Initial and Reauthorizations

Initial Therapy:

- Diagnosis of Advance breast cancer (unresectable); OR
- Diagnosis of Metastatic breast cancer; AND
 - Patient has already trialed one or more Anti-HER2 regimens
- AND all of the following criteria applies for both diagnoses above:
 - HER2-Positive; AND
 - To be used in combination with capecitabine and trastuzumab; AND
 - Baseline liver level monitoring to be collected and monitored through treatment (ALT, AST and bilirubin); AND
 - For Females (with reproductive potential)
 - Must be counseled to use effective contraception during treatment (including 1 week after treatment completion)
 - For Males of female partners (with reproductive potential)
 - Must be counseled to use effective contraception during treatment (including 1 week after treatment completion); AND
 - Patient is 18 years of age or older

Reauthorization:

- Patient has metastatic or advance HER2 positive breast cancer; AND
- No disease progression or unacceptable toxicity; AND
- Liver levels (AST, ALT and bilirubin are being monitored); AND

Effective contraception is being followed (as outlined above) for both males and females through 1 week post therapy

TURALIO (PEXIDARTINIB)

Initial criteria:

- Documented diagnosis of tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations
- Must not be candidate for surgery
- Must not have any active cancer
- Must be enrolled in the Turalio REMs program

Reauthorization criteria:

- Documentation of stable or improvement in tumor volume score (TVS)
- Documentation of stable or improved range of motion
- Documentation of stable or improved physical function

TYSABRI (NATALIZUMAB)

- Multiple Sclerosis, AND
 - Tried/failed/intolerance to Avonex, Betaseron, Copaxone, or Rebif, 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

- Moderate to severe Crohn's Disease, AND
 - Patient does not have perforation, abscess, or obstruction, AND
 - Tried/failed/intolerance to Humira or Remicade

References

1. Costello F, Stuve O, Weber MS, Zamvil SS, Froham E. Combination therapies for multiple sclerosis: scientific rationale, clinical trials, and clinical practice. *Curr Opin Neurol*. 2007;20:281-285.
2. Fernandez O. Combination therapy in multiple sclerosis. *J Neurologic Sci*. 2007;259:95-103.
3. Ghosh S, Goldin E, Gordon FH, et al. Natalizumab Pan-European Study Group. Natalizumab for active Crohn's disease. *N Engl J Med*. 2003;348(1):24-32.
4. Ghosh S, Goldin E, Gordon FH, et al. Natalizumab for active Crohns disease. *N Engl J Med*. 2003;348(1):24-32.
5. Goodin DS, et al. Disease modifying therapies in multiple sclerosis. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002;58:169-178.
6. Goodin DS, Frohman EM, Hurwitz B, et al. Neutralizing antibodies to interferon beta: assessment of their clinical and radiographic impact: an evidence report. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2007;68:977-984.
7. Gordon FH, Lai CWY, Hamilton MI, et al. A randomized placebo-controlled trial of a humanized monoclonal antibody to a4 integrin in active Crohns disease. *Gastroenterology*. 2001;121:268-274.
8. Hyams JS, Wilson DC, Thomas A, et al. International Natalizumab CD305 Trial Group. Natalizumab therapy for moderate to severe Crohn disease in adolescents. *J Ped Gastroenterol & Nutrition*. 2007;44(2):185-191.
9. Keeley KA, Rivey MP, Allington DR. Natalizumab for the treatment of multiple sclerosis and Crohn's disease. *Ann Pharmacother*. 2005;39(11):1833-1843.
10. MacDonald JK, McDonald JW. Natalizumab for induction of remission in Crohn's disease.[update of Cochrane Database Syst Rev. 2006;3:CD006097; PMID: 16856112]. *Cochrane Database of Systematic Reviews*. (1):CD006097, 2007.
11. Montalban X. MS treatment: postmarketing studies. *J Neurologic Sci*. 2007;259:42-45.
12. Natalizumab. In: G.K. McEvoy et al. (Eds.), *American Hospital Formulary Service Drug Information*. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
13. Ransohoff RM. Natalizumab for multiple sclerosis. *N Engl J Med*. 2007;356:2622-2629.
14. Sands BE, Kozarek R, Spainhour J, et al. Safety and tolerability of concurrent natalizumab treatment for patients with Crohn's disease not in remission while receiving infliximab. *Inflam Bowel Dis*. 2007;13(1):2-11.
15. Sandborn WJ, Colombel JF, Enns R, et al. International Efficacy of Natalizumab as Active Crohn's Therapy (ENACT-1) Trial Group. Evaluation of Natalizumab as Continuous Therapy (ENACT-2) Trial Group. Natalizumab induction and maintenance therapy for Crohn's disease *N Engl J Med*. 2005;353(18):1912-1925.
16. Targan SR, Feagan BG, Fedorak RN, et al. International Efficacy of Natalizumab in Crohn's Disease Response and Remission (ENCORE) Trial Group. Natalizumab for the treatment of active Crohn's disease: results of the ENCORE Trial. *Gastroenterol*. 2007;132(5):1672-1683.
17. Tysabri. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

TYVASO AND TYVASO DPI (TREPROSTINIL)

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

- Clinically diagnosed with one of the following:
 - Pulmonary arterial hypertension WHO Group 1. **OR**
 - Pulmonary hypertension associated with interstitial lung disease (WHO Group 3).

Requests for continuing 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
 - For patients with PAH (WHO Group 1), confirm patient has NYHA class III symptoms; AND
 - Prescribed by a pulmonologist or cardiologist; AND
 - Patient is not smoking cigarettes; AND
 - Must have tried and failed a calcium channel blocker if they have a positive vasoreactivity test; AND
 - Must have tried and failed sildenafil; AND
 - Must have tried and failed either bosentan or ambrisentan; AND
 - 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; AND
 - By 12 weeks the patient must show an increase in exercise ability, demonstrated by a 20 meter improvement in 6 minute walking distance

LAST REVISION: 10/1/22

References:

- 1.) Tyvaso [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp.; April 2013

**UKONIQ
(UMBRALISIB)**

Treatment of relapsed or refractory marginal zone lymphoma (MZL)

- Confirm member has a diagnosis of relapsed or refractory marginal zone lymphoma; **AND**
- Member is 18 years of age or older; **AND**
- Member has received at least one prior anti-CD20-based regimen; **AND**
- Prescribed by or in consultation with an

oncologist Treatment of relapsed or refractory follicular lymphoma (FL)

- Confirm member has a diagnosis of relapsed or refractory follicular lymphoma; **AND**
- Member is 18 years of age or older; **AND**
- Member has received at least three prior lines of systemic therapy; **AND**
- Prescribed by or in consultation with an oncologist

Authorization Duration: Initial approval: 6 months, Renewal approval: 12 months

LAST REVISION: 7/1/21

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

ULTOMIRIS (RAVULIZUMAB-CWVZ)

CRITERIA FOR USE

- 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 2 months 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 meningitidis infection
AND
- Patient has tried/failed or intolerant to Soliris

PA CRITERIA FROM THE PLAN: **ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS):**

- A diagnosis of atypical hemolytic uremic syndrome (aHUS) based on clinical presentation of microangiopathic hemolytic anemia, thrombocytopenia, and acute kidney injury, and presentation of complement dysregulation **AND**
- Patient must be vaccinated against meningococcal infection (at least 2 weeks prior to treatment, if not previously vaccinated)
- The patient must be 2 months or older **AND**
- The requested medication must be prescribed by or in consultation with a hematologist, oncologist, immunologist or genetic specialist **AND**
- Patient has tried/failed or intolerant to Soliris

- For renewal: Prescriber attests that patient continues to meet initial criteria **AND**
- Prescriber attests that patient has had disease improvement or stabilization since using the medication.
-

PA CRITERIA FROM THE PLAN: **GENERALIZED MYASTHENIA GRAVIS (gMG):**

- Prescriber attests to a diagnosis of generalized myasthenia gravis (gMG) **AND**
- Prescriber attests that patient has a MG-activities of daily living (MG-ADL) total score of greater than 6 **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

- Prescriber attests that patient has had positive serologic test for anti-ACR antibodies **AND**
- One of the following:
 - 1) Prescriber attests that patient has failed treatment over 1 year or more with 2 or more immunosuppressive therapies either in combination or as monotherapy **OR**
 - 2) Prescriber attests that patient has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIg) **AND**
- Patient must be vaccinated against meningococcal infection (at least 2 weeks prior to treatment, if not previously vaccinated) **AND**
- The patient must be 18 years of age or older **AND**
- The requested medication must be prescribed by or in consultation with a hematologist, oncologist, immunologist or genetic specialist **AND**
- Patient has tried/failed or intolerant to Soliris

- For renewal: Prescriber attests that patient continues to meet initial criteria **AND** Prescriber attests that patient has had disease improvement or stabilization since using the medication.

LAST REVISION: 10/01/22

UPLIZNA (INEBILIZUMAB)

Approval Duration: Initial: 6 months; Renewal: 1 year

Initial Therapy:

- Patient is diagnosed with Neuromyelitis Optica Spectrum Disorder (NMOSD); **AND**
- Diagnosis of NMOSD was confirmed via blood serum test for positive anti-aquaporin-4 antibody; **AND**
- Patient has been evaluated for hepatitis B virus (HBV) and tuberculosis (TB) and is negative for active HBV and TB prior to therapy start; **AND**
- Prescriber attestation that member is not concomitantly receiving therapy with other immunosuppressant type drugs; **AND**
- Prescriber attestation that member will not be using in combination with complement-inhibitor (i.e., eculizumab, ravulizumab) or anti-CD20-directed antibody (i.e., rituximab) therapies; **AND**
- Patient has a history of one or more relapses that required rescue therapy within the year prior to screening **OR** 2 or more relapses that required rescue therapy in the 2 years prior to screening; **AND**
- Patient has an Expanded Disability Status Score (EDSS) of ≤ 8 ; **AND**
- Documentation of baseline relapse rate and visual acuity

Reauthorization:

Requests for continuing 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 diagnosed with Neuromyelitis Optica Spectrum Disorder (NMOSD); AND
- Patient has not experienced any unacceptable toxicity; AND
- Disease response classified as stabilized or improved as defined by at least one of the following:
 - Neurological symptom improvement
 - Decrease in acute relapses
 - Stability or improvement of EDSS score
 - Reduced hospitalizations
 - Reduction in plasma exchange treatments

LAST REVISION: 7/1/22

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.
- **For IV formulation only:** Documentation provided which states patient is unable to utilize oral formulation and IV is being used to decrease treatment disruption for short term.

References

1. Sitbon O, Channick R, Chin KM, et al: Selexipag for the treatment of pulmonary arterial hypertension. N Engl J Med 2015; 373(26):2522-2533.
2. Product Information: UPTRAVI(R) oral tablets, selexipag oral tablets. Actelion Pharmaceuticals US, Inc. (per manufacturer), South San Francisco, CA, 2015.

LAST REVISION: 1/1/22

ULESFIA, XEGLYZE, OVIDE & LINDANE

Indications:

- **Lindane (shampoo):** Treatment of head lice (*Pediculus humanus capitis*), crab lice (*Phthirus 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.**
- **Xeglyze** Indicated for the topical treatment of head lice in those 6 months 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

- **Ovide (lotion):** Indicated for patients infested with *Pediculus humanus capitus* (head lice and their ova) of the scalp hair in **patients \geq 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).
 - **AND**
 - 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.

VASCEPA (ICOSAPENT ETHYL), LOVAZA (OMEGA-3-ACID ETHYL ESTERS)

Criteria for Use:

- Medically accepted indication provided for use; AND
- Member must be greater than or equal to 18 years of age; AND
- Member must meet one of the following:
 - Member has tried and failed any other formulary lipotropic medication (i.e. statin, fibric acid, cholestyramine, ezetimibe, gemfibrozil, niacin, etc) OR
 - Member has a documented triglyceride level of greater than or equal to 500 mg/dL

VENTAVIS (ILOPROST)

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

- 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:

1. Ventavis [prescribing information]. South San Francisco, Ca: Actellion Pharmaceuticals US, Inc.; March 2015

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

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

VERKAZIA (CYCLOSPORINE)

- Diagnosed with a medically accepted indication; AND
- Trial and failure of cromolyn 4% ophthalmic solution.

LAST REVISION: 11/1/21

VERQUVO (VERICIGUAT)

- Confirm member has a diagnosis of chronic heart failure (HF) of NYHA class II – IV; **AND**
- Member is 18 years of age or older; **AND**
- Member has previous HF hospitalization within 6 months or outpatient IV diuretic treatment for HF within 3 months; **AND**
- LVEF is less than 45%; **AND**
- Member had a trial of or contraindication to **ONE** agent from **EACH** of the following classes:
 - ACEi/ARB/Entresto
 - Beta-blocker (bisoprolol, carvedilol, metoprolol)
 - Aldosterone antagonists (spironolactone or eplerenone); **AND**
- Prescribed by or in consultation with a cardiologist

Authorization Duration

12 months

LAST REVISION: 7/1/21

VERZENIO (ABEMACICLIB)

- Patient is taking Verzenio in one of the following indications:
 - 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
 - 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
 - in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women and men with HR-positive, HER2-negative advanced or metastatic breast cancer
 - in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score less than or equal to 20% as determined by an FDA approved test
- Prescribed by an oncologist

Requests for continuing 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
- If patient is a female of child-bearing age, member is **NOT** pregnant or breast feeding

Authorization Dates:

- 12 months

LAST REVISION: 5/1/22

VFEND (VORICONAZOLE)

- 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.
 - 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.

Requests for continuing 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 has any contraindications to the use of voriconazole.
- The patient does not meet the above stated guidelines for approval.

References

1. Virginia Premier

VIBERZI (ELUXADOLINE)

- 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 (desipramine, 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
- Sphincter of Oddi dysfunction
- Alcoholism
- History of Pancreatitis
- Severe Hepatic Impairment
- History of severe constipation or mechanical GI obstruction

References

1. Viberzi (eluxadoline) package insert. Cincinnati, OH: Forest Laboratories, LLC.; 2015 May.

VIIBRYD (VILAZODONE HYDROCHLORIDE)

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

- 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
 - 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

VIJOICE (ALPELISIB)

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

INITIAL:

- Clinically diagnosed with PIK3CA Related Overgrowth Spectrum (PROS); **AND**
- Member is 2 years of age or older; **AND**
- Prescribed by or in conjunction with a geneticist, pediatrician, or surgeon; **AND**
- Patient has at least one target lesion identified on imaging; **AND**
- Documented evidence of a mutation in the PIK3CA gene; **AND**
- The condition is severe or life-threatening and treatment is deemed necessary as determined by the treating physician.

RENEWAL:

- Prescriber attests to lesion stabilization or improvement defined by one of the following:
 - Reductions in lesion volume; OR
 - No new lesions.

Initial approval: 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

LAST REVISION: 10/1/22

References:

1. Vioice (alpelisib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2022.
2. Keppler-Noreuil, K. M., Rios, J. J., Parker, V. E., Semple, R. K., Lindhurst, M. J., Sapp, J. C., Alomari, A., Ezaki, M., Dobyns, W., & Biesecker, L. G. (2015). PIK3CA-related overgrowth spectrum (PROS): diagnostic and testing eligibility criteria, differential diagnosis, and evaluation. *American journal of medical genetics. Part A*, 167A(2), 287–295. <https://doi.org/10.1002/ajmg.a.36836>
3. Retrospective Chart Review Study of Patients With PIK3CA-Related Overgrowth Spectrum Who Have Received Alpelisib- Full Text View – ClinicalTrials.gov. (n.d.). Retrieved June, 10 2022, from <https://clinicaltrials.gov/ct2/show/NCT04285723>

VIMOVO (NAPROXEN/ESOMEPRAZOLE)

- 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

1. Virginia Premier

VIVJOA (OTESECONAZOLE)

- Member has a diagnosis of vulvovaginal candidiasis (RVVC); **AND**
- Member is **NOT** of reproductive potential; **AND**
- Member has tried and failed oral fluconazole.

Approval: 3 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

Please note Quantity Limits Apply: 18 capsules per 365 days

LAST REVISION: 10/1/22

VONJO (PACRITINIB)

- Diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis; **AND**
- Member is 18 years of age or older; **AND**
- Member has a platelet count below $50 \times 10^9/L$

Authorization: 12 months

LAST REVISION: 8/1/2022

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.

Requests for continuing 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 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

VOXZOGO (VOSORITIDE)

Initial therapy:

1. Member has a diagnosis of achondroplasia confirmed through genetic testing; **AND**
2. Member is greater than or equal to 5 years of age; **AND**
3. Documentation of recent annualized growth velocity (AGV) has been submitted; **AND**
4. There has been recent documentation showing that the member has open epiphyses and a current AGV of less than 1.5 centimeters per year; **AND**
5. Member has not received previous treatment with growth hormone, insulin-like growth factor 1, or anabolic steroids in the 6 months prior to request; **AND**
6. Member does not have planned or expected limb-lengthening surgery; **AND**
7. Prescribed by or in conjunction with an endocrinologist, neurologist, orthopedist, or other specialist for this disease.

Renewal therapy:

1. Documentation of an increase in AGV; **AND**
2. Recent documentation showing that the member has open epiphyses.

Approval Duration: 6 months for initial, 12 months for renewal

LAST REVISION: 5/1/22

VRAYLAR (CARIPRAZINE)

Requests for continuing 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 Schizophrenia or Bipolar 1 Disorder (Depressed, Manic or Mixed); **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

VTAMA (TAPINAROF)

1. Must be at least 18 years of old or older AND
2. Must have a diagnosis of mild to moderate plaque psoriasis AND
3. Prior documented trial and failure of 8 weeks for each trial (or contraindication of):
 - a. One (1) topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) AND
 - b. Tacrolimus; AND

Authorization Duration:

Initial approval: 12 months

Renewal approval: 12 months

LAST REVISION: 10/1/22

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

WAKIX (PITOLISANT)

- Diagnosis of Excessive daytime sleepiness (EDS) with Narcolepsy
- Patient must be 18 years old
- Patient must meet one of the following criteria
 - There are no conditions contributing to or worsening symptoms of narcolepsy OR
 - Other conditions contributing to or worsening excessive daytime sleepiness have been addressed and treated
- Must be prescribed by or in consultation with a sleep disorder specialist, psychiatrist or neurologist
- Patient must have tried and failed a trial of generic armodafinil or modafinil, unless the patient has a contraindication to use armodafinil or modafinil OR

- Diagnosis of narcolepsy as demonstrated by cataplexy; AND
- Patient must be 18 years old; AND
- Must be prescribed by or in consultation with a sleep disorder specialist, psychiatrist or neurologist; AND
- The patient has tried TWO of the following: venlafaxine, fluoxetine or a TCA (e.g. clomipramine, imipramine)

Length of Authorization: 1 year

WEIGHT LOSS

PREFERRED AGENTS	NON-PREFERRED AGENTS
Contrave Qsymia Saxenda Xenical Wegovy	Imcivree

Initial Criteria

- BMI \geq 30, if no applicable risk factors **OR**
- BMI \geq 27 with two or more of the following risk factors
 - Coronary heart disease **OR**
 - Dyslipidemia **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

- Hypertension **OR**
- Sleep apnea **OR**
- Type II Diabetes **OR**
- BMI ≥ 30 or $\geq 95^{\text{th}}$ percentile on pediatric growth chart (**Imcivree**) **OR**
- Body weight above 60kg and an initial BMI corresponding to 30kg/m² for adults by international cut-offs (**Saxenda** in pediatric patients 12 years of age and older) **AND**
- Member is 16 years or older **OR**
- **Saxenda** covered for 12 years and older **OR**
- **Imcivree** covered for 6 years and older **OR**
- **Wegovy** covered for 18 years and older **AND**
- None of the following:
 - Contraindications to usage
 - Malabsorption syndromes, cholestasis, pregnancy, and/or lactation
 - History of eating disorder **AND**
- Member has previous failure of weight loss treatment plan (ie. nutritional counseling, exercise regimen and a calorie/fat restricted diet) in the past 6 months and will continue to follow as part of the treatment plan **OR**
- **For Imcivree:**
 - Prescribed by or in consultation with an endocrinologist or geneticist **AND**
 - Member has proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1) or leptin receptor (LEPR) deficiency as confirmed by a genetic test **AND**
 - Member's genetic variants are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)

Documentation for Consideration:

- Current medical status including nutritional or dietetic assessment
- Current therapy for all medical conditions, identifying specific treatments including medications
- Current accurate height and weight
- Current weight loss program including diet and exercise plan
- **For Xenical:** No medical contraindications for utilizing a reversible lipase inhibitor
- **For Contrave:** No concurrent chronic opioid utilization
- **For Saxenda/Wegovy:** No concurrent utilization of Victoza, Ozempic, or other GLP-1 inhibitors

Renewal Criteria:

- **Benzphetamine, diethylpropion, phendimetrazine, phentermine** – If the member achieves at least a 10 lb. weight loss during the initial 3 months of therapy, an additional 3-month SA may be granted. Maximum length of continuous drug therapy is 6 months (waiting period of 6 months before next request).

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

- **Qsymia®** – If the member achieves a weight loss of at least 3% of baseline weight, an additional 3-month SA may be granted. For a subsequent renewal, member must meet a weight loss of at least 5% of baseline weight to qualify for an additional 6-month SA. Maximum length of continuous drug therapy is 12 months (waiting period of 6 months before next request).
- **Alli®/Xenical®** – If the member achieves at least a 10 lb. weight loss, an additional 6-month SA may be granted. Maximum length of continuous drug therapy is 24 months (waiting period of 6 months before next request).
- **Contrave®** – Approve for 6 months with each renewal if weight reduction continues.
- **Saxenda®** – If the member achieves a weight loss of at least 4% of baseline weight, an additional 6-month SA may be granted if weight reduction continues.
- **Imcivree™** – If the member has experienced $\geq 5\%$ reduction in body weight (or $\geq 5\%$ of baseline BMI in those with continued growth potential), an additional 1 year SA may be granted.
- **Wegovy™** - **If the member achieves a weight loss of at least 5% of baseline weight, an additional 6 month SA may be granted.**

Renewal requests will NOT be authorized if members BMI < 24.

Length of Authorization:

Initial request: Varies (drug specific)

- Benzphetamine, diethylpropion, phendimetrazine, phentermine, Qsymia, Contrave®, – **3 months**
- Wegovy™- **6 months**
- Alli®/Xenical® – **6 months**
- Saxenda® and Imcivree™ – **4 months**

WELIREG (BELZUTIFAN)

Initial Approval:

- Confirm member has a diagnosis of Von Hippel-Lindau disease confirmed by germline VHL alternation and require therapy for one of the following conditions; AND
 - Associated renal cell carcinoma
 - Associated pancreatic neuroendocrine tumor
 - Associated CNS hemangioblastoma
- Member is 18 years of age or older; AND;
- Member is not eligible for immediate surgery; AND
- Prescribed by or in consultation with an oncologist.

Renewal Approval:

- Documentation of response to therapy and tolerating 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

Authorization Duration:

Initial approval: 6 months

Renewal approval: 12 months

LAST REVISION: 1/1/22

WINLEVI (CLASCOTERONE)**Initial**

1. Patient must be 12 years of age or older; **AND**
2. Patient must be clinically diagnosed with acne vulgaris; **AND**
3. Must be prescribed by a dermatologist; **AND**
4. Must have tried and failed at least two other topical antimicrobial agents alone or in combination with benzoyl peroxide; **AND**
5. Must have tried and failed tretinoin cream or gel.

XATMEP (METHOTREXATE)

- Dosing will not allow the use of preferred methotrexate tablets; OR
 - Patient is unable to swallow methotrexate tablets

Approval Duration

- Initial – 12 months
- Renewal – 12 months

LAST REVISION: 4/7/22

XCOPRI (CENOBAMATE)**Initial**

1. Patient has a documented diagnosis of partial onset seizures with baseline seizure frequency AND
2. Patient is 18 years of age or older AND
3. Prescriber must be a neurologist or prescriber is consulting with a neurologist AND
4. Documentation that the patient does not have Familial Short QT syndrome AND
5. Documented trial of at least 2 other antiepileptic drugs titrated to an appropriate maintenance dose or documented failure of at least 2 other antiepileptic drugs due to intolerable adverse effects AND
6. Dose does not exceed 400 mg per day

Reauthorization

1. Documentation from prescriber noting an improvement or stability of seizure frequency AND
2. Patient is tolerating current therapy OR
3. Prescriber attestation for new plan members that the patient is continuing 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

XELJANZ (TOFACITINIB)

Treatment of Rheumatoid Arthritis (RA):

- Member has a diagnosis of moderate to severe active RA; **AND**
- Member is 18 years of age or older; **AND**
- Member has trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline); **AND**
- Member has tried and failed Humira and Enbrel.

Treatment of Psoriatic Arthritis:

- Member has a diagnosis of psoriatic arthritis; **AND**
- Member is 18 years of age or older; **AND**
- Member has trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline); **AND**
- Member has tried and failed Humira and Enbrel.

Treatment of Ulcerative Colitis:

- Member has a diagnosis of moderately to severely active ulcerative colitis; **AND**
- Member is 18 years of age or older; **AND**
- Member has tried and failed Humira and Enbrel.

Treatment of Polyarticular course juvenile idiopathic arthritis:

- Member has a diagnosis of active polyarticular course juvenile idiopathic arthritis; **AND**
- Member is 2 years of age or older; **AND**
- Member has tried and failed Humira and Enbrel.

Treatment of Ankylosing Spondylitis:

- Member has a diagnosis of active ankylosing spondylitis; **AND**
- Member is 18 years of age or older; **AND**
- Member has tried and failed Humira and Enbrel.

Approval Duration

- Initial – 12 months
- Renewal – 12 months

Quantity Limit Alert:

- Xeljanz 5 mg tablets: 2 tablets per day, quantities above 60/30 require a quantity limit review.
- Xeljanz 10 mg tablets: 1 tablet per day, quantities above 30/30 require a quantity limit review.
- Xeljanz XR 11 mg tablets: 1 tablet per day, quantities above 30/30 require a quantity limit review.
- Xeljanz XR 22 mg tablets: 1 tablet per day, quantities above 30/30 require a quantity limit review.

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

- Xeljanz Oral Solution: 10 mg per day, quantities above 300 mL/30 require a quantity limit review.

LAST REVISION: 5/1/22

XELODA (CAPECITABINE)

- 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

1. Breast Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
2. Capecitabine In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
3. Colon Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
4. Gastric Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
5. Hepatobiliary Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
6. Pancreatic Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
7. Rectal Cancer. In: National Comprehensive Cancer Network (NCCN) Practice Guidelines in Oncology. The National Comprehensive Cancer Network. Fort Washington, PA. Updated periodically. Available from <http://nccn.org>.
8. Xeloda. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

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

XENLETA (LEFAMULIN ACETATE)

- Diagnosis of community-acquired bacterial pneumonia (CABP) in adults AND
 - If being used for outpatient oral use:
 - Is being used as a continuation of therapy that was initiated in the hospital by an infectious disease specialist OR
 - Is being initiated in the outpatient setting AND
 - Prescribed by or in consultation with an infectious disease specialist AND
 - Confirmed diagnosis of CABP via chest radiograph
 - Documentation of whether therapy is intended to be empiric or directed by culture and sensitivity results
 - If empiric therapy, documentation required noting reason why empiric therapy is required (severity of infection, potential resistant pathogens, patient characteristics justifying use)
 - Trial and inadequate response or intolerance to one alternative antibiotic to which organism is susceptible such as moxifloxacin, levofloxacin, beta-lactam + macrolide, beta-lactam + doxycycline if applicable

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 specialist for the indication provided AND
- Must have at least one of the following conditions:
 - Cervical dystonia, AND
 - Patient is 18 years of age or older; AND
 - Trial and failure of Botox; **OR**
 - Upper limb spasticity, AND
 - Patient is 2 years of age or older; AND
 - Patient has diagnosis of upper limb spasticity
 - Excluding spasticity caused by cerebral palsy for patients 2 to 17 years of age; AND
 - Trial and failure of Botox; **OR**
 - Chronic Sialorrhea, AND
 - Patient is 2 years of age or older;
 - Trial and failure of anticholinergic medication is required; **OR**
 - Blepharospasm, AND
 - Patient is 18 years of age
 - Trial and failure of Botox;

Requests for continuing 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 contraindications:**
 - Pregnancy, OR
 - Sensitivity or allergic reaction to other botulinum toxins, OR
 - Contraindications to the use of dapson, AND
- Not being used used for treatment of glabellar rhytids, AND

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: 50unit and 100unit 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.
 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)

Requests for continuing 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. 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 (Duputyren'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.**

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

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

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 (desipramine, 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

QUANTITY LIMITS

Medication	Strength	Quantity Limits
Xifaxan (rifaximin)	200mg tablets	9 tabs/30 days
Xifaxan (rifaximin)	550mg tablets	60 tabs/30 days
Xifaxan (rifaximin)	550 mg tablet	42 tabs/14 days

APPROVAL DURATION

Diagnosis	Strength	Approval Duration
Hepatic Encephalopathy	550mg tablets	1 Year
Travelers' Diarrhea	200mg tablets	1 Time Only
IBS-D	550mg tablets	14 days

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.
- E. coli is not suspected as the causative pathogen.

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

- 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:
 - Long-acting beta agonist
 - Long-acting muscarinic antagonist
 - Leukotriene modifier
 - Theophylline

AND

- Member exhibits any one (1) of the following signs of poor asthma control
 - Daily use of short-acting inhaled beta2-agonists; OR
 - Diurnal variation in peak expiratory flow (PEF) of greater than 30 %; OR
 - Forced expiratory volume in 1 second (FEV1) less than 60 % predicted; OR
 - PEF less than 80 % of personal best; OR
 - 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:
 - Decreased utilization of rescue medications,

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

- Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids),
- 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.

OR

- Xolair Is being utilized as an add-on maintenance treatment of nasal polyps; 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 is 18 years or older; AND
- Member has tried/failed/intolerance to nasal corticosteroids

Authorization: 12 months

References

1. Buhl R, Soler M, Matz J, et al. Omalizumab provides long-term control in patients with moderate-to-severe allergic asthma. *Eur Respir J* 2002;20:73-78.
2. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. *J Allergy Clin Immunol* 2001;108:184-90.
3. Soler M, Matz J, Townley R. The anti-IgE omalizumab reduces exacerbations and steroid requirement in allergic asthmatics. *Eur Respir J* 2001;18:254-261.
4. National Heart, Lung and Blood Institute, National Asthma Education and Prevention Program:Expert Panel Report 3. Guidelines for the Diagnosis and Management of Asthma. Available from <http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf>.
5. Omalizumab. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
6. Xolair. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

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 prostate cancer, AND
 - ECOG performance status ≤ 2, AND
 - Prostate-specific antigen (PSA) level obtained at time of treatment initiation

Criteria for continuation of therapy:

- PSA level measured at least every 3-6 months, 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
- **Authorization period**
 - Initial – 3 months**
 - Reauthorization – 6 months**
- **Caution:**
 - Seizures
- **Contraindication:**
 - Pregnancy
- **Not approved if:**
 - Does not meet above criteria, OR
 - Has any contraindications to treatment with enzalutamide
- **Special 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

- 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.

Last updated: 6/1/2021

References

1. Virginia Premier

XYREM (SODIUM OXYBATE) and XYWAV (CA,MG,K and SODIUM OXYBATES)

For the treatment of narcolepsy with or without cataplexy:

- Patient must be clinically diagnosed with narcolepsy and have cataplexy or excessive daytime sleepiness or hypersomnia (Xywav only) that is substantial enough to warrant treatment
- For cataplexy, must have tried and failed/intolerant to tricyclic antidepressants or SSRIs
- For excessive daytime sleepiness or hypersomnia, must have tried and failed/intolerant to at least one formulary/preferred stimulant treatment, such as methylphenidate or dextroamphetamine.
- Must be older than 7. (Safety and effectiveness not established in children under 7.)
- 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 or Xywav
- 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.

Requests for continuing 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

LAST REVISION: 1/1/22

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 TRIPTANS: 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

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:

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

Special considerations:

- Zecuity is a single-use transdermal patch composed of a battery operated iontophoretic 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.

Requests for continuing 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. Zecuity. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex.

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

2. Virginia Premier

ZEMPLAR (PARICALCITOL)

- 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 than 180 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

Requests for continuing 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. Goodman WG, et al. Parathyroid hormone (PTH), PTH-derived peptides, and new PTH assays in renal osteodystrophy. *Kidney Int.* 2003; 63:1-11.
2. National Kidney Foundation: K/DOQI clinical practice guidelines: bone metabolism and disease in chronic kidney disease. *American Journal of Kidney Disease.* 2003;42(4 Suppl 3):S1-201.
3. Paricalcitol. In: G.K. McEvoy et al. (Eds.), *American Hospital Formulary Service Drug Information.* Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
4. Zemplar. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

ZEPOSIA (OZANIMOD)

CRITERIA FOR USE

- 1) Individual has a diagnosis of relapsing multiple sclerosis (RMS), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease; **AND**
- 2) The member has had greater than or equal to 1 relapse within the previous 2 years; **AND**
The member had a baseline MRI before initiating the first treatment course (within 3 months prior to start of therapy); **AND**
- 3) Age is 18 years or older; **AND**
- 4) Zeposia is being used as a single-agent therapy; **AND**
- 5) Failure of or intolerance to TWO of the following preferred MS therapies
 - a) Copaxone
 - b) Glatiramer
 - c) Avonex
 - d) Betaseron
 - e) Rebif**AND**
- 6) The member has been tested for antibodies to varicella zoster virus (VZV) or received immunization for VZV four weeks prior to beginning therapy; **AND**
- 7) The member has been screened for the presence of tuberculosis according to local guidelines; **AND**
- 8) The member has been evaluated and screened for the presence of hepatitis B and hepatitis C (HBV/HCV) prior to initiating treatment; **AND**
- 9) The prescriber attests the member has obtained a baseline electrocardiogram (ECG); **AND**
- 10) The prescriber attests the member has had a baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- 11) The prescriber attests the member does NOT have any of the following:
 - a) Recent Myocardial Infarction
 - b) Unstable Angina
 - c) Stroke
 - d) Transient Ischemic Attack
 - e) Decompensated Heart Failure with Hospitalization
 - f) Class III/IV Heart Failure within the Previous 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

- g) Prolonged QTc Interval at Baseline (> 500 msec)
- h) History of Mobitz Type II second or third-degree atrioventricular block or sick sinus
- i) syndrome (unless treated with a functioning pacemaker)

AND

12) The prescriber attests that Zeposia will NOT be used in combination with any of the following:

- a) Will NOT be initiating therapy after previous treatment with alemtuzumab
- b) Monoamine oxidase inhibitor (MAOI; e.g., selegiline, phenelzine, linezolid);
- c) Drugs known to prolong the QT-interval (e.g., fluoroquinolone or macrolide antibiotics, venlafaxine, fluoxetine, quetiapine, ziprasidone, sumatriptan, zolmitriptan); OR
- d) Strong cytochrome p450 2C8 (CYP2C8) inhibitors (e.g., gemfibrozil) or inducers (e.g., rifampin); OR
- e) BCRP inhibitors (e.g., cyclosporine, eltrombopag); OR
- f) Adrenergic or serotonergic drugs which can increase norepinephrine or serotonin (e.g., opioids, selective serotonin reuptake inhibitors [SSRIs], selective norepinephrine reuptake inhibitors [SNRIs], tricyclics, tyramine); OR
- g) Foods with large amounts of tyramine (e.g., > 150 mg), such as aged cheeses, cured meats, craft/unfiltered beers, beans); OR
- h) Other antineoplastic, immunosuppressive or immunomodulating drugs (Note: if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects); AND
- i) Patient will NOT receive live vaccines during and at least 4 weeks prior to and 12 weeks after treatment; AND
- j) Patient does NOT have an active infection, including clinically important localized infections

Treatment of Ulcerative Colitis

1) Confirm member has a diagnosis of moderately to severe active ulcerative colitis

AND

- 2) Member has trial and failure of a compliant regimen of oral corticosteroids unless contraindicated or intravenous corticosteroids (severe UC or failure to respond to oral corticosteroids), **AND**
- 3) Member has trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months, **AND**
- 4) Member has trial and failure of a compliant regimen of parenteral methotrexate for three consecutive months, **AND**
- 5) Member has trial and failure of Humira

Approval duration:

- Initial approval: 12 months
- Renewal approval: 12 months

LAST REVISION: 11/1/21

ZEPZELCA (LURBINECTEDIN)

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

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

Initial Therapy:

- Patient is diagnosed with metastatic Small Cell Lung Cancer; AND
- Patient has previously experienced disease progression on or after platinum-based chemotherapy; AND
- Zepzelca is being used as single agent therapy; AND
- Patient is 18 years of age or older

Reauthorization:

- Patient is diagnosed with metastatic Small Cell Lung Cancer; AND
- Patient has experienced disease response as defined by stabilization or disease or decrease in tumor size or spread; AND
- Patient has not experienced any unacceptable toxicity

ZOKINVY (IONAFARNIB)

- Member must be 12 month of age or older with a body surface areas greater than 0.39 m²; AND
- The members diagnosis has been genetically confirmed;

AND

- Utilized to reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome; OR
- Treatment of processing-deficient Progeroid Laminopathies with either of the following:
 - Heterozygous LMNA mutation with progerin-like protein accumulation
 - Homo zygous or compound herterozygous ZMPSTE24 mutations

Authorization Dates:

12 months

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,

Requests for continuing 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 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%.

-Zolinza will be made accessible to patients through Mercks Accessing Coverage Today (ACT) program. 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

Requests for continuing 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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2. Mycosis Fungoides and the Sezary Syndrome Treatment. National Cancer Institute. <http://www.cancer.gov/cancertopics/pdq/treatment/mycosisfungoides/HealthProfessional>.
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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 zoledronic 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

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

- 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 zoledronic acid, OR
- Hypercalcemia of malignancy
 - Tried/failed/intolerance to generic zoledronic acid

References

1. American College of Rheumatology. Recommendations for the prevention and treatment of glucocorticoid-induced osteoporosis. *Arthritis and Rheumatism*. 2001;44(7):1496-1503.
2. Gennari L, Bilezikian JP. Glucocorticoid-induced osteoporosis: hope on the HORIZON. *The Lancet*. 2009; 373:1225-1226.
3. Lyles KW, Colson-Emeric CS, Magaziner JS, et al. Zoledronic acid and clinical fractures and mortality after hip fracture. *N Engl J Med*. 2007;357:1799-809.
4. National Osteoporosis Foundation. The Clinician's Guide to Prevention and Treatment of Osteoporosis. Available from <http://www.nof.org/professionals/clinical-guidelines>.
5. Reid IR, Miller P, Lyles K, et al. Comparison of a Single Infusion of Zoledronic Acid with Risedronate for Paget's Disease. *N Engl J Med*. 2005;353:898-908.
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9. Zoledronic Acid. In: G.K. McEvoy et al. (Eds.), *American Hospital Formulary Service Drug Information*. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
10. Zometa. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

ZORYVE (ROFUMILAST)

- Prescriber attests to diagnosis of mild to severe plaque psoriasis; **AND**
- Member is 12 years of age or older; **AND**
- Prescribed by or in conjunction with a dermatologist or immunologist/rheumatologist; **AND**
- Member has plaque psoriasis that impacts 20% or less of the body surface area; **AND**
- Member has tried and failed, or has a contraindication to all of the following:
 - A medium to ultra-high potency topical corticosteroid for a 4 week period of duration; **AND**
 - A topical vitamin D analogue in combination with a high potency topical corticosteroid for an 8 week period of duration; **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

- Topical tazarotene in combination with a medium to high potency topical corticosteroid for an 8 week period of duration; **OR**
- Member has plaque psoriasis on sensitive areas (ex. face, palms, etc) and has tried and failed or has a contraindication to any low to medium potency topical corticosteroid for a 2 week treatment duration.

Reauthorization:

- Prescriber documentation provided which supports that member is tolerating therapy and has had disease improvement or stabilization with therapy

LAST REVISION: 1/1/23

ZTALMY (GANAXOLONE)

INITIAL:

- Diagnosis of CDKL5 deficiency that has been confirmed based on genetic testing; **AND**
- Member is 2 years of age or older; **AND**
- Prescribed by a neurologist; **AND**
- Member has documentation of therapeutic failure of at least two previous antiepileptic therapies; **AND**
- Baseline monthly seizure frequency has been documented

RENEWAL:

- Confirmation of a sustained reduction in monthly seizure frequency compared to baseline

Authorization:

Initial: 6 months

Renewal: 12 months

LAST REVISION: 8/1/2022

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

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 to 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 the individual patient. Dosages higher than this have not been demonstrated to provide any clinical advantage.
- Dose reduction of CNS depressants, SUBUTEX, SUBOXONE Sublingual Film and SUBOXONE Sublingual Tablets, or both when both are being taken should be considered.

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

- 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 notes 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, Opioid-derivates, illicit Opioid-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.

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

Renewal authorizations will be for a 180 day period.

ZYMAXID (GATIFLOXACIN)

- Bacterial Conjunctivitis, AND
- Tried/failed/intolerance/bacteria-unsusceptible to ciprofloxacin, or levofloxacin ophthalmic solution.

References

1. Gatifloxacin. In: G.K. McEvoy et al. (Eds.), American Hospital Formulary Service Drug Information. Updated periodically. Stat!Ref, producer. Jackson, WY: Teton Data Systems. Available from <http://www.statref.com>.
2. Hwang DG. Fluoroquinolone resistance in ophthalmology and the potential role for newer ophthalmic fluoroquinolones. *Surv Ophthalmol*. 2004;49 Suppl 2:S79-83.
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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

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

- 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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2. Bactericidal activity of orally available agents against methicillin-resistant *Staphylococcus aureus*. *J Antimicrob Chemother*. 2006 Sep;58(3):680-3.
3. Bassetti M. Vitale F. Melica G. Righi E. Di Biagio A. Molfetta L. Pipino F. Cruciani M. Bassetti D. Linezolid in the treatment of Gram-positive prosthetic joint infections. *Journal of Antimicrobial Chemotherapy*. 2005;55(3):387-90.
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14. Weigelt, J et al. Linezolid eradicates MRSA better than vancomycin from surgical site
15. infections. *American Journal of Surgery*. 2004;188(6):760-6.
16. Zyvox. In: DRUGDEX® System [Internet database]. Greenwood Village, CO: Thomson Micromedex. Updated periodically. Available from: <http://www.micromedex.com/>.

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